FATE THERAPEUTICS INC
Form 10-K
March 05, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017

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 (State or other jurisdiction of incorporation or organization)	65-1311552 (I.R.S. Employer Identification No.)
3535 General Atomics Court, Suite 200, San Diego, CA (Address of principal executive offices)	92121 (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	Name of each exchange on which registered
Common Stock, $0.001 par value	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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	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 $122,330,000 as of June 30, 2017 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 March 2, 2018 was 52,769,156.

INCORPORATION 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, 2017 pursuant to Regulation 14A in connection with the registrant's 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this annual report on Form 10-K.

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FATE THERAPEUTICS, INC.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2017

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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,” “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:

- the initiation, timing, progress and results of our ongoing and planned clinical trials, preclinical studies, and research and development programs;
- our ability to advance our product candidates into, and to successfully conduct and complete, clinical trials;
- the timing and likelihood of, and our ability to obtain and maintain regulatory approval of our product candidates;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain strategic arrangements;
- our ability to enroll patients in our ongoing and planned clinical trials in a timely manner;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- 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 retain and recruit key personnel;
- our ability to obtain funding for our operations;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the accuracy of our estimates regarding our expenses, ongoing losses, capital requirements and revenues;
- 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.

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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

General Description of Our Business

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 an 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 cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs), 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. We believe the use of clonal master iPSC lines may enable the creation of cell therapy product candidates that are well-defined and uniform in composition; that can be reproducibly manufactured at significant scale; and that can be used to treat a large number of patients in an off-the-shelf manner. Utilizing these therapeutic approaches, we program cells of the immune system, including natural killer (NK) cells, T cells and $CD34^+$ cells, and are advancing a pipeline of programmed cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation.

The following table summarizes our programmed cellular immunotherapies currently under development and our cell programming partnerships:

Program	Stage of Development	Therapeutic Area	Commercial Rights
Immuno-Oncology			
FATE-NK100	Phase 1	Relapsed / Refractory AML	Worldwide
FATE-NK100	Phase 1	Recurrent Ovarian Cancer	Worldwide
FATE-NK100	Phase 1	Advanced Solid Tumors	Worldwide
FT500	Preclinical	Advanced Solid Tumors	Worldwide

FT516	Preclinical	Hematologic / Solid Tumors	Worldwide
FT819	Preclinical	Hematologic / Solid Tumors	Worldwide
Immuno-Regulation			
ProTmune™	Phase 1/2	Prevention of Acute GvHD	Worldwide
ToleraCyte™	Preclinical	Type 1 Diabetes	Worldwide
FT300	Preclinical	Immune Disorders	Worldwide
Cell Programming Partnership			
Engineered CAR / TCR T Cells [1]	Preclinical	Hematologic / Solid Tumors	Juno Therapeutics

Notes:

[1] Collaboration excludes all cell types derived from induced pluripotent stem cells including engineered T cells.

Our Cell Programming Approach

The use of human cells as therapeutic entities has disease-transforming potential, and compelling evidence of their medical benefit 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.

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Building upon this well-established medical precedent, the clinical investigation of hematopoietic cells, including NK cells, T cells and $CD34^+$ cells, as therapies for the treatment of human diseases is rapidly expanding. Many of these clinical trials are investigating transformative applications in the field of cancer immunotherapy to control, and potentially eradicate, tumor growth. While advancements in the isolation, expansion and manufacture of cells have opened new avenues for their use as therapeutic entities, we believe the biological properties and therapeutic function of cells, including the activation and/or modification of effector cells to better recognize tumor cells, persist longer or exhibit more potent and specific anti-tumor activity, can be enhanced ex vivo prior to patient administration to maximize therapeutic benefit.

