Fate THERAPEUTICS

Better Cells For Better Therapies®

2019 Annual Report

Developing first-in-class cellular immunotherapies
for cancer and immune disorders
by programming cell function and fate

NK cells | T cells | **CD34+** cells

induced **P**luripotent **S**tem **C**ell Platform

a renewable source for off-the-shelf engineered cell products

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, 2019

☐ **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.)**
3535 General Atomics Court, Suite 200, San Diego, CA	**92121**
(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 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 $1,055,849,000 as of June 28, 2019 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 28, 2020 was 75,931,385.

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, 2019 pursuant to Regulation 14A in connection with the registrant's 2020 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, 2019

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PART I

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;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- our ability and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;
- 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;
- 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;
- the potential of our technology platform, including our induced pluripotent stem cell (iPSC) product platform, and our plans to apply our platform to research, develop and commercialize our product candidates;
- 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;
- our ability to obtain funding for our operations;
- 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.

ITEM 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. 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. For certain of our product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of allogeneic, or healthy donor-sourced, cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties and 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 these therapeutic approaches, we program cells of the blood and immune system and are advancing a pipeline of programmed cellular immunotherapies. The following table summarizes our programmed cellular immunotherapies currently under development:

Product Candidate	Stage of Development	Disease Indication	Commercial Rights
Off-the-shelf, iPSC-derived Cellular Immunotherapies – Hematologic Malignancies			
FT516	Phase 1	AML and B-cell Lymphoma	Worldwide
FT596	Phase 1	B-cell Lymphoma and CLL	Worldwide
FT538	Preclinical	AML and Multiple Myeloma	Worldwide
FT576	Preclinical	Multiple Myeloma	Worldwide
FT819	Preclinical	B-cell Malignancies	Worldwide
FT-ONO1	Research	Hematologic Malignancies	Joint [1]
Off-the-shelf, iPSC-derived Cellular Immunotherapies – Solid Tumors			
FT500	Phase 1	Advanced Solid Tumors	Worldwide
FT516	Phase 1	Advanced Solid Tumors	Worldwide
FT-ONO2	Research	Advanced Solid Tumors	Joint [1]
Allogeneic Cellular Immunotherapies			
ProTmune™	Phase 2	Hematologic Malignancies	Worldwide
FATE-NK100	Phase 1	AML [2]	Worldwide
FATE-NK100	Phase 1	Recurrent Ovarian Cancer [2]	Worldwide
FATE-NK100	Phase 1	Advanced Solid Tumors [2]	Worldwide

Notes:

[1] Subject to Collaboration and Option Agreement with Ono Pharmaceutical Co. Ltd.

[2] Clinical trials in AML and recurrent ovarian cancer are being conducted as investigator-initiated studies at the Masonic Cancer Center, University of Minnesota. We do not intend to continue development of FATE-NK100.

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. One of the most successful and widespread applications of cell therapy is hematopoietic cell transplantation (HCT), with over 60,000 procedures performed worldwide on an annual basis. HCT holds curative potential for patients afflicted with hematologic malignancies, such as leukemia and lymphoma, and with rare genetic disorders, such as hemoglobinopathies, inherited metabolic disorders and immune deficiencies.

Building upon the success of HCT, the clinical investigation of cell-based cancer immunotherapy is rapidly expanding. One particular form of cell-based cancer immunotherapy, chimeric antigen receptor (CAR) T-cell therapy, has recently emerged as a revolutionary and potentially curative therapy for patients with certain hematologic malignancies, including refractory cancers. In fact, in 2017, two CAR T-cell therapies were approved by the United States Food and Drug Administration (FDA) for the treatment of relapsed / refractory B-cell precursor acute lymphoblastic leukemia (ALL) and relapsed / refractory diffuse large B-cell lymphoma (DLBCL).

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 allogeneic, or healthy donor-sourced, cells and 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 universal, off-the-shelf cell products for the treatment of cancer.** Human iPSCs, with their unique dual 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 natural killer (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 lines to produce NK cells and T cells; and regulatory affairs 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 cycles of 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 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 our iPSC-derived NK cell product candidates, including FT500 and FT516. FT500 is the first-ever iPSC-derived cell therapy to be administered to patients in the United States (U.S.), and FT516 is the first-ever engineered iPSC-derived cell therapy administered to patients in the world. We also have a 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 immunotherapies. 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.

- **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 for cancer and immune disorders. We are advancing our product candidates 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, we are developing our product candidate ProTmune as a first-in-class hematopoietic cell graft for the prevention of life-threatening complications, including graft-versus-host disease (GvHD), in patients undergoing allogeneic HCT. GvHD is a leading cause of morbidity and mortality in patients undergoing allogeneic HCT, and there are currently no therapies approved by the FDA for the prevention of GvHD. The FDA has granted Fast Track designation, and the FDA and the European Commission have granted Orphan Drug Designation and Orphan Medicinal Product Designation, respectively, for ProTmune. Due to high incidences of morbidity and mortality and the rare disease nature of many 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.
- **Selectively share our iPSC product platform with industry-leading strategic partners for the development of highly differentiated cellular immunotherapies.** 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 maximize the therapeutic potential of cell therapies for the treatment of cancer. Additionally, 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 into other disease areas. We will continue to seek partnerships with institutions and companies for the research, development and commercialization of iPSC-derived cell product candidates for the treatment of human diseases.

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- 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.

FT500: iPSC-derived NK Cell Product Candidate for Advanced Solid Tumors

Therapies that block inhibitory immunological signaling pathways have transformed the oncology landscape. For example, the use of monoclonal antibody-based therapies commonly referred to as checkpoint inhibitors, which target the PD1 receptor upregulated on activated T cells or its ligands expressed on tumor cells (programmed death ligands 1 and 2 (PD-L1 and PD-L2)), has resulted in long term remissions in multiple tumor indications. Unfortunately, more than 60% of patients treated with checkpoint inhibitors will not respond or will relapse. As a result, there is significant unmet need for novel therapeutic approaches to overcome resistance to checkpoint inhibitors.

One common mechanism of intrinsic and acquired resistance to checkpoint inhibitors is deletions or loss of heterozygosity in beta-2-microglobulin (B2M) an essential component of major histocompatibility complex (MHC) class I molecules which play a critical role in tumor-antigen presentation. A recent longitudinal analysis in a cohort of patients treated with several checkpoint inhibitors identified B2M expression defects in approximately 30% of patients with progressing disease. In fact, loss of heterozygosity in B2M was found to be enriched three-fold in non-responders (~30%) vs. responders (~10%) and was associated with poor overall survival. Additionally, complete loss of B2M expression was found only in non-responders. These findings suggest that defects in B2M expression can contribute to tumor evasion of T-cell responses and disease progression.

One potential strategy to overcome resistance to checkpoint inhibitors, especially in patients whose heterogenous tumor burden includes B2M expression defects, is through the administration of allogeneic NK cells, which have the inherent capability to recognize and directly kill cells with MHC class I down-regulation. The mechanism of killing is through the release of perforins and granzymes, which can lyse tumor cells exposing large amounts of tumor antigens, and the secretion of a number of cytokines and chemokines, both of which can activate and facilitate an adaptive immune response. In addition to direct cytotoxicity, NK cells can also secrete proinflammatory cytokines, which can induce tumor-resident T cells to re-engage and elicit an anti-tumor response, and chemotactic cytokines, which can recruit T cells to the tumor site. As such, allogeneic donor NK cells may have the potential to overcome resistance to checkpoint inhibitors in certain patients by directly killing tumor cells and by potentiating an adaptive immune response.

FT500 is an investigational off-the-shelf NK cell cancer immunotherapy derived from a clonal master iPSC line. To our knowledge, FT500 is the first-ever iPSC-derived cell therapy cleared for clinical investigation in the United States. We are developing FT500 for the treatment of advanced solid tumors.

FT500 is being studied in an ongoing open-label, multi-center, dose-escalation Phase 1 clinical trial. The trial is designed to assess the safety and determine the maximum dose of FT500 in adult patients with advanced solid tumors. The trial includes two treatment regimens: FT500 as a monotherapy in patients that are candidates for salvage therapy (Regimen A); and, in patients who have previously failed or progressed on checkpoint inhibitor therapy, FT500 in combination with the checkpoint inhibitor on which the patient failed or progressed (Regimen B). FT500 is administered in three once-weekly doses (Day 1, Day 8, Day 15) following outpatient lympho-conditioning. For those patients that are clinically stable at Day 29, a second treatment cycle of three once-weekly doses may be administered.

In December 2019, we reported interim results from 12 patients (n=8 in Regimen A; n=4 in Regimen B) as of a November 28, 2019 data cutoff. In Regimen A, three patients were treated at the first dose level of 100 million cells per dose and five patients were treated at the second dose level of 300 million cells per dose; in Regimen B, three patients were treated at the first dose level of 100 million cells per dose, and one patient was treated at the second dose level of 300 million cells per dose, in combination with checkpoint inhibitor therapy. Patient characteristics are presented below:

Cohort / Cell Dose	Age / Sex	Tumor Type	# Lines of Prior Therapy	Refractory to Last Prior Therapy
A1 100M cells / dose	54 / M	Colon	3	Yes
	57 / M	Metastatic salivary gland carcinoma	2	No
	61 / F	Ovary	6	Yes
A2 300M cells / dose	43 / M	Colon	4	No
	52 / F	Colorectal	1	No
	57 / M	Squamous cell carcinoma, left tonsil	2	Yes
	62 / M	Floor of mouth cancer	4	No
	53 / F	Pancreas	4	Yes
B1 100M cells / dose	59 / F	Non-small cell lung cancer	7	Yes
	54 / F	Non-small cell lung cancer	4	Yes
	61 / M	Hepatocellular carcinoma	2	Yes
B2 300M cells / dose	71 / F	Primary peritoneal mesothelioma	2	Yes

As of a November 28, 2019 data cutoff, the key clinical findings include:

- *Safety*. No dose-limiting toxicities, FT500-related severe adverse events, or FT500-related Grade ≥3 adverse events, and no incidents of cytokine release syndrome, neurotoxicity, or GvHD, had been reported in the 12 patients.
- *Tolerability*. All 12 patients completed the first FT500 treatment cycle of three once-weekly doses. Nine of 11 patients initiated a second FT500 treatment cycle, with eight of nine patients having completed the second FT500 treatment cycle. One patient was pending initiation of a second FT500 treatment cycle. The multi-dose, two-cycle treatment schedule was well-tolerated, and there were no treatment discontinuations due to adverse events.
- *Anti-tumor Activity*. In Regimen A, two of three patients in the 100 million cells per dose cohort and two of five patients in the 300 million cells per dose cohort achieved a best overall response of stable disease per iRECIST. In Regimen B, two of three patients in the 100 million cells per dose cohort achieved a best overall response of stable disease per iRECIST. As of the data cutoff, a fourth patient in Regimen B was undergoing treatment in the 300 million cells per dose cohort.

Regimen A

Cohort / Cell Dose	Subject #	# Lines of Prior Therapy	FT500 Doses Received	Safety			Best Overall Response *	Disposition	
				Dose Limiting Toxicities	Related Grade ≥ 3 AEs	Related SAEs		Days on Study	Reason for Study Discontinuation
A1 100M cells / dose	1	3	6	None	None	None	SD	94	Clinical Progression
	2	2	6	None	None	None	iUPD	94	iCPD
	3	6	6	None	None	None	SD	83	iUPD
A2 300M cells / dose	1	4	6	None	None	None	SD	70	iUPD
	2	1	5	None	None	None	SD	55	Clinical Progression
	3	2	3	None	None	None	iUPD	33	iUPD
	4	4	6	None	None	None	iUPD	72	Clinical Progression
	5	4	6	None	None	None	iUPD	90	iCPD

* Per iRECIST SD = stable disease iUPD = immune unconfirmed progressive disease iCPD = immune confirmed progressive disease

Regimen B

Cohort / Cell Dose	Subject #	# Lines of Prior Therapy	FT500 Doses Received	Safety			Best Overall Response *	Disposition	
				Dose Limiting Toxicities	Related Grade ≥ 3 AEs	Related SAEs		Days on Study	Reason for Study Discontinuation
B1 100M cells / dose	1	7	3	None	None	None	SD	76	Patient decision
	2	4	6	None	None	None	SD	98	iUPD
	3	2	6	None	None	None	iUPD	85	iCPD
B2 300M cells / dose	1	2	3 (ongoing)	None	None	None	Pending	On-study	

* Per iRECIST SD = stable disease iUPD = immune unconfirmed progressive disease iCPD = immune confirmed progressive disease

In addition to our clinical assessment, we also evaluated patients' immune response to FT500 to assess the potential for both T-cell and B-cell mediated immunogenicity. The T-cell compartment of nine patients was evaluated for T-cell mediated host-versus-product (FT500) allo-reactivity. A TCR repertoire analysis conducted at multiple time points following treatment with FT500 was not indicative of a robust allo-reactive T-cell response against FT500. In addition, the antibody repertoire of 11 patients was analyzed for targeting of the six HLA class I types expressed by FT500 to assess B-cell mediated host-versus-product (FT500) allo-reactivity. Among the 11 patients, a single FT500 anti-HLA antibody with a mean fluorescence intensity (MFI) level of ≥ 5,000 was detected in a single patient, suggesting that a robust B-cell response against FT500 was not evident. As a point of reference, in patients undergoing haplo-identical hematopoietic stem cell transplant, an MFI level ≥ 5,000 has been correlated with a 5-fold increase in risk of graft rejection.

Upon successful completion of the 300 million cells per dose cohort in Regimen B, we plan to initiate the dose-expansion stage of the FT500 Phase 1 study under an amended clinical protocol, where we intend to administer IL-2 with each dose of FT500 to support the product candidate's activity and to enroll patients with certain cancers that we believe are most amenable to NK cell anti-tumor activity. We expect the dose-expansion stage to enroll up to 15 patients, each of which will be administered FT500 at 300 million cells per dose in combination with checkpoint inhibitor therapy.

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

NK cells play a major role in the anti-tumor efficacy of certain tumor-antigen targeting antibodies. NK cells express CD16, an activating receptor that binds to the Fc portion of IgG antibodies. Once activated through CD16, NK cells are able to destroy antibody-coated target cells and secrete cytokines, such as interferon gamma, to recruit and potentiate adaptive immune cells, including T cells. 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 human tumor types.

CD16 consists of two genomic variants, 158V and 158F, that elicit 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 lymph 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. In preclinical studies, we have shown that FT516 exhibits potent and persistent anti-tumor activity *in vitro* and *in vivo* in multiple tumor cell recognition and killing assays:

- FT516, as compared to conventional NK cells sourced from peripheral blood and from cord blood, exhibits superior direct killing *in vitro* in combination with rituximab in a human lymphoma cell line killing assay (positive for CD20) and in combination with each of trastuzumab and cetuximab in a human ovarian cancer cell line killing assay (positive for both HER2 and EGFR);
- FT516 in combination with rituximab shows a dose-dependent killing response *in vitro* in a CD20+ human lymphoblast-derived B-lymphocyte cell line killing assay;
- FT516 in combination with trastuzumab, as compared to trastuzumab alone, augments anti-tumor activity *in vivo* in a HER2+ ovarian cancer model, where the anti-tumor activity at Week 6 of FT516 plus trastuzumab was durable with no tumor detectable by imaging in 80% of the mice as compared to trastuzumab alone where all mice displayed tumor burden; and
- FT516 in combination with rituximab, as compared to rituximab alone or rituximab in combination with conventional NK cells sourced from peripheral blood, augments anti-tumor activity and promotes prolonged survival *in vivo* in a human lymphoma cancer model, where the median survival following treatment with FT516 plus rituximab exceeded 100 days as compared to approximately 35 days for rituximab alone and for rituximab in combination with conventional NK cells sourced from peripheral blood.

FT516 is being studied in an ongoing open-label, multi-center, dose-escalation Phase 1 clinical trial. The trial is designed to assess the safety and determine the maximum dose of FT516 in adult patients with certain hematologic malignancies. The trial includes two treatment regimens: FT516 as a monotherapy in patients with relapsed / refractory acute myeloid leukemia (AML) with 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-directed monoclonal antibody therapy in patients with advanced B-cell lymphoma who have previously failed or progressed on CD20-directed monoclonal antibody therapy with 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). FT516 is administered in three once-weekly doses (Day 1, Day 8, Day 15), with IL-2 to support the product candidate's activity, following outpatient lympho-conditioning. For those patients that are clinically stable at Day 29, a second treatment cycle of three once-weekly doses may be administered. To our knowledge, FT516 is the first-ever engineered iPSC-derived cell therapy cleared for clinical investigation in the United States.