We are using advanced molecular characterization tools and technologies to identify small molecule and biologic modulators that promote rapid and supra-physiologic activation or inhibition of therapeutically-relevant genes and cell-surface proteins, such as those involved in the homing, proliferation and survival of $CD34^+$ cells or those involved in the persistence, proliferation and anti-tumor activity of NK cells and T cells. We apply our deep understanding of the hematopoietic system to rapidly assess and quantify the potential therapeutic benefits of ex vivo cell programming in the settings of cancer and immune disorders. We believe that this highly differentiated therapeutic approach – systematically and precisely programming the biological properties and therapeutic function of cells ex vivo prior to adoptive transfer – is a reproducible, scalable and cost-effective approach to maximize the safety and efficacy of cell therapies.

Human induced pluripotent stem cells (iPSCs) with their 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 award of 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 for subsequent delivery of the therapy to that same patient.

We believe iPSCs represent an ideal cell source for creating cell therapy products that are well-defined, uniform in composition, have a consistent and dose-dependent pharmacology profile, and can be delivered off-the-shelf for the treatment of large numbers of patients. We are applying our expertise in induced pluripotent stem cell biology to genetically engineer and single-cell isolate and select iPSCs for clonal expansion, characterization and cryopreservation as clonal master iPSC lines. We direct the fate of clonal master iPSC lines to create cells of the immune system, including NK cells, T cells and $CD34^+$ cells, and are advancing a pipeline of off-the-shelf cellular immunotherapies derived from clonal master iPSC lines. Our iPSC product platform is supported by an intellectual property portfolio of over 100 issued patents and 100 pending patent applications that we own or license.

Our Business Strategy

Utilizing our cell programming approach, we seek to program immune cells, including NK cells, T cells and $CD34^+$ cells, and to develop and commercialize first-in-class cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation. The key pillars of our business strategy are to:

- Efficiently develop and commercialize first-in-class cellular immunotherapies for severe, life-threatening diseases where treatment options are limited. We are pioneering the development of first-in-class cellular immunotherapies for cancer and immune disorders. We seek to develop product candidates to improve the lives of patients with severe, life-threatening diseases with significant unmet need and where regulatory agencies offer efficient and expedited development and review programs, such as Fast Track designation, and/or market protection programs, such as Orphan Drug designation. For example, we are developing our product candidate ProTmune as a next-generation hematopoietic cell graft for the prevention of life-threatening complications, including graft-versus-host disease (GvHD), in patients undergoing donor cell-sourced, or 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 U.S. Food and Drug Administration (FDA) for the prevention of GvHD, giving rise to a significant unmet medical need. 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. We also intend to evaluate the potential to pursue expedited development and review programs for FATE-NK100, our first-in-class NK cell cancer immunotherapy comprised of adaptive memory NK cells, to support the product candidate’s development in certain indications. 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.

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- Forge collaborations with leading researchers and top medical centers to accelerate development of and rapidly translate our first-in-class product candidates into first-in-human clinical trials. The research and development of first-in-class product candidates requires an exceptional team of people and scientific and clinical expertise across a range of disciplines. Additionally, first-in-human studies of first-in-class cell therapy product candidates are often conducted under investigator-sponsored clinical trials or at a small number of medical centers. We have and will continue to seek collaborations with leading researchers, investigators and top medical centers for the research, development, and clinical translation of our product candidates. Among our collaborations is a collaboration 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 FATE-NK100, FT500 and FT516 product candidates, and a collaboration with Memorial Sloan Kettering Cancer Center, led by Dr. Michel Sadelain, a renowned T-cell biologist and a recognized founder of chimeric antigen receptor (CAR) T-cell therapy, to support the development of engineered iPSC-derived CAR T-cell immunotherapies, including FT819. We believe this approach to research and product development will maximize our potential to successfully identify first-in-class product candidates, accelerate our product candidates' clinical translation and clinical investigation, and efficiently establish first-in-human proof-of-concept for our product candidates.
- Selectively share our cell programming expertise, including our iPSC product platform, with industry-leading strategic partners for the development of highly differentiated cellular immunotherapies. The clinical investigation of hematopoietic cells, including NK cells, T cells and $CD34^+$ cells, as 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 benefit of hematopoietic cell therapies through ex vivo pharmacologic modulation. As exemplified by our collaboration with Juno Therapeutics, we have and will continue to seek partnerships with leading hematopoietic cell therapy companies so that other companies can apply our expertise toward the development of cell therapies. 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. We will continue to seek additional partnerships with other institutions and companies for the research, development and commercialization of iPSC-derived cell therapy product candidates to enable off-the-shelf treatment of larger patient populations.