We are also developing FT516 for the treatment of advanced solid tumors. In November 2019, we submitted an IND application to the FDA for the clinical investigation of FT516 in combination with monoclonal antibody therapy, including PDL1-, EGFR- and HER2-targeting therapeutic antibodies, across a broad range of solid tumors. In December 2019, the FDA issued a letter informing us that our FT516 IND application for the treatment of advanced solid tumors was allowed and that we can proceed with human clinical investigation. In 2020, we intend to initiate clinical investigation of FT516 in combination with tumor-target antibody therapy in an open-label, multi-center, dose-escalation Phase 1 clinical trial for the treatment of advanced solid tumors.

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

CAR T-cell therapy has shown exceptional promise as a potentially curative therapy for patients with certain hematologic malignancies. 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 created from clonal master engineered iPSC lines as off-the-shelf cancer immunotherapies for the treatment of hematologic malignancies and solid tumors.

In 2017, we entered into a multi-year research collaboration with the University of California, San Diego, led by Dan S. Kaufman, M.D., Ph.D., Professor of Medicine in the Division of Regenerative Medicine and Director of Cell Therapy, to develop off-the-shelf, iPSC-derived CAR NK cell cancer immunotherapies. Dr. Kaufman identified a novel CAR construct specifically designed to augment NK cell signaling that contains the transmembrane domain of NKG2D, the 2B4 co-stimulatory domain, and the CD3ζ signaling domain. In preclinical studies using an ovarian cancer xenograft model, Dr. Kaufman has shown that a single dose of CAR NK cells derived from iPSCs engineered with this specific CAR construct targeting mesothelin markedly inhibited tumor growth and significantly enhanced survival as compared to NK cells derived from iPSCs engineered with a CAR construct commonly used for CAR T-cell cancer immunotherapy.

We are developing FT596, an 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, which contains a NKG2D transmembrane domain, a 2B4 co-stimulatory domain and a CD3-zeta signaling domain, 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 without the need for systemic cytokine support. Together, these features are intended to enable multi-antigen targeting, maximize potency and minimize toxicity in treated patients. In preclinical studies, we have shown that FT596 exhibits potent and persistent anti-tumor activity *in vitro* and *in vivo* in multiple tumor cell recognition and killing assays:

- In a mixed co-culture assay, we have shown increased degranulation (CD107a) and cytokine release (interferon-gamma and TNF-alfa) upon concurrent activation of both the CAR and CD16 receptors in CD19+CD20+ Raji cancer cells with rituximab, as compared to activation of each receptor alone, indicating that dual-antigen engagement may elicit synergistic anti-tumor activity;
- In a humanized mouse model of CD19+ lymphoma, FT596 administered as a monotherapy exhibited durable tumor clearance and extended survival *in vivo* similar to primary CAR T cells; and
- In a mixed cellular composition cytotoxicity assay comprised of CD19+ and CD19- tumor cells, FT596 combined with rituximab effectively eliminated the heterogeneous population of tumor cells, a result that was not observed with single-antigen targeted CAR19 T cells.

We believe this preclinical data demonstrate the anti-tumor potency and the unique multi-antigen targeting functionality of FT596, and the product candidate's potential to effectively overcome CD19 antigen escape.

In September 2019, the FDA issued a letter informing us that our FT596 IND application was allowed, and that we can proceed with human clinical investigation of FT596. To our knowledge, FT596 is the first cellular immunotherapy engineered with three active anti-tumor components to be cleared for clinical investigation by the FDA.

We plan to study FT596 in an open-label, multi-center, dose-escalation Phase 1 clinical trial. The trial is designed to assess the safety and determine the maximum dose of FT596 in adult patients with certain hematologic malignancies. The trial includes three treatment regimens: FT596 as a monotherapy in patients with advanced B-cell lymphoma (Regimen A); FT596 in combination with rituximab in patients with advanced B-cell lymphoma who have previously failed or progressed on rituximab (Regimen B); and FT596 in combination with obinutuzumab in patients with chronic lymphocytic leukemia who have previously failed or progressed on obinutuzumab (Regimen C). FT596 will be administered as a single dose following outpatient lympho-conditioning.

We plan to initiate enrollment of the Phase 1 study of FT596 in the first quarter of 2020. The planned dose-escalation of FT596 to determine the maximum tolerated dose in the three Regimens (A, B, and C), based on a standard 3+3 dose escalation scheme, is as follows: (i) initial treatment in Regimen A at 30 million cells per dose; (ii) dose escalation in Regimen B at 30 million cells per dose, 90 million cells per dose, 300 million cells per dose and 900 million cells per dose; and (iii) treatment in Regimen A and Regimen C at the maximum tolerated dose of FT596 determined during Regimen B dose escalation. In the dose-expansion stage of the Phase 1 study of FT596, indication-specific expansion cohorts with Regimen A, B and C will be enrolled independently.

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 number of patients are expected to relapse.

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

We are developing FT538, an 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 without the need for systemic cytokine support; and a 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.

In preclinical studies, we have shown that FT538 cells are entirely resistant to daratumumab-induced fratricide. Additionally, in a cytotoxic re-stimulation assays, FT538 plus daratumumab resulted in 86% cytotoxicity against multiple myeloma target cells upon first exposure and 92% cytotoxicity upon re-stimulation, as compared to peripheral blood NK cells plus daratumumab which resulted in a loss of cytotoxic capacity from 74% upon first exposure to 58% upon re-stimulation.

We plan to submit an IND application during the first half of 2020 to initiate an open-label, multi-center, dose-escalation Phase 1 clinical trial of FT538 in combination with daratumumab for the treatment of multiple myeloma.

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 cell-surface proteins 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.

We are developing FT576, an 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 without the need for systemic cytokine support; and a 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 plan to submit an IND application during the second half of 2020 to initiate an open-label, multi-center, dose-escalation Phase 1 clinical trial of FT576 as a monotherapy and in combination with daratumumab for the treatment of multiple myeloma.

FT819: iPSC-derived, TCR-KO, TRAC-targeted CAR19 Engineered T-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. In 2017, two CAR T-cell therapies were 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 T-cell product candidates created 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 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 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 exclusive 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 efficacy, persistence and long-term cytotoxicity as well as a decrease in T-cell exhaustion.

We are developing FT819, an 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, under our collaboration with Memorial Sloan Kettering Cancer Center. 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.

As proof-of-principle for the unique advantages arising from selecting a single engineered iPSC clone for the production of CAR T-cell therapy, we assessed approximately 750 clones after engineering a pool of cells using CRISPR, and found that only about 2% of clones met our standards for overall quality including containing both bi-allelic disruption of the TCR, proper insertion of the CAR into the TRAC locus without random transgene integrations, and no evidence of off-target genomic modifications or translocations. We selected the top-performing clone for generation of the master engineered iPSC line for FT819.

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; and
- effectively control tumor progression *in vivo* comparable to peripheral blood CD19-specific CAR T cells in a preclinical mouse model of acute lymphoblastic leukemia.

Over the past twelve months, we have further optimized our processes for making T cells from iPSCs, and have now shown the production of pure T-lymphocytes consisting of both CD8+ and CD4+ T cells having a global gene expression profile that is highly-similar to primary T cells based on a principal component analysis. In December 2019, we presented new *in vivo* preclinical data demonstrating that FT819 exhibits durable tumor control and extended survival. In a xenograft model of disseminated lymphoblastic leukemia, FT819 demonstrated enhanced tumor clearance and control of leukemia as compared to primary CAR19 T cells. At Day 35 following administration, a bone marrow assessment showed that FT819 persisted and continued to demonstrate tumor clearance, whereas primary CAR T cells, while persisting, were not able to control tumor growth.

We plan to submit an IND application in mid-2020 to initiate an open-label, multi-center, dose-escalation Phase 1 clinical trial of FT819 for the treatment of certain hematologic malignancies.

Other iPSC-derived Cell Product Candidates

Autoimmune diseases arise from abnormal immune responses in which the body's immune system attacks and damages its own tissues. Some of the most common autoimmune diseases include rheumatoid arthritis, type-1 diabetes, systemic lupus erythematosus (SLE or lupus), multiple sclerosis, inflammatory bowel disease, celiac disease and asthma. It is estimated that more than 23 million people in the U.S. suffer from autoimmunity, which makes it the third most common category of illness in the U.S. after cancer and heart disease.

Auto-reactive T-lymphocytes are key players in aberrant autoimmune responses. We believe that certain biological mechanisms, which have been demonstrated to suppress T-cell activity against cancer cells, can be exploited to suppress auto-reactive T-cell destruction of normal tissues. For example, myeloid-derived suppressor cells (MDSCs) are a naturally occurring population of cells that are often found in the tumor microenvironment, where these cells function to inhibit antigen-specific and non-specific T-cell activation and proliferation through a diverse set of mechanisms. While MDSCs can impede T-cell responses against cancer, the cells' potent immuno-suppressive properties may serve to immunologically check auto-reactive T-lymphocytes that are directly responsible for the destruction of healthy tissue in certain autoimmune and inflammatory disorders.

MDSCs are rare in healthy donors and, although abundant in tumor-bearing patients, repurposing tumor-derived MDSCs for therapeutic use may pose undesirable risks. As a result, a need exists to generate MDSCs in large quantities, particularly from healthy donor sources, in order to explore the therapeutic potential of MDSCs. Using a proprietary, efficient and reproducible differentiation process, we have shown the potential to create a substantially pure population of iPSC-derived MDSCs that is well-defined. Preclinical studies of iPSC-derived MDSCs have shown that the cells suppress T-cell activity and proliferation *in vitro* and attenuate GvHD *in vivo* in a xenogeneic mouse model. Importantly, these immuno-regulatory properties were demonstrated using immunologically-mismatched cells.

We are developing FT301, an off-the-shelf, immuno-regulatory cell product candidate derived from a clonal master iPSC line. We believe FT301 has broad therapeutic potential across multiple disease indications, including graft-versus-host disease, multiple sclerosis, ulcerative colitis and others

Our Allogeneic Cellular Immunotherapy Pipeline

ProTmune™

Allogeneic HCT has been performed globally for decades with curative intent in patients with a wide range of hematologic malignancies and rare genetic disorders. The procedure involves transferring hematopoietic cells sourced from a healthy donor to a patient following the administration of chemotherapy and/or radiation therapy. The biological properties of the various cell populations present in the allogeneic hematopoietic cell graft play an essential role in determining outcomes of HCT. Donor-sourced $CD34^+$ cells have the unique ability to engraft and reconstitute a new blood and immune system, and donor-sourced immune cells, such as T cells, have an important protective role following HCT in eradicating residual cancer cells and providing protection against life-threatening infections. The engraftment of donor-sourced $CD34^+$ cells is essential for successful reconstitution, and any delay in, or failure of, engraftment leaves a patient severely immuno-compromised and exposed to exceedingly high risk of early morbidity and mortality. Additionally, while the donor-sourced immune cells impart a critical immunotherapeutic effect, allo-reactive T cells can cause GvHD, a serious complication where donor-sourced T cells recognize antigens on a patient's cells as foreign and attack the patient's cells.

According to the Center for International Blood and Marrow Transplant Research, approximately 30,000 allogeneic HCT procedures are performed globally each year. Hematopoietic cells for use in allogeneic HCT can be obtained from multiple donor sources including umbilical cord blood, bone marrow and mobilized peripheral blood (mPB). Approximately 65% of allogeneic HCT procedures utilize mPB as the donor hematopoietic cell source. While the use of mPB is associated with faster rates of neutrophil engraftment compared to other cell sources like bone marrow and umbilical cord blood, approximately 35-60% of patients undergoing mPB HCT develop acute GvHD and 70-80% of patients undergoing mPB HCT experience at least one severe infection within the first 180 days following HCT. Additionally, approximately 50% of patients undergoing HCT experience cancer relapse or die within the first two years following HCT. We believe our cell programming approach has the potential to reduce the three leading causes of morbidity and mortality associated with allogeneic HCT – namely, graft-versus-host disease, severe infections and disease relapse – and to improve outcomes in patients undergoing allogeneic HCT.

We are developing ProTmune as an investigational programmed cellular immunotherapy for use as a next-generation allogeneic HCT cell graft. ProTmune is produced by modulating donor-sourced mPB *ex vivo* with two small molecules, 16,16-dimethyl prostaglandin E2 (FT1050) and dexamethasone (FT4145), to enhance the biological properties and therapeutic function of the graft's cells. The programmed mPB graft is administered to a patient as a one-time intravenous therapy. Based on preclinical data, we believe ProTmune has the potential to suppress the GvHD response and maintain the anti-tumor, or graft-versus-leukemia (GvL), activity of donor T cells. We have demonstrated that FT1050-FT4145 programmed $CD4^+$ and $CD8^+$ T cells of mPB are functionally less allo-reactive *in vitro*, exhibiting a decrease both in the expression levels of T-cell activation markers, including ICOS and 41BB, and in the production of pro-inflammatory cytokines, and an increase in the production of potent anti-inflammatory cytokines including IL-10.

We are conducting a multi-center Phase 1/2 clinical trial of ProTmune in adult subjects with hematologic malignancies undergoing mPB HCT following myeloablative conditioning, a clinical trial which we refer to as the PROTECT study. The primary objectives of the PROTECT study are to evaluate safety and tolerability, and to assess the potential of ProTmune to prevent acute GvHD, which is a leading cause of morbidity and mortality in patients undergoing HCT. There are currently no FDA-approved therapies for the prevention of GvHD in patients undergoing allogeneic HCT, giving rise to a significant unmet medical need. All subjects in the PROTECT study are being followed for a period of two years following HCT.

In December 2018, we reported clinical data from the Phase 1 stage of PROTECT. The Phase 1 stage of PROTECT included seven subjects. Underlying hematologic diseases included three subjects with acute lymphoblastic leukemia (ALL), three with acute myeloid leukemia (AML) and one with myelodysplastic syndrome (MDS). As of a November 26, 2018 data cut-off, five of seven subjects remained on study with median time on study of 516 days [Day 151 – 616], and the following key safety and efficacy data were reported:

- ProTmune was well-tolerated. There were no events of graft failure and no serious adverse events related to ProTmune reported by investigators.
- There were no reported events of cancer relapse.

- At Day 100, all seven subjects receiving ProTmune were alive and relapse-free; and three subjects experienced acute GvHD during the first 100 days following HCT, all of whom responded to standard-of-care steroid treatment. The median time to resolution of the maximum GvHD grade was 7 days [range: 5-8 days].
- At Day 365, five of seven subjects receiving ProTmune were alive and relapse-free, with non-relapse mortality occurring in two subjects (Subject 1 on Day 228; Subject 3 on Day 151); and three of seven subjects were alive, relapse-free and without moderate-to-severe chronic GvHD.

A tabular summary of the reported clinical data from the Phase 1 stage of PROTECT is presented below:

PROTECT Phase 1 Clinical Data (as of November 26, 2018 data cut-off)							
Subject	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Days on Study	228	616	151	524	516	481	468
Hematologic Malignancy	MDS	AML	AML	ALL	ALL	ALL	AML
CD34+ cell dose ($x10^6$/kg)	10.3	4.6	10.9	4.8	3.2	3.0	9.4
CD3+ cell dose ($x10^8$/kg)	3.1	1.8	2.6	2.8	2.0	1.2	2.8
ProTmune-related SAEs	None	None	None	None	None	None	None
Day of Neutrophil Engraftment [1]	Day 14	Day 18	Day 22	Day 15	Day 16	Day 18	Day 19
Day 100 Acute GvHD / Grade (CIBMTR)	None	None	Grade 2	None	Grade 2	Grade 3	None
Treatment Responsive	---	---	*Yes*	---	*Yes*	*Yes*	---
Time to Resolution of Maximum Grade	---	---	*7 days*	---	*8 days*	*5 days*	---
Day 365 Moderate-to-Severe Chronic GvHD	n/a	None	n/a	None	None	Yes	Yes
Cancer Relapse-free	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall Survival	No	Yes	No	Yes	Yes	Yes	Yes
[1] *As measured from the day following HCT*							

The ongoing Phase 2 stage of PROTECT is a randomized, controlled and double-blinded clinical trial assessing the safety and efficacy of ProTmune in up to 80 adult subjects with hematologic malignancies undergoing matched unrelated donor HCT following myeloablative conditioning. In November 2019, we reported that the Phase 2 stage of PROTECT was fully enrolled. Subjects were randomized, in a 1:1 ratio, to receive either ProTmune or a conventional matched unrelated donor mobilized peripheral blood cell graft. The primary efficacy endpoint of PROTECT is cumulative incidence of Grades 2-4 acute GvHD by Day 100 following HCT, where prospective clinical studies have shown that 40% to 80% of patients undergoing matched unrelated donor transplant experience Grades 2-4 acute GvHD. The secondary efficacy endpoint of PROTECT is the proportion of subject alive without relapse and without moderate or severe chronic GvHD by Day 365 following HCT. Additional endpoints, such as rates of cancer relapse, chronic GvHD, non-relapse mortality, and overall survival, are also being assessed.