Our Product Pipeline & Partnerships

Immuno-Oncology Product Candidates

FATE-NK100 Adaptive Memory Natural Killer Cell Product Candidate

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. Unlike T cells that require specific tumor antigen recognition to elicit an effective immune response, natural killer 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 killing by binding to stress ligands expressed by cells and releasing toxic granules; indirect killing by producing and releasing 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 therapeutic antibodies through a process known as antibody-dependent cellular cytotoxicity (ADCC).

Adaptive memory NK cells are a highly specialized and functionally distinct subset of natural killer 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 adaptive memory NK cell product candidate for cancer. In the setting of allogeneic HCT, a retrospective study by investigators at the University of Minnesota found that HCT recipients with a high absolute number of adaptive memory NK cells (>2.5 cells/μl of blood; n=54) at six months post-HCT had a 2-year disease relapse rate of 16%, as compared to 46% in recipients with a low absolute number of adaptive memory NK cells (0.1–2.5 cells/μl of blood; n=16). Additionally, published preclinical findings from the University of Minnesota investigators demonstrated that adaptive memory NK cells have enhanced effector function, long-term persistence and greater resistance to immune checkpoint pathways.

We are developing FATE-NK100, a first-in-class natural killer cell cancer immunotherapy comprised of adaptive memory NK cells. 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. We produce FATE-NK100 using these pharmacological modulators in a seven-day manufacturing process. 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.

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As described in the publication, we have observed in preclinical studies that FATE-NK100 has enhanced anti-tumor activity across a broad range of liquid and solid tumors, improved persistence and increased resistance to immune checkpoint pathways as compared to conventional NK cell therapies that are being clinically administered today. Additionally, we have observed in preclinical studies that FATE-NK100 significantly augments ADCC against cancer cells when administered in combination with a monoclonal antibody, including antibodies that target CD20, HER2 and EGFR antigens.

FATE-NK100 is produced using the peripheral blood of a healthy donor in a feeder-free, seven-day manufacturing process during which NK cells are programmed ex vivo with our combination of pharmacological modulators. While patient-specific T cells are most commonly utilized in cancer immunotherapy, NK cells sourced from healthy donors have been safely administered to patients for over a decade without eliciting GvHD or triggering significant side effects, such as cytokine release syndrome. FATE-NK100 is currently being evaluated in three clinical trials.

The VOYAGE Study. VOYAGE is an ongoing open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 in subjects with refractory or relapsed acute myelogenous lymphoma (AML). The primary objective of the clinical trial is to assess the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100 as a monotherapy when administered after lymphodepleting chemotherapy followed by a short course of sub-cutaneous interleukin-2 (IL-2) administration. Up to three dose levels of FATE-NK100 are intended to be assessed using an accelerated dose-escalation design, proceeding in cohorts of one subject per dose level until a dose-limiting toxicity (DLT) is observed. If a DLT is observed at a dose level, an additional three subjects will be enrolled at that dose level. Following enrollment of these three additional subjects, the study will convert to the standard “3+3” design using cohorts of three subjects per dose level. Under the standard “3+3” design, if no DLT is observed in the first three subjects of a cohort, dose escalation will proceed to the next cohort. If a DLT is observed in the first three subjects of a cohort, an additional three subjects are treated at that dose level. If, at any time, more than one subject at a dose level experiences a DLT, the dose level shall be considered to exceed the maximum dose level and dose escalation will stop. A total of ten subjects is expected to be enrolled at the maximum dose level. Other endpoints include rates of complete response and of disease-free and overall survival.