In June 2016, the FDA granted Fast Track designation for ProTmune for the reduction of incidence and severity of acute GvHD in patients undergoing allogeneic HCT. In September 2016, the FDA granted Orphan Drug Designation and, in October 2016, the European Commission granted Orphan Medicinal Product Designation, for ProTmune. The orphan designation granted in each jurisdiction broadly covers subjects undergoing allogeneic HCT across diseases for which the procedure is performed, including blood cancers and genetic disorders.

FATE-NK100

Adaptive memory NK cells are a highly specialized and functionally distinct subset of NK cells. In July 2015, we entered into a research collaboration with the University of Minnesota led by Dr. Jeffrey S. Miller, Professor of Medicine at the University of Minnesota and Deputy Director of the University of Minnesota Masonic Comprehensive Cancer Center, to develop an allogeneic adaptive memory NK cell product candidate for cancer, which we refer to as FATE-NK100.

Through the application of our cell programming expertise and our specific knowledge of modulators involved in the persistence, proliferation and anti-tumor activity of immune cells, we identified a combination of pharmacological modulators consisting of a cytokine and a small molecule (FT1238) that induces the robust formation of adaptive memory NK cells in therapeutically-relevant quantities. Using peripheral blood cells sourced from a healthy donor, FATE-NK100 is produced in a feeder-free, seven-day manufacturing process during which donor-sourced NK cells are programmed *ex vivo* with our combination of pharmacological modulators. In August 2017, preclinical data describing the unique properties and anti-tumor activity of FATE-NK100 were published in Cancer Research (doi:10.1158/0008-5472.CAN-17-0799), a peer-reviewed journal of the American Association of Cancer Research.

FATE-NK100 was evaluated in three separate clinical studies: (1) an open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 as a monotherapy in subjects with refractory or relapsed acute myelogenous lymphoma (AML), which was conducted at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study; (2) an open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 as a monotherapy in women with ovarian, fallopian tube or primary peritoneal cancer resistant to, or recurrent on, platinum-based treatment, which was conducted at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study; and (3) an open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 as a monotherapy and in combination with monoclonal antibody therapy in subjects with advanced solid tumors who have failed approved therapies.

In 2019, we elected to discontinue further development of FATE-NK100 with the advancement of our off-the-shelf, engineered iPSC-derived NK cell product candidates into clinical development.

Our Partnerships

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). Pursuant to the agreement, we are jointly conducting research and development activities under a joint development plan with Ono, with the goal of advancing each Candidate 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 (a) Candidate 1 in Asia, where we retain 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 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. We maintain worldwide rights of manufacture for both 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. Further, Ono has 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 develop and commercialize Candidate 1 and Candidate 2. Such fees are in addition to the upfront payment and research and development fees.

Subject to Ono's exercise of the options and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, we are entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 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. 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 each Candidate 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.

California Institute of Regenerative Medicine (CIRM)

In April 2018, we executed an award agreement with the California Institute of Regenerative Medicine (CIRM) pursuant to which CIRM awarded us up to $4.0 million to advance our 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, 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 to the FDA for our FT516 product candidate for the treatment of advanced solid tumors, and the IND application was allowed by the FDA in December 2019.

The Award is subject to certain co-funding requirements by us, and we are required to provide progress and financial update reports to CIRM. 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.

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 25, 2020, our intellectual property portfolio is composed of over 300 issued patents and 150 patent applications that we license from academic and research institutions, and over 200 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

As of February 25, 2020, we own over 15 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 patents issued from these patent applications will expire on dates ranging from 2031 to 2040.

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 25, 2020, 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 patents that may issue from these pending patent applications will expire on 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 patents that may issue from patent applications pending in the U.S. and internationally in this portfolio will have statutory expiration dates ranging from 2026 to 2032.

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 patents that may issue from patent applications pending in the U.S. and internationally in this portfolio will have expiration dates between 2038 and 2039.

We also have licensed exclusive rights to three families of patent applications from the University of Minnesota. This portfolio includes over 20 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 patents that may issue from patent applications pending in this portfolio will expire in 2035 or 2036.

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 patents that may issue from patent applications pending in the U.S. and internationally in this portfolio will have expiration dates between 2034 and 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. These issued patents and any patents that may issue from these pending patent applications will expire around 2037.

Intellectual Property Relating to the Programming of Hematopoietic Cells

As of February 25, 2020, we own 12 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 90 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 2039.

Additionally, we have an exclusive license to an intellectual property portfolio consisting of two families of issued patents and pending patent applications co-owned by the Children's Medical Center Corporation and The General Hospital Corporation. As of February 25, 2020, we currently have exclusive rights to over 50 issued patents or patent applications in the United States and worldwide relating to methods for programming hematopoietic stem cells *ex vivo* using modulators that up-regulate the prostaglandin signaling pathway or its downstream mediators. These patent rights consist of issued patents (including U.S. Patents 8,168,428 and 8,563,310) claiming methods for the *ex vivo* programming of hematopoietic stem cells using FT1050, including hematopoietic stem cells obtained from mobilized peripheral blood, cord blood, and bone marrow. Pending patent applications in the United States and foreign jurisdictions are directed to therapeutic compositions of hematopoietic stem cells in which the cells have been modulated by increasing prostaglandin activity, methods of preparing these compositions, and methods of promoting hematopoietic reconstitution, expansion and self-renewal using modulators that increase prostaglandin signaling activity. Any U.S. patents within this portfolio that have issued or may yet issue will have a statutory expiration date in 2027.

We have also licensed exclusive rights to two families of issued patents and patent applications from the Indiana University Research and Technology Corporation. This portfolio includes patent applications claiming methods of enhancing HCT procedures by altering prostaglandin activity in hematopoietic stem cells as well as an issued U.S. patent and patent applications claiming methods of enhancing viral transduction efficiency in the genetic engineering of stem cells, including hematopoietic stem cells. These applications describe methods of increasing mobilization of stem cells from a stem cell donor, and methods for increasing hematopoietic stem cells homing and engraftment in a stem cell transplant recipient. One family of applications is directed to preferentially modulating certain receptors present on hematopoietic stem cells to increase the therapeutic potential of such cells for homing and engraftment. Claims in these applications specifically cover the modulation of mobilized peripheral blood by altering prostaglandin activity and methods for increasing viral transduction efficiency for gene therapy. Any patents that have issued or that may issue from patent applications in this portfolio will expire in 2029 or 2030.

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.

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.

Children's Medical Center Corporation

In May 2009, we entered into a license agreement with Children's Medical Center Corporation (CMCC) for rights relating to therapeutic compositions of modulated HSCs and methods for promoting reconstitution of the hematopoietic system using modulators of the prostaglandin pathway, as described in more detail above under "Intellectual Property Relating to the Programming of Hematopoietic Cells." Under our agreement with CMCC, 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, in all fields. CMCC retains a non-exclusive right to practice and use the patent rights for research, educational, clinical or charitable purposes, and also to license other academic and nonprofit organizations to practice the patent rights for research, educational, and charitable purposes (but excluding any clinical use and commercialization of the patent rights to the extent granted to us under the license agreement). Our license is also subject to pre-existing rights of the U.S. government and rights retained by the Howard Hughes Medical Institute and the General Hospital Corporation to use the patent rights for research purposes. Additionally, if we make any discovery or invention that is described in a patent application and is not within the scope of the licensed patent rights but would not have been made but for the licensed patent rights, we are required to disclose the invention to CMCC and enter into a non-exclusive license agreement with CMCC, for no more than a nominal fee, for CMCC to practice the invention solely for internal research purposes or clinical purposes and not for commercial purposes.

Under the terms of the license agreement, we are required to pay to CMCC an annual license maintenance fee during the term of the agreement. We also are required to make payments to CMCC of up to $5.0 million per product in development, regulatory and sales milestones. If commercial sales of a licensed product commence, we will pay CMCC royalties at percentage rates ranging in the low- to mid-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 until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, CMCC is also entitled to receive a percentage of the sublicensing income received by us.

Under the license with CMCC, we are obligated to use commercially reasonable efforts to bring a licensed product to market as soon as practicable, and also to use good faith and diligent efforts to manufacture and distribute a licensed product, and make licensed products reasonably available to the public during the term of the agreement. We are also required to use good faith and diligent efforts to meet the milestones set forth in development plans as part of the agreement, subject to any revisions to the development plans that may be permitted under certain circumstances. Additionally, if a third party expresses interest in an area under the license that we are not pursuing, under the terms of our agreement with CMCC, we may be required to sublicense rights in that area to the third party.

The agreement will continue until the last to expire of the patent rights. We may terminate the agreement by providing prior written notice to CMCC, and CMCC has the right to terminate the agreement if we fail to pay royalties or otherwise materially breach the agreement and fail to cure such breach within a specified grace period. CMCC may also terminate the agreement should we cease operations or in the event of our bankruptcy or insolvency.

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 cGMP compliant manufacturing facility for the clinical production of our iPSC-derived cell product candidates. Our 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 new 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 a future headquarters facility, which is designed to include cGMP manufacturing. The lease is expected to commence, subject to certain conditions, in May 2021, and once complete, we intend to manufacture our iPSC-derived cell product candidates at this facility.

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.

ProTmune™

ProTmune is a composition of *ex vivo* programmed human mobilized peripheral blood cells. ProTmune is produced by treating qualified human mobilized peripheral blood with two small molecules, FT1050 and FT4145, in a multi-step process that is performed on the day of HCT. Currently, the manufacture of ProTmune is performed at clinical cell processing facilities operated by or affiliated with our clinical sites. The manufacturing process consists of functionally closed unit operations. We aim to continue to develop manufacturing processes to further standardize the manufacture of ProTmune across clinical cell processing facilities.

Human peripheral blood cells sourced from a healthy donor, whose tissue type closely matches the patient's, are used as the starting cellular source material for the manufacture of ProTmune. HCT centers can electronically access a worldwide network of donor registries, which collect and transfer human peripheral blood cells sourced from healthy donors, to source these cells on behalf of patients. We expect donor registries to continue to collect and transfer, and HCT centers to continue to source, human peripheral blood cells for our manufacture of ProTmune. Other components used in the manufacture of ProTmune include programming media as well as disposable materials, such as bags and tubing sets. To date, we have obtained all components required for the manufacture of ProTmune, including FT1050, FT4145 and programming media, 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 human peripheral blood cells and certain components used in the manufacture of ProTmune.

For the conduct of our Phase 1/2 clinical trial of ProTmune, the clinical cell processing facility at each participating site is qualified and trained by our technical staff to manufacture ProTmune. Our technical representative(s) are on-site at the clinical cell processing facility for each of the first two subjects administered ProTmune at a participating site. ProTmune is released immediately by the clinical cell processing facility staff after final processing, including filtration, final packaging, rapid release testing, and labeling. In the future, we may manufacture ProTmune at facilities operated by us, by transplant centers, or by third parties.

Marketing & Sales

We currently intend to commercialize any products that we may successfully develop. We currently have no experience in marketing or selling therapeutic products. To market any of our products independently would 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;
- 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 cGMPs to assure that the facilities, methods and controls are adequate, and, if applicable, the FDA's 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; 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. Further, an independent institutional review board (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.

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.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended indication, particularly for long-term safety follow-up. The FDA has statutory authority to require post-market clinical trials to address safety issues. 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 regenerative advanced therapy.

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, 2020, the user fee for an application requiring clinical data, such as a BLA and an NDA, is $2,942,965. PDUFA also imposes an annual prescription drug product program fee for biologics and drugs ($325,424). 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 applicant 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.

Expedited Development and Review Programs

The FDA has a Fast Track program intended to facilitate the development and expedite the review of new drugs and biological products that are intended to treat a serious or life-threatening condition or disease and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a biological product or drug may request the FDA to designate the biologic or drug as a Fast Track product at any time during clinical development. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product or drug designated for priority review in an effort to facilitate the review. 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 as a condition for accelerated approval pre-approval of promotional materials.

The FDCA also requires FDA to expedite the development and review of a breakthrough therapy. A biological product or drug can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a biological product or drug be designated as a breakthrough therapy at any time during the clinical development of the product. If so designated, FDA shall act to expedite the development and review of the product's marketing application, including by meeting with, and providing advice to, the sponsor throughout the product'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.

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

Accelerated Approval for Regenerative Advanced Therapies

As part of the Cures Act, Congress amended the FDCA to create an accelerated approval program for regenerative advanced therapies, which include cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Regenerative advanced therapies do not include those human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the PHS Act and 21 CFR Part 1271. The new 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. A drug sponsor may request that FDA designate a drug as a regenerative advanced therapy concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA or NDA for a regenerative advanced therapy 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 regenerative advanced therapy 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.

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, a 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 (PPACA). 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 Designation

Under the Orphan Drug Act, the FDA may grant orphan 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 designation must be requested before submitting a BLA or NDA. After the FDA grants orphan designation, the identity of the applicant, the name of the therapeutic agent and its designated orphan use are disclosed publicly by the FDA. Orphan 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 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.

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 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. 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% 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;
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- imposed an annual, nondeductible fee and tax on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs;
- imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission; and
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding was allocated to support the mission of the CMMI through 2019, and pursuant to the federal fiscal year 2020 budget, CMMI is expected to receive funding for ten more years.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," to $0 effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA.

Since January 2017, the Trump administration has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, the Trump administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, the Trump administration signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The Bipartisan Health Care Stabilization Act of 2017, as well as the follow-on Bipartisan Health Care Stabilization Act of 2018 were introduced to appropriate funds to stabilize CSR payments; however, the future of this effort is unclear. On June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently finalized regulations that would give 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however, on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals 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. Moreover, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Congress also could consider additional legislation to repeal, replace, or further modify elements of the ACA. Thus, the full impact of the ACA, or any law repealing, replacing or modifying elements of it, and the political uncertainty regarding any repeal, replacement or modification of the ACA, on our business remains unclear. We expect that additional federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare drugs, biologics and services.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint," or plan, aimed at improving the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics. Under the plan, the FDA is directed to issue guidance to address certain practices that aim to delay or block generic competition, while also issuing new policies to bring more biosimilars to market as alternatives to brand-name biologics. More recently, the Trump administration announced a complex proposal to reduce Medicare spending by substantially reducing the price of physician-administered drugs, including biologics such as cellular therapeutics, under Medicare Part B. Under this proposal, pharmacy-benefit managers would have an increased role in managing drugs and pricing in the Part B program, and the price paid by Medicare for drugs under Part B would be linked to the prices paid for such drugs in other industrialized countries as reflected in an International Pricing Index, and in most cases these prices are lower than in the U.S. However, if the International Pricing Index model were adopted as proposed, it would not take effect until 2020 at the earliest and would phase in over five years, and it is therefore difficult to predict the impact it will have on our business. The proposal also includes a new payment model for reimbursing physicians for administering drugs under Part B, and the consequences of this payment model on the prescribing practices of physicians are uncertain. The U.S. Department of Health and Human Services (HHS) has started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act) was signed into law. The law, 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.

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 and Kite were the first to achieve 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.

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 companies are currently focused on the development of cellular immunotherapies for the treatment of cancer including Adaptimmune Limited, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, bluebird bio, Inc., Celgene Corporation (acquired by Bristol-Myers Squibb Company), Cellectis SA, Celyad SA, CRISPR Therapeutics AG, Editas Medicine, Inc., Gilead Sciences, Inc., Green Cross Corporation, Intrexon Corporation, Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), NantKwest, Inc., Novartis AG, Precision BioSciences, Inc., Sorrento Therapeutics, Inc. and ZIOPHARM Oncology, Inc.. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We are developing ProTmune as a next-generation mobilized peripheral blood graft for patients undergoing allogeneic HCT. ProTmune is designed to prevent GvHD and other life-threatening complications that compromise the procedure's curative potential. There are currently no FDA-approved therapies for the prevention of acute GvHD. Corticosteroids, or steroids, remain the first-line of treatment for GvHD, and second-line therapy consists of off-label use of immunosuppressive agents. We are aware of other companies and medical centers that are developing prophylaxes for GvHD and treatments for GvHD and other life-threatening complications of HCT, including AbbVie Inc., Bristol-Myers Squibb Company, Incyte Corporation, Jazz Pharmaceuticals plc, Kamada Ltd., and Mesoblast Limited.

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.

Employees

As of December 31, 2019, we employed 178 employees, all of whom are full-time employees, including 86 in research and development, 69 in clinical development, manufacturing and regulatory affairs and 23 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 consider our employee relations to be good.

Corporate Information

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Our principal executive office is located at 3535 General Atomics Court, Suite 200, San Diego, CA 92121, 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 and Media 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

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, including ProTmune, FT500, or FT516. Furthermore, we have not initiated or conducted any clinical trials necessary to support an application for approval to market FT596, FT819 or any other product candidates that we may identify. 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 our competitors;

- difficulties determining suitable doses 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 product candidates, including FT819 and any other product candidates that we may identify;
- the occurrence of unexpected safety issues or adverse events in any ongoing or future clinical trial of our product candidates;
- 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 IRB approval at each site for the conduct of our clinical trials;
- governmental or regulatory delays, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines;
- 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, cell processing facilities at our clinical trial sites, 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;
- 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;
- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;
- 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 due to safety issues, side effects, or other reasons; and
- approval of competitive agents that may materially alter the standard of care or otherwise 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 will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to 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.

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 research and development activities and our current or planned clinical development 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 preclinical studies or clinical trials;
- 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;
- 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;
- 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
- our prioritization of other product candidates for advancement, including a decision to cease research and development of any existing product candidate due to 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 favorable marketing exclusivity, including greater market acceptance or commercial potential, or more advantageous intellectual property position.

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. 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. 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.

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, including FT500, FT516, and FT596, 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. 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 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 CMOs or other third party manufacturers will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. The requirements to manufacture ProTmune in close proximity to transplant centers within a short period of time before transplantation present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. 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 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. 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.

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.

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 meet demand.

While certain components required for the production of our product candidates are currently manufactured internally at our facilities, we rely, and expect to continue to rely, on third parties for the manufacture of other components and also to manufacture our product candidates for use in conducting clinical trials. As such, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including clinical cell processing facilities operated by our clinical trial sites, and larger-scale facilities operated by either 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 FT500, FT516, and FT596 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. For example, we may encounter problems with shortages of qualified personnel, key contractors, laboratory equipment, and materials and supplies for the manufacture of our product candidates. Further, delays in commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including new facilities, could delay our development plans, including the initiation and conduct of our ongoing and planned clinical trials, and thereby limit our opportunities for growth. In addition, we and our third-party manufacturers may have limited manufacturing capacity for certain product candidates or components, and we may not be able to locate additional or replacement manufacturing capacity on a reasonable basis or at all.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with manufacturing operations, including difficulties with production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations, 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. 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 the manufacturing facilities, 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, financial condition and results of operations.

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 product candidates are currently in research, preclinical or clinical development. Only a small number of research and development programs ultimately result in commercially successful drugs. The development of cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop programmed cellular immunotherapies is ongoing. We may determine to incorporate information learned from this research into the design of our ongoing Phase 2 clinical trial of ProTmune and 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. 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. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our 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 such as FT500, FT516, and FT596, 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;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates, including ProTmune;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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.

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, 2019, our cash and cash equivalents and investments were $260.9 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 current Phase 1/2 PROTECT clinical trial of ProTmune, our ongoing and planned clinical trials of FT500, FT516 and FT596, and any additional clinical trials we may initiate, conduct or support for our product candidates, including for our other iPSC-derived cell 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;
- 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 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.

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.

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 of ProTmune, FT500, or FT516, or the initiation of clinical trials for FT596 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 cancer and immune disorders, including NK- and T-cell immuno-oncology programs that encompass off-the-shelf engineered product candidates derived from clonal master iPSC lines, and immuno-regulatory programs. 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 or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our current product candidates in our ongoing clinical trials, as well as patients who may undergo treatment with FT596 and other product candidates that we may develop, 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, particularly FT500, FT516, FT596, and any other iPSC-derived cell product candidates we may develop, 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 stem cell therapies 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. 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 product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to prevent acute graft-versus-host disease in patients undergoing allogeneic HSCT, which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for ProTmune.

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, and results from earlier studies, may not be predictive of the final results, or of later studies or future clinical trials.

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Although 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. While we have demonstrated in preclinical models that a single administration of ProTmune resulted in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, we may not observe similar results in future preclinical or clinical studies of ProTmune, including our Phase 1/2 PROTECT study. Additionally, the data reported from the Phase 1 stage of PROTECT as of the November 26, 2018 data cut-off date may not continue for these subjects or be repeated or observed in ongoing or future studies involving ProTmune, including in the Phase 2 stage of the PROTECT study. It is possible that subjects for whom events of acute GvHD have been reduced or eliminated may experience acute GvHD in the future, as there is limited data concerning long-term safety and efficacy following treatment with ProTmune. Accordingly, ProTmune may not demonstrate in the Phase 2 stage of PROTECT, or in subsequent trials, an adequate safety or efficacy profile to support further development or commercialization.

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 that enroll in our current or future clinical trials.

From time to time, we also publish interim, "top-line," or preliminary data from our clinical studies. 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. 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.

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, 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 expect to rely on orphan drug status to develop and commercialize certain of our product candidates, but our existing 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 expect to rely on orphan drug exclusivity for ProTmune and may rely on orphan drug exclusivity for other 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. We have been granted orphan drug designation in the United States for *ex vivo* programmed mobilized peripheral blood for the prevention of GvHD in patients undergoing allogeneic hematopoietic cell transplantation, and in the European Union for ProTmune for treatment in hematopoietic stem cell transplantation. While we have been granted these orphan designations, even if we 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. In addition, we may be unable to obtain orphan drug designations for any other product candidates that we are currently developing or may pursue.

For any product candidate for which we are 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 and health information privacy and security laws. Any 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. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. It is possible that some of our business activities could be subject to challenge under one or more of these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Reliance on Third Parties

We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. 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, including cell processing facilities associated with clinical trial sites, 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 In addition, we have not yet caused 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.

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, or in the event of problems with any of the manufacturing facilities that we rely on to manufacture our product candidates or materials, we may not be able to locate additional or replacement facilities for 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.

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. Any failure by third parties that are manufacturing our product candidates or components for such product candidates to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of such components or product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, 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.

We currently depend on third-party cell processing facilities for the manufacture of ProTmune under specific conditions. Any failure by these facilities 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, these product candidates.

Clinical cell processing facilities operated by or affiliated with our clinical sites currently manufacture ProTmune for use in our clinical trials of these product candidates. We will be required by the FDA to standardize the manufacture of ProTmune, and any other product candidates we may develop, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the anticipated manufacture of these product candidates for commercialization may require each of the clinical cell processing facilities at which ProTmune are manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a BLA or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with regulatory requirements and to properly execute the protocol for the manufacture of any of our product candidates. In particular, if the FDA requires each of the clinical cell processing facilities to comply with cGMP, there can be no guarantee that they will be able to do so. Because of these manufacturing requirements, if the applicable clinical cell processing facilities are unable to manufacture any of our product candidates, including ProTmune, in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we may be required to identify alternative processes or facilities for the manufacture of such product candidate, which may require us to spend significant additional time and resources, and would impair our ability to manufacture, complete the clinical development of, and to commercialize, such product candidate. To comply with applicable regulatory and manufacturing requirements, the clinical cell processing facility may be required to possess or obtain certain equipment, including but not limited to biosafety cabinets, warming devices, cell washing devices, freezers or other materials, or to modify aspects of its operations, including its physical facility or layout, environmental systems, monitoring systems, quality systems or training procedures. If a clinical cell processing facility is unwilling or unable to comply with these regulatory or manufacturing requirements, it will be restricted or prohibited from manufacturing such product candidate and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of such product candidate or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

We expect to depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangement with Ono under the Ono Agreement, 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.

For some programs, we currently depend, and expect to continue to depend, on third-party collaborators and strategic partners to design and conduct our clinical trials. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. In addition, if any of these collaborators or strategic partners withdraw support for our programs or proposed products, or otherwise impair their development, our business could be negatively affected.

In addition, we currently depend, and expect to continue to depend, upon strategic collaboration partners for the financial resources and conduct of activities for the development and commercialization of certain of our product candidates. For example, under the Ono Agreement we have agreed to jointly develop and commercialize with Ono two iPSC-derived CAR T cell product candidates, and additionally we are relying on Ono for the conduct of certain activities relating to the development and commercialization of these products. As such, we will not have sole control over the course of development of these product candidates arising under the Ono Agreement, or any other product candidates that we may develop under a future strategic partnership or collaboration arrangement. This lack of control over the development and commercialization of certain of our product candidates could cause delays or other difficulties in the development and commercialization of such product candidates, which may prevent completion of research and development activities and intended IND filings in a timely fashion, if at all. Our reliance on strategic collaboration partners, including Ono, for the development and commercialization of our product candidates entails risks to which we may not otherwise be subject, including:

- a collaboration partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaboration partner may cease development in therapeutic areas which are the subject of our partnerships;
- a collaboration partner may change the success criteria for a particular program or potential product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation or conduct of certain activities by a collaboration partner could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidates;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may exercise its rights under the agreement to terminate the partnership;
- a dispute may arise between us and a collaboration partner concerning the research, development or commercialization of a program or product candidate resulting in a delay in milestones, royalty payments or termination of a program; and
- a collaboration partner may use our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of the Ono Agreement or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payments, sharing of profits, and other benefits under such agreement. Any of these events could have a material adverse effect on our ability to develop and commercialize our product candidates, including the two iPSC-derived CAR T cell product candidates being developed under the Ono Agreement, and may adversely impact our results of operations and financial condition.

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 clinical cell processing facilities and CMOs have purchased equipment, materials and disposables, such as automated cell washing devices, automated cell warming units, commercially available media and cell transfer and wash sets, 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 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, including our pharmacologic modulators and components for our cell processing media. An inability to continue to source product from any of these suppliers, which could be due to 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 satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of 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 face a variety of challenges and uncertainties associated with our dependence on human donor material for the manufacture of ProTmune.

ProTmune is manufactured from the blood of third-party donors, and therefore, the manufacture of ProTmune is subject to the availability and quality of the third-party donor material. The selection of the appropriate donor material for manufacture of ProTmune requires close coordination between clinical and manufacturing personnel.

ProTmune is manufactured using mobilized peripheral blood (mPB), which is currently procured directly by the clinical cell processing facilities from the National Marrow Donor Program (NMDP) for our ongoing Phase 1/2 PROTECT clinical study. The availability of mPB for the manufacture of ProTmune depends on a number of regulatory, political, economic and technical factors outside of our control, including:

- government policies relating to the regulation of mPB for clinical use;
- NMDP and individual blood bank policies and practices relating to mPB acquisition and banking;
- the pricing of mPB;
- the methods used in searching for and matching mPB to patients, which involve emerging technology related to current and future mPB parameters that guide the selection of an appropriate unit of mPB for transplantation; and
- methods for the procurement and shipment of mPB and its handling and storage at clinical sites.

Additionally, we do not have control over the supply, availability, price or types of mPB that these clinical cell processing facilities use in the manufacture of ProTmune. We rely heavily, and expect to continue to rely heavily, on these third parties to procure mPB that is collected in compliance with government regulations and within the current standard of care. In addition, we may identify specific characteristics of specific units of mPB, such as the volume and red blood cell content, which may limit the ability to use such units in the manufacture of ProTmune even though this mPB may otherwise be suitable for use in allogeneic transplant. As a result, the requirement for mPB to meet our specifications may limit the potential inventory of mPB eligible for use in the manufacture of ProTmune for our ongoing and any future clinical trials and for commercial supplies of ProTmune, if approved.

In the United States, the banking and use of mPB does not require a BLA, and mPB is not an FDA licensed product. However, the FDA does require that units of mPB adhere to and meet the standards set forth by the Foundation for Accreditation for Cell Therapy (FACT), the NMDP, and the American Association of Blood Banks (AABB), as applicable. In our current Phase 1/2 PROTECT clinical trial of ProTmune, ProTmune is manufactured using unlicensed mPB units. It may be possible that in the future, regulatory policy could change, and the FDA may later require that mPB units be licensed, and that ProTmune be manufactured using only licensed mPB units. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

Further, manufacture of ProTmune from donor material involves complex processes, with specialized equipment and highly skilled and trained personnel. The processes for manufacturing ProTmune are susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Such contaminations increase the risk of adverse side effects and result in delays in the development of ProTmune.

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, cell processing laboratories, and clinical research organizations (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.

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. 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 ProTmune and 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, including ProTmune, FT596 and FT819 through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, 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. 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 part*e 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 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. If any third-party patents were held by a court of competent jurisdiction to cover aspects of the manufacture of any of our product candidates, any compositions formed during the manufacture, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property rights, unless that third-party grants us rights to use its intellectual property. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

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. Trade secrets, however, may be difficult to protect, and if our employees, collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors, which would adversely affect our business position.

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 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 product candidates, and the targeted indication of HSCT procedures in general and our cellular immunotherapy product candidates in particular, 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, including in the area of orphan drug products. 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 new products could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments, such as HSCT or cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payers. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payer will decide with respect to reimbursement levels for novel products such as ours. Our products may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, 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.

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 payers, 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.

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 orphan indications and other rare diseases. 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.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Since its enactment, there have been many judicial, President, and Congressional challenges to numerous aspects of the ACA. As a result, the full impact on our business of the ACA, the potential impacts of any challenges including any laws repealing and/or replacing elements of it, as well as the political uncertainty surrounding any repeal or replacement legislation, remain unclear.

Additionally, at the federal level, statutes and regulations routinely impact a variety of parameters relating to federal programs and Medicare. In July 2018, the Centers for Medicare and Medicaid Services (CMS) published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these federal and state laws and regulations, as well as other new laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

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.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our existing product candidates or any future product candidates we may develop. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional non-clinical or clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our existing product candidates or other product candidates we may develop, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of HSCT and cellular immunotherapy, some of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies. Any adverse developments in the field of cellular immunotherapy generally, and in the practice of HSCT in particular, will negatively affect our ability to develop and commercialize our product candidates. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the need for patients to undergo HSCT procedures is obviated due to the development and commercialization of therapeutics targeting the underlying cause of diseases addressed by HSCT, our business prospects will be significantly harmed.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. 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 obviate the need for HSCT, may be competitive to product 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.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. 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.

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 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.

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.

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.

Our business activities may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, physician payment transparency laws, health information privacy and security laws, and anti-bribery and anti-corruption laws. Our actual or perceived failure to comply with such laws or their relevant foreign counterparts could adversely affect our business.

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and various federal and state fraud and abuse laws, including, without limitation, physician sunshine laws and regulations, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits improper payments or offers of payments, either directly or indirectly, to foreign governments and their officials and political parties by U.S. persons in order to influence official action, or otherwise obtain or retain business. Additionally, the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Affordable Care Act, and their implementing regulations, require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for knowingly and willfully defrauding any healthcare benefit program or 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.

We and any potential collaborators may be subject to 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. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to 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.

In addition, as of May 25, 2018, the General Data Protection Regulation (GDPR) regulates the collection and use of personal data in the EU. The GDPR covers any business, regardless of its location, that provides goods or services to residents in the EU and, thus, could incorporate our activities 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. 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. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is unclear whether the authorities will conduct random audits of companies doing business in the EU, or act solely after complaints are filed claiming a violation of the GDPR. The lack of compliance standards and precedent, enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes 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. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a 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.

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. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the PPACA may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, 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, 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 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 current economic climate and financial market conditions could adversely impact 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 and consultants may be vulnerable to damage from computer viruses and unauthorized access. In the past, we have experienced a cybersecurity breach. Although this incident was resolved without any material costs or disruptions to our business, if a similar event were to occur in the future and cause interruptions in our operations, it could result in a material disruption of development programs and business operations. 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, and similar events relating to their computer systems could also have a material adverse effect on our business. 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.

Certain data breaches must also be reported to affected individuals and the government, 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.

Risks Related to Our Financial Condition and the Ownership 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, 2019, we had an accumulated deficit of $383.5 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, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., 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; and
- general economic and market conditions.

These and other market and industry factors 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. In addition, 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, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and this could divert the time and attention of our management.

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 28, 2020, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 42.8% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 8 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 8 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 51.4%. 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. 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. As a result, all of these shares are currently available for resale to the public, which may result in dilution to our stockholders. During 2019, 25,000 shares of the Class A Convertible Preferred Stock were converted into 125,000 shares of common stock. In addition, pursuant to a shelf registration statement declared effective by the SEC in May 2018, we may sell up to a remaining $6.2 million in shares of our common stock, preferred stock, debt securities, warrants and/or units, and pursuant to a shelf registration statement declared effective by the SEC in August 2017, we may sell up to a remaining $54.0 million in the aggregate of shares of our common stock, preferred stock, debt securities, warrants and/or units. The August 2017 registration statement also provides for the resale by Juno of up to one million shares of common stock held by Juno pursuant to the Stock Purchase Agreement entered into in May 2015. Further, in November 2018 we filed a Form S-3 pursuant to which we may issue up to $50.0 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.

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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act of 2017 (the Tax Act), that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions, limiting the deduction for net operating losses and eliminating net operating loss carrybacks (though any such tax losses may be carried forward indefinitely), in each case, for losses arising in our taxable years beginning after December 31, 2017, allowing for the expensing of capital expenditures and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Act on our business, whether adverse or favorable, is uncertain, and may not become evident for some period of time. We urge you to consult with your own legal and tax advisors with respect to applicable tax laws, including this legislation, and the potential tax consequences of investing in our common stock.