The Phase 1 clinical trial currently is being conducted at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study. On November 10, 2017, we reported initial clinical data from the ongoing VOYAGE study. The subject in the first dose cohort of VOYAGE presented in primary induction failure with 87% leukemic blasts in the bone marrow. Two weeks following a single infusion of FATE-NK100, a bone marrow biopsy showed residual AML with 48% leukemic blasts in the bone marrow. The subject in the second dose cohort presented in relapse, was refractory to conventional NK cell therapy and had 50% leukemic blasts in the bone marrow. Two weeks following a single infusion of FATE-NK100, a bone marrow biopsy showed a morphologic leukemia-free state; however, the response was not durable. No dose-limiting toxicities were reported in either the first or the second dose cohort.

The APOLLO Study. APOLLO is an ongoing open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 in women with ovarian, fallopian tube or primary peritoneal cancer resistant to, or recurrent on, platinum-based treatment. The primary objective of the clinical trial is to assess the safety and determine the maximum dose of a single infusion via intraperitoneal catheter of FATE-NK100 as a monotherapy when administered after outpatient lymphoconditioning chemotherapy followed by a short course of sub-cutaneous IL-2 administration. Up to three dose levels of FATE-NK100 are intended to be assessed using an accelerated dose-escalation design, proceeding in cohorts of one subject per dose level until a DLT is observed. If a DLT is observed at a dose level, an additional three subjects will be enrolled at that dose level. Following enrollment of these three additional subjects, the study will convert to the standard “3+3” design using cohorts of three subjects per dose level. A total of ten subjects is expected to be enrolled at the maximum dose level. Other endpoints include objective response rates and progression-free and overall survival.

The Phase 1 clinical trial is being conducted currently at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study. On December 8, 2017, we announced that the first subject had been treated with FATE-NK100 in the APOLLO study.

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The DIMENSION Study. DIMENSION is 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. The primary objective of the clinical trial is to assess the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100 when administered after outpatient lymphoconditioning chemotherapy followed by a short course of sub-cutaneous IL-2 administration. Other endpoints include objective response rates and progression-free and overall survival. The DIMENSION study is designed with three treatment regimens, where enrollment in Regimens B and C will only begin after clearance of the first dose level in Regimen A:

- Regimen A: FATE-NK100 as a monotherapy in subjects with advanced solid tumor malignancies. Regimen A will test three dose levels of FATE-NK100 using accelerated-dose escalation. In the event a DLT is observed, the clinical trial will convert immediately to a "3+3" design. We intend to have the third dose level follow a traditional "3+3" design to confirm tolerability. A twenty-subject expansion cohort is expected to be enrolled at the maximum dose level.
- Regimen B: FATE-NK100 in combination with trastuzumab in subjects with human epidermal growth factor receptor 2 positive (HER2+) advanced breast cancer, HER2+ advanced gastric cancer or other advanced HER2+ solid tumors. Regimen B will test four dose levels of FATE-NK100 using accelerated-dose escalation. In the event a DLT is observed, the clinical trial will convert immediately to a "3+3" design. We intend to have the third and fourth dose levels follow a traditional "3+3" design to confirm tolerability. A twenty-subject expansion cohort is expected to be enrolled at the maximum dose level.
- Regimen C: FATE-NK100 in combination with cetuximab in subjects with advanced colorectal cancer (CRC) or head and neck squamous cell cancer (HNSCC), or other epidermal growth factor receptor 1 positive (EGFR1+) advanced solid tumors. Regimen C will test four dose levels of FATE-NK100 using accelerated-dose escalation. In the event a DLT is observed, the clinical trial will convert immediately to a "3+3" design. We intend to have the third and fourth dose levels follow a traditional "3+3" design to confirm tolerability. A twenty-subject expansion cohort is expected to be enrolled at the maximum dose level.

On February 20, 2018, we announced that the first subject had received treatment with FATE-NK100 in the DIMENSION study.

FT500 iPSC-derived NK Cell Product Candidate for Checkpoint Inhibitor Combination

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 (programmed death ligands 1 and 2 (PD-L1 and PD-L2)) expressed on tumor cells, have achieved 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, or B2M, an essential component of tumor-antigen expression and T-cell response. 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 tumor-specific 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 donor NK cells, which have the inherent capability to directly kill cells that have down-regulated B2M expression. The mechanism of killing is through the release of perforins exposing large amounts of tumor antigens and through the secretion of a number of cytokines and chemokines, both of which can activate and facilitate an adaptive immune response. As such, allogeneic donor NK cells may have the potential to overcome resistance in certain patients by directly killing tumor cells and by creating a favorable environment for successful checkpoint inhibitor therapy and an adaptive immune response.

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We are developing FT500 as an off-the-shelf NK cell cancer immunotherapy for the treatment of advanced solid tumors, both as a monotherapy and in combination with checkpoint inhibitors. FT500 is created from a clonal master iPSC line. Using a proprietary, efficient and reproducible differentiation process, we have shown that one iPSC can create over one million NK cells, providing a substantially pure population of NK cells that is well-defined and of uniform composition. In preclinical studies, FT500 displays multiple potential mechanisms by which it may synergize with T cells to activate the immune system in patients with tumors that are non-responsive to checkpoint inhibitors alone.

In January 2017, we amended our July 2015 collaboration with the University of Minnesota to include process development and scale-up activities to support the manufacture of FT500 in accordance with current good manufacturing practices (GMP) for Phase 1 clinical studies. In November 2017, we received a Pre-Investigational New Drug, or IND, meeting written response from the FDA for FT500. The written response and subsequent FDA correspondence aligned our approach to safety testing, product manufacture, quality assessment and clinical trial design in support of our IND submission. In December 2017, we announced that production of FT500 to enable IND filing had commenced at University of Minnesota, Molecular and Cellular Therapeutics, a state-of-the-art, FDA-registered GMP facility. We are currently preparing an IND application to evaluate the safety and activity of multiple dosing cycles of FT500 in combination with FDA-approved checkpoint inhibitor therapy for the treatment of advanced solid tumor malignancies in subjects that have progressed on checkpoint inhibitor therapy.

FT516 Engineered iPSC-derived NK Cell Product Candidate for Targeted Monoclonal Antibody Combination

NK cells play a major role in the anti-tumor efficacy of certain tumor-antigen targeting monoclonal antibodies. NK cells express CD16, an activating receptor that can bind to the Fc portion of IgG antibodies and transmit immune response signals. Once activated through CD16, NK cells are able to lyse antibody-coated target cells and secrete cytokines, such as interferon gamma, to recruit adaptive immune cells, including T cells. This mechanism of ADCC has been proven critical to the treatment of a wide range of human tumor types.

The anti-tumor efficacy of several FDA-approved monoclonal antibody therapies, including trastuzumab (FDA-approved for certain breast and gastric cancers), cetuximab (FDA-approved for certain head and neck, non-small cell lung and colorectal cancers) and rituximab (FDA-approved for certain cancers of the blood and lymph system), has been shown to be NK cell-dependent. Additionally, a number of clinical studies with these FDA-approved monoclonal antibodies have demonstrated that their anti-tumor efficacy is significantly enhanced in patients having a single nucleotide polymorphism resulting in the expression of a high-affinity CD16 isoform with increased strength of binding to IgG antibodies. Only about 10% of humans are homozygous for this allele.