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, 2019, we had federal and California net operating loss carryforwards of $168.2 million and $168.2 million, respectively, which begin to expire in various amounts in 2027. As of December 31, 2019, we also had federal and California research and development tax credit carryforwards of $13.4 million and $8.5 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 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 2019. We have not analyzed periods subsequent to December 2019. 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. In addition, under the Tax Act the amount of NOLs generated in taxable periods beginning after December 31, 2017, 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. The Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Facilities

As of December 31, 2019, we occupied approximately 72,000 square feet of office and laboratory space in San Diego, California under a non-cancelable operating lease through December 2028. In addition, we have additional operating leases for office and laboratory space in New York, New York and San Diego, California that had not commenced as of December 31, 2019. 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

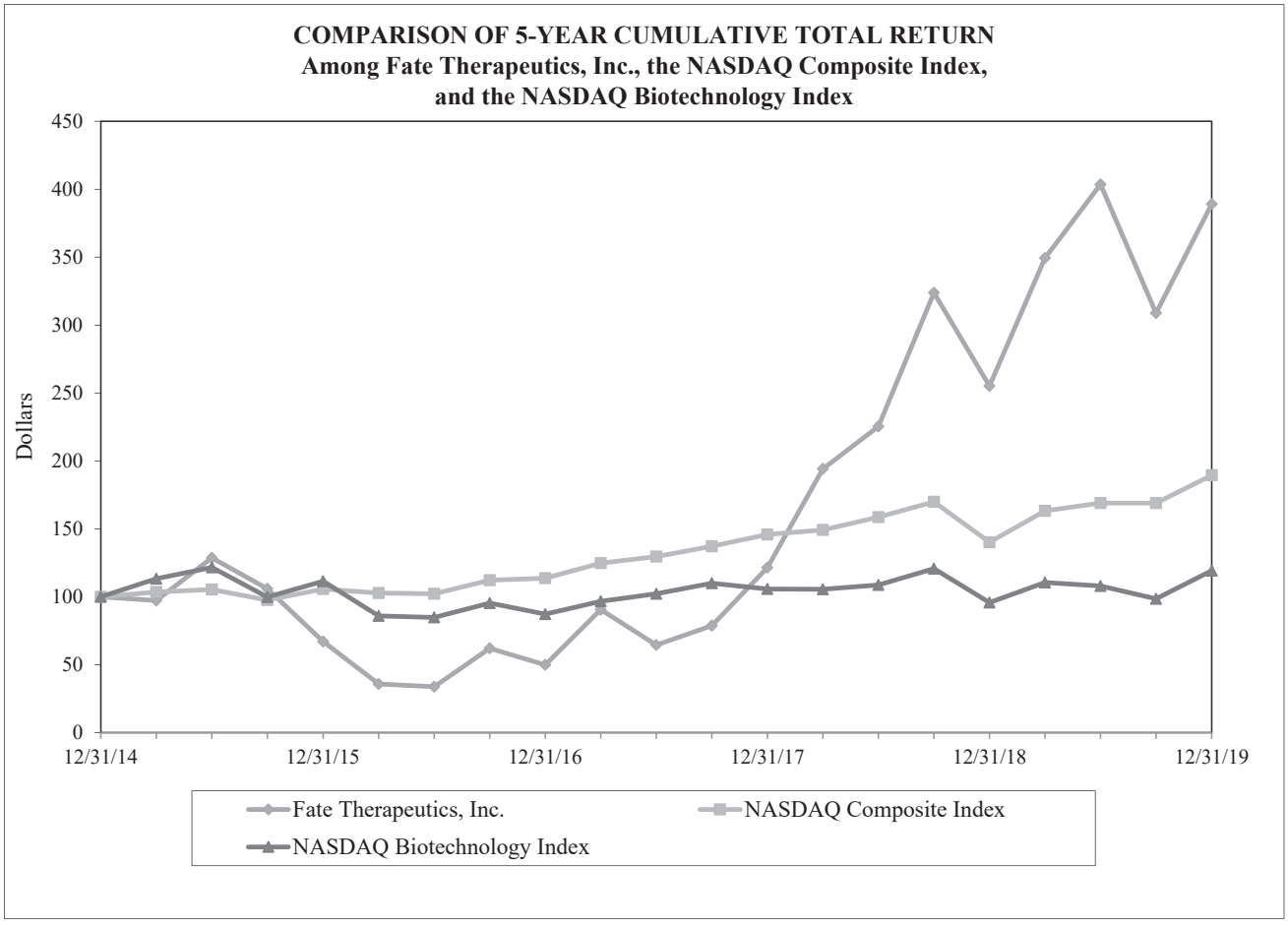
Our ticker symbol is "FATE", as traded and reported by The NASDAQ Global Market.

Holders of Common Stock

As of February 27, 2020, there were approximately 35 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, 2019. 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, 2014. 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, 2019, 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, 2019.

ITEM 6. Selected Financial Data

The following selected data should be read in conjunction with our financial statements located elsewhere in this Annual Report on Form 10-K and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations".

	Years Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Collaboration revenue	$ 10,680	$ 4,740	$ 4,106	$ 4,402	$ 2,431
Operating expenses:					
Research and development	87,770	56,024	34,358	26,452	19,861
General and administrative	23,637	15,808	11,873	9,913	10,352
Total operating expenses	111,407	71,832	46,231	36,365	30,213
Loss from operations	(100,727)	(67,092)	(42,125)	(31,963)	(27,782)
Total other income (expense), net	2,578	494	(827)	(1,499)	(2,210)
Net loss	(98,149)	(66,598)	(42,952)	(33,462)	(29,992)
Other comprehensive income (loss)	24	1	(2)	(1)	—
Comprehensive loss	$ (98,125)	$ (66,597)	$ (42,954)	$ (33,463)	$ (29,992)
Net loss per common share, basic and diluted	$ (1.44)	$ (1.19)	$ (1.02)	$ (1.05)	$ (1.18)
Weighted-average common shares used to compute basic and diluted net loss per share	68,190,741	56,195,650	41,982,167	31,754,140	25,484,262

	December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 99,814	$ 190,514	$ 88,952	$ 88,609	$ 64,809
Short-term investments and related maturity receivables	121,613	10,493	11,997	3,503	—
Working capital	199,283	177,933	91,547	78,136	52,211
Long-term investments	39,440	—	—	—	—
Total assets	302,274	213,032	105,292	95,048	67,958
Long-term debt, current portion	—	2,438	—	8,187	7,550
Long-term debt, net of current portion	—	12,446	14,808	2,501	10,688
Deferred revenue, current portion	2,787	7,588	2,105	2,105	2,401
Deferred revenue, net of current portion	3,775	7,500	724	2,829	4,934
Convertible preferred stock	35,956	36,289	36,289	36,289	—
Accumulated deficit	(383,545)	(285,396)	(218,798)	(175,846)	(142,384)
Total stockholders' equity	$ 244,756	$ 160,469	$ 77,189	$ 73,154	$ 38,038

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 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 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, 2018 as filed with the Securities and Exchange Commission on March 5, 2019.

Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. 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. For certain of our product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of healthy donor-sourced cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties and 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 these therapeutic approaches, we program cells of the blood and immune system, including natural killer (NK) cells, T cells and $CD34^+$ cells, and are advancing a pipeline of programmed cellular immunotherapies.

We have entered into a research collaboration and license agreement with the Regents of the University of Minnesota to develop off-the-shelf, engineered NK cell cancer immunotherapies derived from clonal master iPSC lines. Additionally, we have entered into a research collaboration and license agreement with Memorial Sloan Kettering Cancer Center (Memorial Sloan Kettering) to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines.

We have 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 chimeric antigen receptor (CAR) T-cell product candidates.

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;
- 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 Ono, University of Minnesota and Memorial Sloan Kettering;

- 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 revenues from sales of any therapeutic products 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.

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. Our revenues have been derived from collaboration agreements and government grants.

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. 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, of which $6.5 million has been received as of December 31, 2019.

We concluded that Ono represented a customer and in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, 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.

During the years ended December 31, 2019 and 2018, we recognized $9.3 million and $0.6 million, respectively, of collaboration revenue under the Ono Agreement. As of December 31, 2019, aggregate deferred revenue related to the Ono Agreement was $6.6 million.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies.

In connection with the Juno Agreement, during the years ended December 31, 2019 and 2018, we recognized $1.4 million and $4.1 million, respectively, as collaboration revenue in the consolidated statements of operations and comprehensive loss.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled. The final quarterly research payment of $0.2 million was received during May 2019 and no additional payments are expected.

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 Ono, University of Minnesota and Memorial Sloan Kettering. Our current planned research and development activities over the next twelve months consist primarily of the following:

- conducting clinical trials of our product candidates;
- 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;
- source 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 Ono, University of Minnesota and Memorial Sloan Kettering.

Due to the inherently unpredictable nature of preclinical and clinical development, 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 of our product candidates. Clinical and preclinical development timelines and costs, and the potential of development 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 plans and capital requirements.

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 primarily of interest income earned on cash and cash equivalents, interest income from investments (including the amortization of discounts and premiums), and interest expense.

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 accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, 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. To date, for collaboration arrangements that represent a single performance obligation, the revenues are recognized over time based on costs incurred compared to total estimated costs.

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 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.

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. For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with 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.

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. Due to the lack of an adequate history of a public market for the trading of our common stock and a lack of adequate company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. 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 8 of the notes to the consolidated financial statements for additional information.

The fair value of 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.

Total stock-based compensation expense for the years ended December 31, 2019, 2018, and 2017, was $17.4 million, $6.3 million, and $3.6 million, respectively. Expense related to unvested stock option grants not yet recognized as of December 31, 2019 was $40.4 million and the weighted-average period over which these grants are expected to vest is 2.9 years. As of December 31, 2019, the unrecognized compensation cost related to outstanding restricted stock units was $6.2 million, which is expected to be recognized as expense over approximately 2.7 years.

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, 2019 and 2018

The following table summarizes the results of our operations for the years ended December 31, 2019 and 2018:

	Years Ended December 31,		
	2019	2018	Increase
	(in thousands)		
Collaboration revenue	$ 10,680	$ 4,740	$ 5,940
Research and development expenses	87,770	56,024	31,746
General and administrative expenses	23,637	15,808	7,829
Total other income, net	2,578	494	2,084

Revenue. During the years ended December 31, 2019 and 2018, we recognized revenue of $10.7 million and $4.7 million, respectively, under our collaboration agreements with Ono and Juno.

Research and development expenses. Research and development expenses were $87.8 million for the year ended December 31, 2019, compared to $56.0 million for the year ended December 31, 2018. The increase in research and development expenses was attributable primarily to the following:

- $14.7 million increase in employee compensation and benefits expense, including employee-stock based compensation expense;
- $10.3 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;
- $9.3 million increase in third-party professional consultant and service provider expenses relating to the manufacture and clinical development of our product candidates and the conduct of our research activities, including under our collaboration agreements;
- $2.4 million increase in facility lease expense due to an office and lab expansion in January 2019.

These increases were partially offset by an aggregate decrease of $6.7 million in licensing expense resulting from the Amended and Restated Exclusive License with MSK that occurred in May 2018 and the Exclusive License Agreement with the J. David Gladstone Institutes that occurred in September 2018. No such expense was present in fiscal year 2019. See Note 2 of the consolidated financial statements for additional detail.

General and administrative expenses. General and administrative expenses were $23.6 million for the year ended December 31, 2019, compared to $15.8 million for the year ended December 31, 2018. The increase in general and administrative expenses was attributable primarily to a $6.5 million increase in employee compensation and benefits expense, including employee stock-based compensation expense and an increase of $0.5 million in facility lease and related expense.

Other income, net. Other income, net was $2.6 million and $0.5 million for the years ended December 31, 2019 and 2018, respectively. Other income, net for each period consisted primarily of interest income earned on cash and cash equivalents, interest income from investments (including the amortization of discounts and premiums) and interest expense relating to our term loan with Silicon Valley Bank.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of December 31, 2019, we had an accumulated deficit of $383.5 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:

	2019	2018	2017
		(in thousands)	
Net cash used in operating activities	$ (83,175)	$ (38,650)	$ (36,817)
Net cash used in investing activities	(157,453)	(463)	(10,196)
Net cash provided by financing activities	149,928	140,780	47,356
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (90,700)	$ 101,667	$ 343

Operating Activities

Cash used in operating activities increased from $38.7 million for the year ended December 31, 2018 to $83.2 million for the year ended December 31, 2019. The change in cash used in operating activities was attributable primarily to our increase in net loss and a decrease in the deferred revenue balance from 2018 to 2019, partially offset by an increase in stock-based compensation expense.

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 has agreed to pay us 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 each Candidate 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 (a) Candidate 1 in Asia, with us retaining rights for development and commercialization in all other territories of the world and (b) 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.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize the Candidates and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, we are entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 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, 2019, we have not received any such payments. 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 each Candidate in specified territories, with such royalties subject to certain reductions. As of December 31, 2019, no royalties have been paid to us.

As a direct result of our entry into the Ono Agreement, we incurred an aggregate of $2.0 million in sublicense consideration to certain of our existing licensors. The $2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs.* As of December 31, 2019, all such consideration has been paid, with $1.0 million paid during the year ended December 31, 2019.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement with Juno Therapeutics, Inc. (the Juno Agreement) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. During the year ended December 31, 2019, we received $1.2 million in research payments related to the Juno Agreement.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled and the overall agreement terminated upon our receipt of the final quarterly research payment of $0.2 million.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, we entered into an Amended and Restated Exclusive License Agreement with Memorial Sloan Kettering Cancer Center (MSK). The agreement amends and restates the license agreement entered into between us and MSK on August 19, 2016. In consideration for the additional rights granted under the May 2018 agreement, we issued 500,000 shares of our common stock to MSK, which shares were valued at $4.8 million on the date of agreement. We also paid an upfront cash fee of $0.5 million, and we are obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones and royalty payments to MSK on net sales of licensed products. We are also obligated to pay MSK a percentage of certain sublicense income received by us. Furthermore, in the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive additional milestone payments, where the amount of such payments owed to MSK are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone.

J. David Gladstone Institutes License Agreement

On September 11, 2018, we entered into an exclusive license agreement with the J. David Gladstone Institutes (Gladstone). Pursuant to the license agreement with Gladstone, we issued 100,000 shares of our common stock to Gladstone, which shares were valued at $1.3 million on the date of the agreement. We also paid an upfront cash fee of $0.1 million, and we are obligated to pay milestone payments in an aggregate amount of up to approximately $1.9 million upon the achievement of specified clinical, regulatory and commercial milestones and as well as royalties to Gladstone in the low single digits on net sales of licensed products. We are also obligated to pay Gladstone a tiered percentage in the low to mid-single digits of certain sublicense income received by us.

Investing Activities

During the years ended December 31, 2019 and 2018, investing activities used cash of $157.5 million and $0.5 million, respectively. During the year ended December 31, 2019 we purchased $248.9 million of investments, which were partially offset by $98.8 million in maturities of investments. During the year ended December 31, 2018, we purchased $55.7 million of investments, offset by $57.5 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 $149.9 million for the year ended December 31, 2019, which primarily consisted of $162.4 million of net proceeds from our September 2019 public offering of common stock and $2.5 million in proceeds from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options net of issuance costs. These proceeds were partially offset by $15.0 million in repayments on our long-term debt facility.

Financing activities provided cash of $140.8 million for the year ended December 31, 2018, which primarily consisted of the $134.6 million of net proceeds from our September 2018 public offering of common stock and $3.5 million of proceeds from the California Institute for Regenerative Medicine (CIRM) award.

From our inception through December 31, 2019 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, 2019, we had aggregate cash and cash equivalents and investments of $260.9 million.

Public Offering of Common Stock

In September 2019, we completed a public offering of common stock in which investors, certain of which are affiliated with our directors, purchased 9,890,000 shares of our common stock at a price of $17.50 per share under our shelf registration statement. Gross proceeds from the offering were $173.1 million. After giving effect to $10.7 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were $162.4 million.

In September 2018, we completed a public offering of common stock in which investors, certain of which are affiliated with our directors, purchased 10,648,149 shares of our common stock at a price of $13.50 per share under our shelf registration statement. Gross proceeds from the offering were $143.8 million. After giving effect to $8.9 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were $134.9 million.

In December 2017, we completed a public offering of common stock in which investors purchased 10,953,750 shares of our common stock at a price of $4.20 per share under a shelf registration statement. Gross proceeds from the offering were $46.0 million. After giving effect to an estimated $3.0 million in underwriting discounts, commissions and expenses related to the offering (of which $0.3 million was paid during 2018), net proceeds were $43.0 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 December 2018, we discussed with CIRM our intent to pursue the clinical development of FT516 in relapsed / refractory hematologic malignancies in addition to advanced solid tumors, and our preference to first submit an IND application for FT516 in relapsed / refractory hematologic malignancies rather than in advanced solid tumors. In January 2019, we submitted our IND application for FT516 in relapsed / refractory hematologic malignancies, which IND submission was allowed by the FDA in February 2019. We agreed with CIRM to suspend the Award until such time as we elected to proceed with our submission of an IND application for FT516 in advanced solid tumors. In November 2019, we submitted an IND application for FT516 in advanced solid tumors and the Award was taken off of suspension by CIRM in January 2020. In February 2020, we received a $0.4 million disbursement based on a milestone achievement.