We are developing a targeted NK cell product candidate, which is created from a master clonal iPSC line engineered to express a high-affinity, non-cleavable CD16 (hnCD16) Fc receptor, as an off-the-shelf immunotherapy for the treatment of cancer. We refer to this product candidate as FT516. We have created a novel hnCD16 Fc receptor that incorporates two unique modifications designed to augment the receptor's binding affinity to IgG antibodies and to block the shedding of the receptor's expression on the surface of NK cells upon activation. We have engineered iPSCs to express this novel hnCD16 Fc receptor, isolated and selected a single engineered iPSC, and clonally-expanded this

single engineered iPSC to generate a clonal master iPSC line expressing this novel hnCD16 Fc receptor. Using a proprietary, efficient and reproducible differentiation process, we have shown that one iPSC can create over one million NK cells, providing a substantially pure population of NK cells that is well-defined and of uniform composition.

We are developing FT516 as an off-the-shelf cancer immunotherapy for the treatment of liquid and solid tumors, both as a monotherapy and in combination with tumor-antigen targeting monoclonal antibody therapy. 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 exhibits superior direct killing in combination with each of rituximab, trastuzumab and cetuximab in vitro, as compared to conventional NK cells sourced from peripheral blood and cord blood, in a killing assay of a human lymphoma cell line positive for CD20 (rituximab) and a human ovarian cancer cell line that is positive for both HER2 (trastuzumab) and EGFR expression (cetuximab);
- FT516 shows a dose-dependent killing response in combination with rituximab in vitro in a $CD20^+$ human lymphoblast-derived B-lymphocyte cell line killing assay; and
- FT516 augments anti-tumor activity in combination with trastuzumab in vivo, as compared to mice treated with trastuzumab alone, 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.

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In January 2017, we amended our July 2015 collaboration with the University of Minnesota to include process development and scale-up activities to support the manufacture of FT516 in accordance with current good manufacturing practices for Phase 1 clinical studies. In March 2017, we received a Pre-IND meeting written response from the FDA for FT516. The written response and subsequent FDA correspondence aligned our approach to safety testing, product manufacture, quality assessment and clinical trial design in support of our IND submission. We expect to file an IND application to evaluate the safety and activity of multiple dosing cycles of FT516 in combination with FDA-approved tumor-antigen targeting monoclonal antibody therapy for the treatment of advanced solid tumor and hematologic malignancies.

Additional Engineered iPSC-derived NK Cell Product Candidates

We are applying our iPSC product platform to develop other clonal master iPSC lines and additional engineered iPSC-derived NK cell product candidates, including in collaboration with leading researchers and top medical centers. For example, we entered into a research collaboration with the University of California, San Diego to develop off-the-shelf, CAR-NK cell cancer immunotherapies. The two-year collaboration is being led by Dan S. Kaufman, M.D., Ph.D., Professor of Medicine in the Division of Regenerative Medicine and Director of Cell Therapy at UC San Diego School of Medicine.

In December 2017, Dr. Kaufman presented initial preclinical data of a CAR-targeted NK cell product candidate, which was derived from a master iPSC line engineered with a specific CAR construct containing a NKG2D transmembrane domain, a 2B4 co-stimulatory domain and a CD3 signaling domain. In preclinical studies using an ovarian cancer xenograft model, Dr. Kaufman showed that a single dose of these CAR-NK cells markedly inhibited tumor growth and significantly enhanced survival as compared to NK cells containing a CAR construct commonly used for T-cell immunotherapy.

FT819 Engineered CAR19 iPSC-derived T-Cell Product Candidate

Current engineered T-cell immunotherapies undergoing clinical investigation are most often patient-specific and their delivery requires the extraction, engineering, expansion and re-introduction of each individual patient’s T cells. This multi-step manufacturing process is resource intensive, logistically challenging and complex, and significant hurdles remain to ensure that patient-specific T-cell immunotherapies can be efficiently and consistently manufactured, and safely and reliably delivered, at the scale necessary to support broad patient access and wide-spread commercialization. For example, the overall safety and efficacy of patient-specific T-cell immunotherapies may be limited by: the inherent qualities, quantities and properties of the T cells extracted from each individual patient; the genetic engineering of the extracted T cells, where the site of genetic engineering is often random and variable from cell to cell and, as a result, may disrupt normal T-cell biology and function; and the activation and expansion of the extracted T cells during manufacture, where T cells by their inherent nature can become exhausted.

We are developing chimeric antigen receptor (CAR) T-cell product candidates created from clonal master iPSC lines as off-the-shelf cancer immunotherapies for the treatment of liquid and solid tumors. In September 2016, we announced a partnership with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf engineered T-cell product candidates using clonal master iPSC lines. Additionally, we launched a majority-owned subsidiary, Tfinity Therapeutics, Inc., to focus exclusively on the advancement of off-the-shelf T-cell immunotherapies across a wide range of diseases. Tfinity Therapeutics holds an option to license intellectual property that we own or control for the development and commercialization of T-cell immunotherapies created from iPSCs.

Research and development activities under the multi-year 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. Dr. Sadelain has published preclinical results demonstrating that CD19 CAR-targeted T cells created from engineered iPSCs are capable of profound tumor clearance in vivo. Under the collaboration, we are currently engineering therapeutic attributes into human iPSCs, such as antigen targeting, lack of alloreactivity and enhanced persistence, and are optimizing the differentiation of these engineered iPSCs to create T cells for characterization and functional assessment.

In connection with the formation of the partnership with Memorial Sloan Kettering Cancer Center, we exclusively licensed from Memorial Sloan Kettering foundational intellectual property covering iPSC-derived immune cells, including T cells and NK cells derived from iPSCs engineered with chimeric antigen receptors, for human therapeutic use. We also secured an exclusive option to exclusively license intellectual property arising from all research and development activities under the collaboration.

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In December 2017, we provided an update on our collaboration with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf engineered T-cell product candidates using clonal master iPSC lines. Under the collaboration, CD8 + T cells have been generated from a clonal master iPSC line which was engineered to both eliminate T-cell receptor (TCR) expression and insert a CAR into the T-cell receptor constant (TRAC) locus. Preclinical data from the collaboration showed that these CAR-targeted, TCR-null CD8 + T cells display antigen-specific anti-tumor potency, including cytokine release and targeted cellular cytotoxicity. We also announced our plans to develop FT819, a first-of-kind CAR19 T-cell product candidate derived from a clonal master iPSC line engineered to eliminate TCR expression and to promote TRAC-regulated CAR19 expression.

Immuno-Regulation Product Candidates

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 donor-sourced hematopoietic cells to a patient following the administration of chemotherapy and/or radiation therapy. The biological properties of the various cell populations present in the donor-sourced hematopoietic cell graft play an essential role in determining outcomes of allogeneic 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. We believe our cell programming approach has the potential to prevent severe, life-threatening complications and improve outcomes in patients undergoing 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.

In December 2017, 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). At Day 28 following HCT, all seven subjects receiving ProTmune met the safety objectives of neutrophil engraftment and survival. There were no events of graft failure and no serious adverse events related to ProTmune reported by investigators. The median time to neutrophil engraftment was 18 days [14-22 days]. At Day 100 following HCT:

- there were no events of graft failure;
- there were no serious adverse events related to ProTmune reported by investigators;
- all seven subjects receiving ProTmune were alive and relapse-free; and

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- three subjects experienced acute GvHD, 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].

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

PROTECT Day 100 Clinical Data							
Subject	1	2	3	4	5	6	7
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
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	---
Cancer Relapse-free	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Survival	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[1] As measured from the day following HCT

All subjects receiving ProTmune in the Phase 1 stage of PROTECT are being followed for a period of two years following HCT. As of a November 29, 2017 data cut-off, five of seven subjects remained on study with median time on study of 154 days [Day 106 – 254]. There were no events of graft failure and no serious adverse events related to ProTmune reported by investigators. All subjects remained relapse-free. Non-relapse mortality was reported in two subjects (Subject 1 on Day 228; Subject 3 on Day 151). It should be noted that these data are current as of the respective data cut-off dates, are preliminary in nature and our PROTECT studies are not complete.