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.

Silicon Valley Bank Debt Facility

On July 30, 2014, we entered into an Amended and Restated Loan and Security Agreement (Restated LSA) with Silicon Valley Bank (Bank), collateralized by substantially all of our assets, excluding certain intellectual property. The Restated LSA amends and restates the Loan and Security Agreement, dated as of January 5, 2009, as amended, by and between us and the Bank (Loan Agreement). Pursuant to the Restated LSA, the Bank agreed to make loans to us in an aggregate principal amount of up to $20.0 million, comprised of (i) a $10.0 million term loan, funded at the closing date (Term A Loan) and (ii) subject to the achievement of a specified clinical milestone, additional term loans totaling up to $10.0 million in the aggregate, which were available until December 31, 2014 (each, Term B Loan). On December 24, 2014, we elected to draw $10.0 million under the Term B Loan.

On July 14, 2017, we entered into an amendment (SVB Loan Amendment) of the Restated LSA with the Bank where the Bank extended an additional term loan to us in the principal amount of $15.0 million (2017 Term Loan), a portion of which was applied to repay in full all amounts previously outstanding under the Restated LSA. Following such repayment in full of our existing outstanding debt with the Bank under the Restated LSA, cash proceeds from the remaining portion of the 2017 Term Loan were $7.5 million.

On November 13, 2019 we used cash on hand in the amount of $14.2 million to repay in full all outstanding obligations related to the Restated LSA and SVB Loan Amendment. Accordingly, all of our obligations under the Restated LSA and SVB Loan Amendment have been paid and discharged in full, and all security interests and other liens granted by us to the Bank to secure our obligations have been terminated and released.

In connection with the SVB Loan Amendment, we issued to the Bank on the First Amendment Effective Date a warrant to purchase up to an aggregate of 91,463 shares of our common stock, subject to adjustment, at an exercise price equal to $3.28 per share. All such warrants have been exercised as of December 31, 2019.

Registration Statements on Form S-3

In November 2018, we filed an automatic shelf registration statement (File No. 333-228513), 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, if any, under the automatic shelf registration statement would be established at the time of such offering. Additionally, we entered into a sales agreement with Leerink Partners LLC (Leerink) 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 $50.0 million through Leerink as its sales agent.

In May 2018, the SEC declared effective a shelf registration statement filed by us in May 2018 (File No. 333-224680). 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, if any, under the shelf registration statement would be established at the time of such offering. As of December 31, 2019, after giving effect to our September 2018 public offering, we are eligible to issue an aggregate of $6.2 million in securities under this shelf registration statement.

In August 2017, the SEC declared effective a shelf registration statement filed by us in August 2017 (File No. 333-219987). 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, if any, under the shelf registration statement would be established at the time of such offering. As of December 31, 2019, after giving effect to our December 2017 public offering, we are eligible to issue an aggregate of $54.0 million in securities under the shelf registration statement. In addition, this registration statement registered for resale one million shares of common stock held by Juno, which were issued in May 2015 in conjunction with the Juno Agreement.

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 and development of, and seek regulatory approvals for, our product candidates and conduct additional research and development activities pursuant to our collaboration agreement with 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, 2019 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 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 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 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 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 and development of our product candidates and to perform our research and development obligations under our collaboration agreement with Ono, and we may be forced to seek additional funds sooner than expected to pursue our research and development activities. 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 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.

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 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;
- the extent to which milestones are achieved under our collaboration agreement with Ono 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.

If we cannot continue or expand our research 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

The following table summarizes our contractual obligations at December 31, 2019 that are expected to affect our liquidity and cash flows in future periods:

(in thousands)	Total	Less than 1 Year	Years 1 - 3	Years 3 - 5	More than 5 Years
Operating lease obligations	38,201	3,760	7,862	8,341	18,238
Total	$ 38,201	$ 3,760	$ 7,862	$ 8,341	$ 18,238

We lease our headquarters office and laboratory space under a non-cancelable operating lease. In May 2018, we amended the operating lease, extending the term of the lease through approximately 2028 and agreeing to lease additional space comprising approximately 24,000 square feet in the same building as our existing space for a total occupancy of approximately 72,000 square feet under the lease. In addition to rent, the lease is subject to certain fixed amenities fees. The above table includes all such fixed fees. The lease is subject to additional variable charges for common area maintenance and other costs. We maintain the right to terminate the lease after October 2025, subject to our delivery to the landlord of twelve months' prior written notice and an early termination payment of $2.5 million. See Note 7 of the consolidated financial statements for additional detail.

During January 2020, we entered into a new lease agreement for a future headquarters facility. The lease shall commence, subject to certain conditions, in May 2021 and has a term of 15 years from the commencement date, with the option to extend the lease for two successive five-year terms. Total future minimum lease payments under the lease are $157.6 million, payable in monthly installments beginning on the lease commencement date. These obligations are not included in the above contractual obligations table as of December 31, 2019. We have a one-time option to terminate the lease after 10 years from the commencement date, subject to a payment of a $30.0 million early termination fee.

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 or in the table above 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 Children's Medical Center Corporation pursuant to which we license certain patents relating to our *ex vivo* cell programming approach and our programmed hematopoietic cell therapies, 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 $5.0 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 this agreement, and we will be required to pay a percentage of any sublicense income.

- 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.

We enter into contracts in the normal course of business, including with clinical sites and 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.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk primarily related to changes in interest rates. As of December 31, 2019, 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.

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 March 2, 2020, expressed an unqualified opinion thereon

Adoption of ASU No. 2016-02

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

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 Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that is communicated or required to be communicated to the audit committee and that: (1) relates to an account or disclosure that is material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of acritical 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 separate opinions on the critical audit matter or on the account or disclosure to which it relates.

Estimated total costs expected to be incurred under the Ono Collaboration

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 the Ono collaboration agreement 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 actual costs incurred compared to the estimated total costs expected to be incurred. 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 assumption relates to the estimated total costs expected to be incurred under the 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 to complete and the review of the estimates to complete 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 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 the total and remaining costs to be incurred. In addition, we performed sensitivity analyses, including assessing the reasonableness of the estimated costs to be incurred 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

March 2, 2020

Fate Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except par value and share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 99,814	$ 190,514
Accounts receivable	—	500
Short-term investments and related maturity receivables	121,613	10,493
Prepaid expenses and other current assets	5,662	3,689
Total current assets	227,089	205,196
Long-term investments	39,440	—
Property and equipment, net	11,419	5,125
Operating lease right-of-use assets	22,752	—
Restricted cash	227	227
Collaboration contract asset	1,338	1,958
Other assets	9	526
Total assets	$ 302,274	$ 213,032
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,822	$ 4,205
Accrued expenses	14,697	10,926
CIRM award liability, current portion	2,808	2,106
Deferred revenue, current portion	2,787	7,588
Operating lease liabilities, current portion	1,692	—
Long-term debt, current portion	—	2,438
Total current liabilities	27,806	27,263
Deferred rent	—	3,401
Accrued expenses	—	549
Deferred revenue, net of current portion	3,775	7,500
CIRM award liability, net of current portion	702	1,404
Operating lease liabilities, net of current portion	25,235	—
Long-term debt, net of current portion	—	12,446
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares—5,000,000 at December 31, 2019 and December 31, 2018; designated Class A Convertible Preferred shares—2,819,549 at December 31, 2019 and December 31, 2018; Class A Convertible Preferred shares issued and outstanding—2,794,549 at December 31, 2019 and 2,819,549 at December 31, 2018	3	3
Common stock, $0.001 par value; authorized shares—150,000,000 at December 31, 2019 and December 31, 2018; issued and outstanding—75,730,260 at December 31, 2019 and 64,693,681 at December 31, 2018	76	65
Additional paid-in capital	628,200	445,799
Accumulated other comprehensive gain (loss)	22	(2)
Accumulated deficit	(383,545)	(285,396)
Total stockholders' equity	244,756	160,469
Total liabilities and stockholders' equity	$ 302,274	$ 213,032

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,		
	2019	2018	2017
Collaboration revenue	$ 10,680	$ 4,740	$ 4,106
Operating expenses:			
Research and development	87,770	56,024	34,358
General and administrative	23,637	15,808	11,873
Total operating expenses	111,407	71,832	46,231
Loss from operations	(100,727)	(67,092)	(42,125)
Other income (expense):			
Interest income	4,330	2,190	559
Interest expense	(1,752)	(1,696)	(1,268)
Loss on extinguishment of debt	—	—	(118)
Total other income (expense), net	2,578	494	(827)
Net loss	$ (98,149)	$ (66,598)	$ (42,952)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities, net	24	1	(2)
Comprehensive loss	$ (98,125)	$ (66,597)	$ (42,954)
Net loss per common share, basic and diluted	$ (1.44)	$ (1.19)	$ (1.02)
Weighted–average common shares used to compute basic and diluted net loss per share	68,190,741	56,195,650	41,982,167

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, 2016	2,819,549	$ 3	41,386,506	$ 41	$248,957	$ (1)	$ (175,846)	$ 73,154
Exercise of stock options, net of issuance costs	—	—	83,220	—	226	—	—	226
Issuance of common stock upon vesting of restricted stock units	—	—	225,125	1	(1)	—	—	—
Stock–based compensation	—	—	—	—	3,606	—	—	3,606
Public offering of common stock, net of offering costs	—	—	10,953,750	11	42,968	—	—	42,979
Private placement issuances of common stock, net of offering costs	—	—	—	—	(13)	—	—	(13)
Private placement issuance of Series A convertible preferred stock, net of offering costs	—	—	—	—	(26)	—	—	(26)
Issuance of warrants for common stock	—	—	—	—	217	—	—	217
Unrealized loss on investments	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	(42,952)	(42,952)
Balance at December 31, 2017	2,819,549	$ 3	52,648,601	$ 53	$295,934	$ (3)	$ (218,798)	$ 77,189
Exercise of stock options, net of issuance costs	—	—	694,830	1	2,692	—	—	2,693
Stock–based compensation	—	—	—	—	6,293	—	—	6,293
Public offering of common stock, net of offering costs	—	—	10,648,149	11	134,780	—	—	134,791
Issuance of common stock upon cashless warrant exercise	—	—	102,101	—	—	—	—	—
Issuance of common stock for license agreements	—	—	600,000	—	6,100	—	—	6,100
Unrealized gain on investments	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(66,598)	(66,598)
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

See accompanying notes

Fate Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2019	2018	2017
Operating activities:			
Net loss	$ (98,149)	$ (66,598)	$ (42,952)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	2,193	1,204	971
Stock–based compensation	17,410	6,293	3,606
Amortization of debt discounts and debt issuance costs	115	76	81
Accretion and amortization of premiums and discounts on investments, net	(478)	(335)	(25)
Amortization of collaboration contract asset	620	42	—
Noncash interest expense	—	373	321
Deferred rent	—	192	1,085
Deferred revenue	(8,526)	12,259	(2,105)
Issuance on common stock for license agreement	—	6,100	—
Non-cash loss on extinguishment of debt	—	—	30
Cash payments included in loss on extinguishment of debt	—	—	88
Changes in assets and liabilities:			
Accounts receivable	500	(500)	—
Prepaid expenses and other assets	(1,911)	(2,010)	(428)
Accounts payable and accrued expenses	4,277	4,254	2,511
Right-of-use assets and lease liabilities, net	774	—	—
Net cash used in operating activities	(83,175)	(38,650)	(36,817)
Investing activities			
Purchases of property and equipment	(7,395)	(2,303)	(1,725)
Purchases of investments	(248,858)	(55,660)	(39,971)
Maturities of investments	98,800	57,500	31,500
Net cash used in investing activities	(157,453)	(463)	(10,196)
Financing activities			
Issuance of common stock from equity incentive plans, net of repurchases and issuance costs	2,522	2,693	205
Proceeds from public offering of common stock, net of issuance costs	162,406	134,577	43,206
Proceeds from private placement issuances of common stock, net of issuance costs	—	—	(65)
Proceeds from private placement issuance of preferred stock, net of issuance costs	—	—	(128)
Proceeds from CIRM award	—	3,510	—
Proceeds from long–term debt	—	—	15,000
Payments of debt issuance costs	—	—	(10)
Payments included in loss on extinguishment of debt	—	—	(88)
Principal repayments of long–term debt	(15,000)	—	(10,764)
Net cash provided by financing activities	149,928	140,780	47,356
Net change in cash, cash equivalents and restricted cash	(90,700)	101,667	343
Cash, cash equivalents and restricted cash at beginning of the period	190,741	89,074	88,731
Cash, cash equivalents and restricted cash at end of the period	$ 100,041	$ 190,741	$ 89,074
Supplemental disclosure of cash flow information			
Interest paid	$ 2,291	$ 1,242	$ 2,314
Supplemental schedule of noncash investing and financing activities			
Issuance of warrants for common stock in connection with long–term debt	$ —	$ —	$ 217
Purchases of property and equipment in accounts payable	$ 602	$ 37	$ 48

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 cancer and immune disorders. The Company's therapeutic pipeline is comprised of immuno-oncology programs, including off-the-shelf engineered NK- and T-cell product candidates derived from clonal master induced pluripotent stem cell (iPSC) lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation. The Company's product candidates are based on its proprietary cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of December 31, 2019, 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 September 2019, the Company completed a public offering of common stock in which investors, certain of which are affiliated with the directors of the Company, purchased 9,890,000 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.

In September 2018, the Company completed a public offering of common stock in which investors, including investors affiliated with the directors of the Company, purchased 10,648,149 shares of its common stock at a price of $13.50 per share under a shelf registration statement. Gross proceeds from the offering were $143.8 million, and, after giving effect to $8.9 million of costs related to the offering, net proceeds were $134.9 million.

In December 2017, the Company completed a public offering of common stock in which investors purchased 10,953,750 shares of its common stock at a price of $4.20 per share under a shelf registration statement. Gross proceeds from the offering were $46.0 million, and after giving effect to $3.0 million of costs related to the offering (of which $0.3 million was paid during the year ended December 31, 2018), net proceeds were $43.0 million.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with United States generally accepted accounting principles (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 accrued expenses. 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.

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 carrying amounts of 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 input as described below, the Company believes that the fair value of long-term debt approximates its carrying value.

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.

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and investments. Cash equivalents consisted of money market funds and investments consisted of U.S. treasuries and corporate debt securities. The following table presents the Company's assets which were measured at fair value on a recurring basis as of December 31, 2019 and 2018 (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, 2019:				
Cash equivalents				
Money market funds	$ 84,814	$ 84,814	$ —	$ —
Investments				
U.S. Treasury debt securities	60,303	60,303	—	—
Corporate debt securities	100,750	—	100,750	—
Total assets measured at fair value on a recurring basis	$ 245,867	$ 145,117	$ 100,750	$ —
As of December 31, 2018:				
Cash equivalents				
Money market funds	$ 190,514	$ 190,514	$ —	$ —
Investments				
U.S. Treasury debt securities	10,493	10,493	—	—
Total assets measured at fair value on a recurring basis	$ 201,007	$ 201,007	$ —	$ —

The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers.

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.

As of December 31, 2019 and 2018, the Company had no material liabilities measured at fair value on a recurring 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, 2019, 2018 and 2017 (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Cash and cash equivalents	$ 99,814	$ 190,514	$ 88,952
Restricted cash	227	227	122
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 100,041	$ 190,741	$ 89,074

Amounts included in restricted cash represent security deposits required to secure the Company's credit card limit and its facilities lease.

Investments

Investments are accounted for as available-for-sale securities and are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). 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. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on investments classified as available-for-sale securities are included in other income or expense. 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

Effective January 1, 2019, 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 condensed 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 a ROU asset and lease obligation 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, 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.

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. For stock option grants for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants 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 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 included unrealized gains and losses 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. Dilutive common stock equivalents comprised 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 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,		
	2019	2018	2017
Warrants for common stock	—	85,094	225,756
Common stock options	9,327,742	6,980,581	5,458,043
Restricted stock units	520,000	188,625	212,625
Series A convertible preferred stock (if converted)	13,972,745	14,097,745	14,097,745
Total	23,820,487	21,352,045	19,994,169

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 as of the date of the issuance of these financial statements.

Recently Adopted Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2018-07. ASU 2018-07 expands the scope of Accounting Standards Codification (ASC) 718, *Compensation-Stock Compensation,* to include share-based payment transactions for acquiring goods and services from nonemployees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of ASC 718 will be measured at the grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018. The Company adopted the update in the first quarter of fiscal year 2019 using the modified retrospective method. The adoption did not have a material effect on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (ASC 842), which requires a lessee to recognize a lease liability and a right-of-use asset for all leases with lease terms of more than 12 months. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those years, and early adoption is permitted. Companies may adopt this guidance using a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. In July 2018, the FASB issued ASU 2018-11, which provides the option of an additional transition method that allows entities to initially apply the new lease guidance at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company adopted the standard effective January 1, 2019 using the optional transition method as detailed in ASU 2018-11, which resulted in an increase in operating right-of-use assets of $16.6 million and an increase in total liabilities of $18.2 million on the consolidated balance sheet as of the effective date. There was no material impact on the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2019 as a result of the adoption of ASU 2016-02. There was no impact to the consolidated financial statements for the prior periods presented due to the transition method elected. The Company elected the package of practical expedients permitted under the transition guidance, which among other things, allowed the Company to carry forward the historical lease classification. Additionally, the Company elected the hindsight provision for determining the lease term and elected to aggregate all lease and non-lease components for each class of underlying assets into a single lease component.

Recently Issued Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the expected impact of the guidance, but does not believe the adoption of this guidance will have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13 (ASU 2018-13). ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* amends the disclosure requirements in ASC 820 by adding, changing, or removing certain disclosures. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the expected impact of the guidance, but does not believe the adoption of this guidance will have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the expected impact of the guidance, but does not believe the adoption of this guidance will have a material impact on the Company's consolidated financial statements.

2. Collaboration and License Agreements

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).

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 each Candidate 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 (a) Candidate 1 in Asia, with the Company retaining rights for development and commercialization in all other territories of the world and (b) 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 (each, an Option).

For each Candidate, 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 both Candidates.

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 Ono 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. The Company received $5.0 million in October 2018 as a prepayment for the first year of research and development.

Further, under the terms of the Ono Agreement, Ono has agreed to pay the Company up to an additional $40.0 million, subject to the achievement of a preclinical milestone (Option Milestone) and the exercise by Ono of the Options (Option Exercise Fees) during the Option Period. Such fees are in addition to the upfront payment and research and development fees.

Subject to Ono's exercise of the Options and to the achievement of certain clinical, regulatory and commercial milestones (Milestones) with respect to each Candidate in specified territories, the Company is entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 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 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 of each Candidate in specified territories, with such royalties subject to certain reductions.

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, *Collaborative Arrangements* and determined that the Ono Agreement is applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Ono 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. As a result, the license is classified as symbolic intellectual property under ASC 606. 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 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, whether a significant financing component exists under the Ono Agreement. Such assessment evaluated whether: (i) a substantial amount of the consideration is variable, (ii) the amount, or timing of payment, of the consideration would have varied based on the occurrence or non-occurrence of future events that are not substantially within the control of the Company or Ono, and (iii) the timing of the transfer of the performance obligations is at the discretion of Ono. Based on its assessment, the Company concluded that there was not a significant financing component.

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.

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 will be recognized as revenue over time in conjunction with the Company's conduct of research services over the estimated four-year period based on actual costs incurred compared to estimated total costs expected to be incurred under the Ono Agreement, as the research and development activities are the primary component of the combined performance obligation. 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. To date, the Company has received $6.5 million of research and development fees.

The Company has not assigned a transaction price to any Option Milestone, Milestones or Option Exercise Fees given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Royalties.

As a direct result of the Company's entry into the Ono Agreement, the Company incurred an aggregate of $2.0 million in sublicense consideration to existing licensors of the Company. The $2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is amortized to research and development expense in conjunction with the Company's revenue recognition under the Ono Agreement. During the year ended December 31, 2019, the Company recognized $0.6 million of such expense. As of December 31, 2019, the contract asset had a balance of $1.3 million.

The Company recognized revenue of $9.3 million under the Ono Agreement during the year ended December 31, 2019. 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, 2018, the Company recognized revenue of $0.6 million under the Ono Agreement. Such revenue comprised $0.4 million associated with research services and $0.2 million associated with the upfront payment. As of December 31, 2019, aggregate deferred revenue related to the Ono Agreement was $6.6 million, of which $2.8 million is classified as current.

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. No additional funding is expected from Juno.

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.

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. Total revenue recognized under the Juno Agreement for the year ended December 31, 2018 was $4.1 million, which comprised $2.1 million associated with the upfront fee and the equity premium and $2.0 million associated with research services. Total revenue recognized under the Juno Agreement for the year ended December 31, 2017 was $4.1 million, which comprised $2.1 million associated with the upfront fee and the equity premium and $2.0 million associated with research services. No additional revenue is expected to be recognized under the Juno Agreement in future periods.

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 issued 500,000 shares of the Company's common stock to MSK (the MSK Shares) and, in return, MSK returned its entire interest in Tfinity Therapeutics, Inc. (Tfinity) to the Company. As a result, as of the effective date of the Amended MSK License, Tfinity is a wholly-owned subsidiary of the Company. The MSK Shares were issued pursuant to an exemption from registration under the Securities Act of 1933, as amended (the Securities Act), in reliance on Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering.

Additionally, the Company paid an upfront fee of $0.5 million. The Company is also 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.

Furthermore, in the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive additional milestone payments, where the amount of such payments owed to MSK are contingent upon certain increases in the price of the Company's common stock following the date of achievement of such clinical milestone.

Given the high degree of uncertainty surrounding the achievement of clinical milestones and the requisite increase in the price of the Company's common stock, the Company has not recorded a liability for such payments.

During the year ended December 31, 2018, the Company recognized an aggregate of $5.3 million of research and development expenses, consisting of the $0.5 million upfront cash payment to MSK and the issuance of the MSK Shares, valued at $4.8 million, associated with the Amended MSK License.

Gladstone License Agreement

On September 11, 2018, the Company entered into an exclusive license agreement (the Gladstone License Agreement) with the J. David Gladstone Institutes (Gladstone).

Pursuant to the Gladstone License Agreement, Gladstone granted to the Company exclusive licenses to certain patents and patent applications (the Patent Rights) for the research, development, manufacturing, and commercialization of human therapeutics derived from iPSCs. The Patent Rights cover the use of the CRISPR and engineered nuclease-deactivated CRISPR-associated protein-9 (dCas9) system, known as the CRISPR activation (CRISPRa) system, for cellular reprogramming and iPSC generation.

In consideration for the rights granted under the Gladstone License Agreement, the Company issued to Gladstone 100,000 shares of the Company's common stock (the Gladstone Shares). The Gladstone Shares were issued pursuant to an exemption from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering.

Additionally, the Company paid Gladstone an upfront fee of $0.1 million and is obligated to pay Gladstone milestone payments in an aggregate amount of up to approximately $1.9 million upon the achievement of specified clinical, regulatory and commercial milestones as well as tiered royalties in the low single digits on net sales of human therapeutic products covered by the Patent Rights. The Company is also obligated to pay Gladstone a tiered percentage in the low- to mid-single digits of certain income received by the Company in connection with the sublicense of the Patent Rights.

During the year ended December 31, 2018, the Company recognized an aggregate of $1.4 million of research and development expenses, consisting of the $0.1 million upfront cash payment to Gladstone and the issuance of the Gladstone Shares, valued at $1.3 million, associated with the Gladstone License Agreement.

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. In December 2018, the Company discussed with CIRM its intent to pursue the clinical development of FT516 in relapsed / refractory hematologic malignancies in addition to advanced solid tumors, and the Company's preference to first submit an IND application for FT516 in relapsed / refractory hematologic malignancies rather than in advanced solid tumors. In January 2019, the Company submitted its IND application for FT516 in relapsed / refractory hematologic malignancies, which IND submission was allowed by the FDA in February 2019. The Company and CIRM agreed to suspend the Award until such time as the Company elected to proceed with its submission of an IND application for FT516 in advanced solid tumors. In November 2019, the Company filed an IND application for FT516 in advanced solid tumors and the Award was taken off of suspension by CIRM in January 2020. In February 2020, the Company received a $0.4 million disbursement based on a milestone achievement.

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, 2019, the Company has received aggregate disbursements under the Award in the amount of $3.5 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 and corporate debt securities with maturities ranging from three to eighteen months from the purchase date. These securities are classified as short-term and long-term investments in the accompanying consolidated balance sheets based on each security's contractual maturity date and are accounted for as available-for-sale securities.

The following table summarizes the Company's investments accounted for as available-for-sale securities as of December 31, 2019 and 2018 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
December 31, 2019					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 50,445	$ (4)	$ 16	$ 50,457
Corporate debt securities	1 or less	71,171	(24)	9	71,156
Total short-term investments		$ 121,616	$ (28)	$ 25	$ 121,613
Classified as non-current assets:					
U.S. Treasury debt securities	Greater than 1	$ 9,841	$ —	$ 5	$ 9,846
Corporate debt securities	Greater than 1	29,572	(1)	23	29,594
Total long-term investments		$ 39,413	$ (1)	$ 28	$ 39,440
December 31, 2018					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 10,495	$ (2)	$ —	$ 10,493
Total short-term investments		$ 10,495	$ (2)	$ —	$ 10,493

The Company reviews its investment holdings at the end of each reporting period and determines if any unrealized losses are other-than-temporary 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, 2019, 2018 and 2017 the Company did not recognize any impairment or realized gains or losses on sales of investments and the Company does not consider any of its investments as other-than-temporarily impaired.

5. Property and Equipment

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

	December 31, 2019	2018
Furniture and fixtures	$ 899	$ 516
Computer and office equipment	917	688
Software	103	103
Leasehold improvements—building	2,465	288
Scientific equipment	15,355	7,868
Construction-in-process	198	1,987
Total property and equipment, gross	19,937	11,450
Less accumulated depreciation and amortization	(8,518)	(6,325)
Total property and equipment, net	$ 11,419	$ 5,125

Depreciation expense related to property and equipment was $2.2 million, $1.2 million, and $1.0 million, for the years ended December 31, 2019, 2018, and 2017, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2019, 2018, and 2017. As of December 31, 2019, $0.6 million of fixed assets had not been paid.

6. Accrued Expenses and Long-Term Debt

Accrued Expenses

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

	December 31, 2019	December 31, 2018
Accrued payroll and other employee benefits	$ 5,329	$ 2,938
Accrued clinical trial related costs	5,976	4,729
Accrued other	3,392	3,259
Total current accrued expenses	$ 14,697	$ 10,926

Long-term accrued expenses represented the accrual for the final payment fee associated with our long-term debt.

Long-Term Debt

Long-term debt and unamortized discount balances are as follows (in thousands):

	December 31, 2019	December 31, 2018
Long-term debt	$ —	$ 15,000
Less debt issuance costs and discount, net of current portion	—	(54)
Long-term debt, net of long-term portion of debt issuance costs and discount	—	14,946
Less current portion of long-term debt	—	(2,500)
Long-term debt, net	$ —	$ 12,446
Current portion of long-term debt	$ —	$ 2,500
Less current portion of debt issuance costs and discount	—	(62)
Current portion of long-term debt, net	$ —	$ 2,438

Silicon Valley Bank Debt Facilities

On July 30, 2014, the Company entered into the Amended and Restated Loan and Security Agreement (the Restated LSA) with Silicon Valley Bank (the Bank), collateralized by substantially all of the Company's assets, excluding certain intellectual property. The Restated LSA amends and restates the Loan and Security Agreement, dated as of January 5, 2009, as amended, by and between the Company and the Bank (Loan Agreement). Pursuant to the Restated LSA, the Bank agreed to make loans to the Company in an aggregate principal amount of up to $20.0 million, comprised of (i) a $10.0 million term loan, funded at the closing date (the Term A Loan) and (ii) subject to the achievement of a specified clinical milestone, additional term loans totaling up to $10.0 million in the aggregate, which were available until December 31, 2014 (each, a Term B Loan). On December 24, 2014, the Company elected to draw on the full $10.0 million under a Term B Loan.

On July 14, 2017 (the First Amendment Effective Date), the Company and the Bank entered into the First Amendment (the SVB Loan Amendment) to the Restated LSA between the Company and the Bank dated July 30, 2014. Pursuant to the SVB Loan Amendment, the Bank extended an additional term loan to the Company on July 14, 2017 in the principal amount of $15.0 million (the 2017 Term Loan), a portion of which was applied to repay in full the Company's existing outstanding debt with the Bank under the Restated LSA, which included outstanding principal, accrued interest, and final payment fees. Following such repayment in full of the Company's existing outstanding debt with the Bank under the Restated LSA, cash proceeds to the Company from the remaining portion of the 2017 Term Loan were $7.5 million. The Company determined the repayment of the Restated LSA and issuance of the 2017 Term Loan was a debt extinguishment and accounted for the 2017 Term Loan at fair value as of the First Amendment Effective Date accordingly.

On November 13, 2019, the Company repaid in full all outstanding obligations under the 2017 Term Loan. The Company used cash on hand in the amount of $14.2 million for the repayment of such obligations associated with the 2017 Term Loan, including the repayment of $13.0 million in principal and $1.2 million associated with the final fee and outstanding interest. The Company expensed the remaining debt issuance cost capitalized of $0.1 million to interest expense upon the repayment of the 2017 Term Loan.

The 2017 Term Loan was scheduled to mature on January 1, 2022 (the Term Loan Maturity Date) and beared interest at a floating per annum rate equal to the greater of (i) 3.50% above the Prime Rate (as defined in the SVB Loan Amendment) or (ii) 7.25%; provided, however, that in no event would such interest rate exceed 8.25%. Interest was payable on a monthly basis on the first day of each month.

From August 1, 2017 through January 1, 2019 (the Interest-only Period), the Company was required to make monthly payments of interest only. In January 2019, after achievement of a product development milestone, the Company elected to extend the Interest-only Period from January 1, 2019 through and including to July 31, 2019. The Company was required to repay the principal, plus monthly payments of accrued interest, in 30 equal monthly installments based on a 30-month amortization schedule.

The Company's final payment in November 2019 included all outstanding principal and accrued and unpaid interest under the 2017 Term Loan, plus a 7.5%, or $1.1 million, final payment fee. This final payment fee was accrued as interest expense over the term of the 2017 Term Loan and recorded in accrued expenses. As a result of the Company's early repayment of the 2017 Term Loan during November 2019, the unaccrued balance of the final payment fee of $0.3 million was recorded in interest expense during the year ended December 31, 2019.

For the years ended December 31, 2019, 2018, and 2017, the Company recorded $1.8 million, $1.7 million, and $0.8 million respectively, in aggregate interest expense related to the 2017 Term Loan.

Warrants

In connection with the funding of the Term B Loan under the Restated LSA, the Company issued the Bank and one of its affiliates fully-exercisable warrants to purchase an aggregate of 98,039 shares of the Company's common stock (the 2014 Warrants) at an exercise price of $4.08 per share. In March 2018, a portion of the 2014 Warrants were exercised in exchange for 34,149 shares of the Company's common stock in a cashless transaction. During July 2019, the remaining balance of the 2014 Warrants outstanding was exercised for 39,263 shares of the Company's common stock in a cashless transaction. As a result, none of the 2014 Warrants remain outstanding as of December 31, 2019.

In connection with the SVB Loan Amendment, the Company issued to the Bank on the First Amendment Effective Date a fully exercisable warrant (the 2017 Warrant), expiring in July 2024, to purchase up to an aggregate of 91,463 shares of the Company's common stock, subject to adjustment, at an exercise price equal to $3.28 per share. The aggregate fair value of the 2017 Warrant was determined to be $0.2 million using the Black-Scholes option pricing model and was recorded as a debt discount on the 2017 Term Loan. This debt discount is amortized to interest expense over the term of the 2017 Term Loan using the effective interest method. The Company determined the effective interest rate of the 2017 Term Loan to be 10.2% as of the First Amendment Effective Date. During September 2018, the 2017 Warrant was fully exercised in exchange for 67,952 shares of the Company's common stock in a cashless transaction.

In connection with a prior debt agreement between the Company and the Bank in 2009, the Company issued the Bank fully exercisable warrants to purchase an aggregate of 36,074 shares of the Company's common stock at a weighted-average exercise price of $7.21 per share. During January 2019, a portion of the warrants were exercised in exchange for 1,245 shares of the Company's common stock in a cashless transaction. During July 2019, the remaining balance of the warrants outstanding was exercised for 21,012 shares of the Company's common stock in a cashless transaction. No warrants related to the prior debt agreement remain outstanding as of December 31, 2019.

7. Leases

The Company leases its headquarters office and laboratory space under a non-cancelable operating lease. In May 2018, the Company amended this lease, extending the term of the lease through the end of 2028 and agreeing to lease additional space in the same building as its existing space beginning in January 2019. The additional space leased as a result of the amendment was considered a separate lease under ASC 842 and was recorded on the consolidated balance sheets as of the lease inception date during January 2019, resulting in an increase in operating right-of-use assets of $7.7 million and an increase in the aggregate lease liability of $9.6 million. The Company can extend the term of each lease for five years after the end of 2028 at the then prevalent market rate, subject to the Company's delivery to the landlord of twelve months' prior written notice. Additionally, the Company maintains the right to terminate each lease after October 2025, subject to the Company's delivery to the landlord of twelve month's prior written notice and an early termination payment of $2.5 million. As of the date of adoption of ASC 842 and upon the lease inception date, the Company was not reasonably certain that it would exercise the extension option or the termination option, and as such, did not include these options in the determination of the total lease terms. The leases are subject to additional variable charges for common area maintenance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. Further, the leases are subject to certain fixed amenities fees for the duration of the lease. These costs are considered non-lease components, which have been aggregated with the lease components into a single lease component for purposes of determining the total future lease payments. In connection with the leases, the Company has a cash-collateralized irrevocable standby letter of credit in the amount of $0.2 million.

As of December 31, 2019, future minimum payments under the Company's operating leases were $38.2 million, which will be paid over a remaining weighted-average lease term of 9.0 years. The weighted-average discount rate for the operating lease liabilities was 8.0%, which was the Company's incremental borrowing rate at the date of adopting ASC 842 and upon lease inception.

For the year ended December 31, 2019, total operating lease expense was $6.1 million, which consisted of $3.8 million associated with the straight-line recognition of fixed payments, and $2.3 million associated with variable costs associated with the leases. For both the years ended December 31, 2018 and 2017, aggregate contractual rent expense was $2.3 million.

Total short-term lease expense associated with short-term leases for the year ended December 31, 2019 was $1.1 million.

Future minimum payments under the Company's operating leases as of December 31, 2019 are as follows (in thousands):

	Operating Lease Payments
Years Ending December 31,	
2020	$ 3,760
2021	3,873
2022	3,989
2023	4,109
2024	4,232
Thereafter	18,238
Total undiscounted lease payments	$ 38,201
Less: imputed interest	(11,274)
Total lease liability	$ 26,927

The Company has an additional operating lease for office and laboratory space in New York that had not yet commenced as of December 31, 2019. The lease commenced in January 2020 and has a lease term of two years. Total future minimum payments under the operating lease are $0.3 million.

In January 2020, the Company entered into a lease agreement for office, laboratory, and GMP manufacturing space (the Premises). The Premises are located in San Diego, California and the Company intends to move its corporate headquarters to the Premises in the middle of 2021. See Note 13 of the notes to the consolidated financial statements for additional information on this lease.

8. 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, 2019, 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.

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 2019 and January 2018, an additional 200,000 shares and 400,000 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.

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 years ended December 31, 2019, 2018 and 2017:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in 000s)
Outstanding at December 31, 2016	3,910,350	$ 3.77	8.28	$ 682
Granted	2,522,920	3.09		
Exercised	(83,220)	2.79		
Cancelled	(892,007)	3.50		
Outstanding at December 31, 2017	5,458,043	$ 3.52	7.99	$ 14,754
Granted	3,251,980	8.30		
Exercised	(694,830)	3.88		
Cancelled	(1,034,612)	4.36		
Outstanding at December 31, 2018	6,980,581	$ 5.58	7.87	$ 51,497
Granted	3,488,200	16.52		
Exercised	(787,434)	3.31		
Cancelled	(353,605)	10.70		
Outstanding at December 31, 2019	9,327,742	$ 9.67	7.73	$ 92,567
Options vested and expected to vest at December 31, 2019	9,323,962	$ 9.66	7.73	$ 92,550
Options exercisable at December 31, 2019	4,594,888	$ 6.43	6.80	$ 60,403

For the year ended December 31, 2019, the weighted average grant date fair value of stock options granted per share was equal to $11.52. For the years ended December 31, 2018 and 2017, the weighted average grant date fair value of stock options granted to employees and directors was equal to $8.28 and $2.29, respectively.

As of December 31, 2019, 2018 and 2017, the unrecognized compensation cost related to outstanding options (excluding those with unachieved performance-based conditions) was $40.4 million, $15.9 million and $5.8 million, respectively, which was expected to be recognized as expense over approximately 2.9 years, 3.1 years and 2.6 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, 2019, 2018, and 2017, was $10.7 million, $5.5 million, and $0.1 million, respectively. Total cash received upon the exercise of stock options was $2.5 million for the year ended December 31, 2019.

Restricted Stock Units. The following table summarizes restricted stock unit activity and related information under all equity plans for the years ended December 31, 2019, 2018 and 2017:

	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, 2016	525,250	$ 4.89	2.80	$ 1,318
Granted	—	—		
Vested	(225,125)	4.89		
Cancelled	(87,500)	4.89		
Outstanding at December 31, 2017	212,625	$ 4.89	1.80	$ 1,299
Granted	—	—		
Vested	—	—		
Cancelled	(24,000)	4.89		
Outstanding at December 31, 2018	188,625	$ 4.89	0.80	$ 1,299
Granted	520,000	16.41		
Vested	(172,625)	4.89		
Cancelled	(16,000)	4.89		
Outstanding at December 31, 2019	520,000	$ 16.41	2.64	$ 10,176
Restricted stock units expected to vest at December 31, 2019	520,000	$ 16.41	2.64	$ 10,176

As of December 31, 2019, 2018 and 2017, the unrecognized compensation cost related to outstanding restricted stock units was $6.2 million, $0.4 million, and $0.9 million respectively, which was expected to be recognized as expense over approximately 2.7 years, 0.8 years, and 1.8 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,		
	2019	2018	2017
Research and development	$ 9,804	$ 3,654	$ 2,095
General and administrative	7,606	2,639	1,511
Total stock-based compensation expense	$ 17,410	$ 6,293	$ 3,606

Stock Option Grants Valuation. As of January 1, 2019, the Company adopted ASU 2018-07, which aligned the guidance on share-based payments to nonemployees with that for share-based payments to employees. In accordance with ASU 2018-07, the measurement of equity-classified nonemployee awards is fixed at the grant date and entities are not required to remeasure nonemployee equity awards at each reporting date until such time that the measurement date is established. 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,		
	2019	2018	2017
Risk–free interest rate	2.4%	2.5%	2.0%
Expected volatility	80.1%	79.3%	90.1%
Expected term (in years)	6.1	6.0	6.0
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. Due to the Company's limited operating history and limited company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are 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. As the Company does not have sufficient historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Warrants to Purchase Common Stock in Connection with Debt Issuance

As a result of the financing of the Loan Amendment on July 14, 2017, the Company issued SVB fully-exercisable warrants to purchase an aggregate of 91,463 shares of the Company's common stock at an exercise price of $3.28 per share. The warrants would have expired in July 2024. In September 2018, the 2017 Warrant was fully exercised in exchange for 67,952 shares of the Company's common stock in a cashless transaction. See Note 6 of the notes to the consolidated financial statements for additional information on the debt issuance.

The fair value of the warrants was determined to be $0.2 million, which was recorded to additional paid-in capital as a debt discount. The weighted- average assumptions used in the Black-Scholes option pricing model to determine the fair value of the warrants issued were as follows:

	As of July 14, 2017
Risk–free interest rate	2.1%
Expected volatility	88%
Expected term (in years)	7.0
Expected dividend yield	0.0%

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

	December 31,	
	2019	2018
Common stock warrants	—	85,094
Convertible preferred stock (if converted)	13,972,745	14,097,745
Common stock options	9,327,742	6,980,581
Restricted stock units	520,000	188,625
Awards available under the 2013 Plan	2,880,235	3,605,510
Awards available under the Inducement Plan	279,178	379,178
Employee stock purchase plan	729,000	729,000
Total	27,708,900	26,065,733

9. 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,		
	2019	2018	2017
Tax computed at federal statutory rate	$ (20,611)	$ (13,985)	$ (14,603)
State tax, net of federal tax benefit	(2,088)	(1,620)	(1,315)
Permanent differences	175	22	795
Stock compensation	359	(307)	539
R&D tax credits	(7,285)	(3,301)	(2,934)
Reserve for uncertain tax positions	2,163	1,160	1,326
Tax Cuts and Jobs Act	—	—	25,280
Other	77	304	46
Valuation allowance	27,210	17,727	(9,134)
Income tax expense	$ —	$ —	$ —

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

	December 31,	
	2019	2018
Deferred tax assets:		
Section 59e amortization	$ 32,781	$ 19,069
Net operating losses	37,563	30,981
R&D tax credits	16,391	9,163
Depreciation and amortization	1,650	1,653
Deferred revenue	2,115	3,906
Stock compensation	2,346	1,482
Lease liability	5,655	—
Other	846	1,106
Total deferred tax assets	99,347	67,360
Deferred tax liabilities:		
Right-of-use assets	(4,778)	—
Total deferred tax liabilities	(4,778)	—
Net of deferred tax assets and liabilities	94,569	67,360
Valuation allowance	(94,569)	(67,360)
Net deferred tax assets	$ —	$ —

A valuation allowance of $94.6 million and $67.4 million at December 31, 2019 and 2018, respectively, has been established to offset the deferred tax assets, as realization of such assets is uncertain.

At December 31, 2019, the Company had federal and California net operating loss (NOL) carryforwards of $168.2 million and $168.2 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, 2019, the Company had federal and California research and development (R&D) credit carryforwards of $13.4 million and $8.5 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 the Company's 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 Code, 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, 2019 and concluded there were no ownership changes subsequent to December 31, 2015. 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, and has historically filed income tax returns in Canada. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal, Californian and Canadian tax authorities for years beginning in 2016, 2015, and 2015, 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,		
	2019	2018	2017
Beginning unrecognized tax benefits	$ 13,547	$ 11,800	$ 7,730
Increase related to current year tax positions	3,196	1,798	4,077
Increase related to prior year tax positions	79	148	6
Decrease related to prior year tax positions	—	(199)	(13)
Ending unrecognized tax benefits	$ 16,822	$ 13,547	$ 11,800

The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2019 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, 2019 would reduce the effective tax rate if recognized. The Company has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

The Tax Cuts and Jobs Act (the Act) was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 34% to 21%. The reduction in the federal corporate tax rate caused the Company to remeasure its deferred tax assets and liabilities at December 31, 2017. The remeasurement resulted in a provisional income tax expense of $25.3 million, offset by an equal reduction in the valuation allowance during the year ended December 31, 2017. During 2018, the Company finalized its analysis of the provisional impact associated with the remeasurement of deferred tax assets. There was no change in the provisional remeasurement amount previously recorded during 2017.

10. 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. No matching contributions have been made by the Company since the adoption of the 401(k) plan.

11. 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.

12. Selected Quarterly Financial Data (Unaudited)

The following tables show a summary of the Company's quarterly financial information for each quarter of 2019 and 2018 (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2019				
Revenues	$ 2,632	$ 2,817	$ 2,429	$ 2,802
Total operating expenses	23,078	26,901	29,548	31,880
Net loss	(19,760)	(23,478)	(26,609)	(28,302)
Basic and diluted net loss per common share [(1)]	$ (0.30)	$ (0.36)	$ (0.40)	$ (0.37)
2018				
Revenues	$ 1,026	$ 1,027	$ 1,026	$ 1,661
Total operating expenses	15,080	20,632	17,718	18,402
Net loss	(14,135)	(19,654)	(16,782)	(16,027)
Basic and diluted net loss per common share [(1)]	$ (0.27)	$ (0.37)	$ (0.31)	$ (0.25)

(1) Basic and diluted loss per share are computed independently for each of the quarters presented. As such, the sum of the quarterly basic and diluted loss per share information may not equal annual basic and diluted loss per share information.

13. Subsequent Events

In January 2020, the Company entered into a lease agreement for office, laboratory, and GMP manufacturing space (the Premises). The Premises is located in San Diego, California and the Company intends to move its corporate headquarters to the Premises in the middle of 2021.

Lease payments shall commence, subject to certain conditions, 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 terms. 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.

Total future minimum payments under the lease, assuming a 15-year term from the Rent Commencement Date, are $157.6 million, which are to be paid in monthly installments beginning May 2021. The landlord of the Premises will contribute an aggregate of up to $30.0 million toward tenant improvements of the Premises. In connection with the lease, the Company will maintain a letter of credit for the benefit of the landlord in an initial amount of $15.0 million, which amount is subject to reduction over time.

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 the individual serving as 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, the individual serving as our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019, 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 the individual serving as 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, 2019, 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, 2019. The report of Ernst & Young LLP is included with the financial statements included under Part II, Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2019 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated March 2, 2020 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, CA
March 2, 2020

ITEM 9B. Other Information

None.

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, 2019 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

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, as currently in effect	S-1/A	333-190608	3.2	August 29, 2013
3.2	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-190608	3.4	August 29, 2013
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
4.2	Warrant to Purchase Stock issued to Silicon Valley Bank on January 5, 2009	S-1	333-190608	4.2	August 13, 2013
4.3	First Amendment to Warrant to Purchase Stock dated January 5, 2009 by and between the Registrant and SVB Financial Group, dated August 25, 2011	S-1	333-190608	4.3	August 13, 2013
4.4	Warrant to Purchase Stock issued to Silicon Valley Bank on August 25, 2011	S-1	333-190608	4.4	August 13, 2013
4.5	Form of Warrant to Purchase Common Stock issuable to Silicon Valley Bank and its affiliates	8-K	001-36076	10.2	August 5, 2014
4.6	Description of Securities	—	—	—	Filed herewith
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	8-K	001-36076	10.1	May 2, 2017
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	—	—	—	Filed herewith
10.8#	Fate Therapeutics, Inc. Inducement Equity Plan	—	—	—	Filed herewith
10.9#	Form of Stock Option Agreement under Fate Therapeutics, Inc. Inducement Equity Plan	S-8	333-211484	99.2	May 20, 2016
10.10#	Form of Restricted Stock Unit Award Agreement under Fate Therapeutics, Inc. Inducement Equity Plan	S-8	333-211484	99.3	May 20, 2016
10.11†	Exclusive License Agreement by and between the Registrant and Children's Medical Center Corporation, dated May 13, 2009	S-1	333-190608	10.9	August 13, 2013

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.12	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
10.13	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
10.14	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
10.15	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
10.16	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
10.17	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
10.18	Form of Indemnification Agreement	S-1/A	333-190608	10.20	August 29, 2013
10.19†	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	10.23	March 12, 2015
10.20†	License Agreement between the Registrant and The Scripps Research Institute, dated as of July 13, 2009	10-K	001-36076	10.24	March 12, 2015
10.21†	License Agreement between the Registrant and The Scripps Research Institute, dated as of May 25, 2010	10-K	001-36076	10.25	March 12, 2015
10.22†	License Agreement between the Registrant and The Scripps Research Institute, dated as of August 26, 2010	10-K	001-36076	10.26	March 12, 2015
10.23	Securities Purchase Agreement, dated August 6, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.1	August 8, 2016
10.24	Registration Rights Agreement, dated August 6, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.2	August 8, 2016
10.25	Securities Purchase Agreement, dated November 21, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.1	November 22, 2016
10.26	Registration Rights Agreement, dated November 21, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.2	November 22, 2016
10.27#	Severance and Change in Control Policy	10-K	001-36076	10.32	March 5, 2018
10.28#	Offer Letter by and between the Registrant and Cindy R. Tahl, dated October 23, 2009	10-K	001-36076	10.33	March 5, 2019

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.29	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
10.30	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
10.31†	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
10.32†	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
10.33#	Offer Letter by and between the Registrant and Bahram Valamehr, dated November 23, 2009	10-K	001-36076	10.38	March 5, 2019
10.34†	Lease Agreement by and between the Registrant and Scripps Summit Investments LLC, dated January 7, 2020	—	—	—	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 and 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 and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	XBRL Instance Document	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	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: March 2, 2020

By: /s/ J. SCOTT WOLCHKO
J. Scott Wolchko
President and Chief Executive Officer
(Principal Executive Officer and Authorized Signatory)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints J. Scott Wolchko 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, Principal Financial Officer, and Principal Accounting Officer)	March 2, 2020
/s/ WILLIAM H. RASTETTER William H. Rastetter, Ph.D.	Chairman of the Board and Director	March 2, 2020
/s/ JOHN D. MENDLEIN John D. Mendlein, Ph.D., J.D.	Vice Chairman of the Board and Director	March 2, 2020
/s/ SHEFALI AGARWAL Shefali Agarwal, M.D.	Director	March 2, 2020
/s/ TIMOTHY P. COUGHLIN Timothy P. Coughlin	Director	March 2, 2020
/s/ ROBERT S. EPSTEIN Robert S. Epstein	Director	March 2, 2020
/s/ KARIN JOOSS Karin Jooss, Ph.D.	Director	March 2, 2020
/s/ AMIR NASHAT Amir Nashat, Sc.D.	Director	March 2, 2020
/s/ MICHAEL LEE Michael Lee	Director	March 2, 2020

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