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 60 adult subjects with hematologic malignancies undergoing matched unrelated donor HCT following myeloablative conditioning. Subjects are being 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. Additional endpoints, such as rates of cancer relapse, chronic GvHD, non-relapse mortality and overall survival, are also being assessed. Fourteen U.S. centers are currently open for enrollment in the Phase 2 stage of PROTECT.

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.

ToleraCyte™

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.

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Auto-reactive T lymphocytes are key players in aberrant autoimmune responses. We believe that certain biological mechanisms, which have been demonstrated to suppress activation of T cells in the presence of tumor cells, can be exploited to suppress auto-reactive T-cell destruction of normal tissues. Cancerous cells often evade the immune system by expressing programmed cell death ligand-1 (PD-L1), a ligand that binds to the cell-surface receptor PD-1 on T lymphocytes and prevents T-cell activation. The PD-1 / PD-L1 biological axis has been clinically-validated as a potent immune checkpoint pathway, as certain monoclonal antibodies, commonly referred to as immune checkpoint inhibitors, have been shown to block the interaction between PD-L1 and PD-1, boosting the immune system and enhancing T-cell killing of cancer cells. We believe $CD34^+$ cells possess intrinsic immuno-regulatory properties that are triggered under certain physiological conditions and, once triggered, have the potential to suppress activated T cells and induce immune tolerance.

In June 2015, we entered into a collaboration with Boston Children's Hospital and its investigator, Paolo Fiorina, M.D., Ph.D., Assistant Professor of Pediatrics at Boston Children's Hospital and Harvard Medical School. Dr. Fiorina and his team have extensively studied the cellular mechanisms and molecular pathways involved in the autoimmune-mediated destruction of pancreatic beta cells that result in insulin deficiency and onset of type-1 diabetes. Preclinical data from the Fiorina laboratory, which was presented at the American Diabetes Association's 75th Scientific Sessions in June 2015, demonstrated that genetically engineered $PD\text{-}L1^+$ hematopoietic cells adoptively transferred into hyperglycemic mice traffic to the pancreas, reduce aberrant T-cell activity and revert hyperglycemia in a well-established murine model of type-1 diabetes.

We have conducted preclinical development of a pharmacologically programmed $CD34^+$ cell therapy with potent immuno-regulatory properties, which we refer to as ToleraCyte, for the treatment of autoimmune and inflammatory diseases. Through the application of our cell programming expertise and our specific knowledge of modulators involved in the trafficking of $CD34^+$ cells, we have identified a small molecule combination that significantly upregulates the chemokine receptor CXCR4 on $CD34^+$ cells and enhances the cells' ability to traffic to sites of inflammation. Additionally, these programmed $CD34^+$ cells have the potential to express powerful T-cell regulatory factors, including PD L1 and IDO1. We believe that ToleraCyte has the potential to preferentially traffic to and immunologically check autoreactive T cells that are directly responsible for the destruction of healthy tissue in certain autoimmune and inflammatory disorders.

In June 2016, we presented preclinical data at the American Diabetes Association's 76th Scientific Sessions exploring the disease-modifying potential of ToleraCyte in humanized and mouse models of type-1 diabetes using immunologically matched programmed cells. In in vivo studies using hyperglycemic NOD mice designed to mimic new-onset type-1 diabetes, a one-time administration of programmed cells resulted in the durable correction of disease, as compared to vehicle-treated cells. Additionally, in pre-hyperglycemic NOD mice, a one-time administration of programmed cells demonstrated a statistically significant delay in the onset of disease. Finally, in a humanized model of type-1 diabetes, programmed $CD34^+$ cells showed enhanced trafficking to the pancreas and regulation of T-cell activation. These studies support the premise that ToleraCyte may serve as a disease-modifying immunotherapy for patients with type-1 diabetes and other autoimmune diseases.

In October 2016, we held a pre-IND meeting with the FDA to support the clinical translation of ToleraCyte using $CD34^+$ cells sourced from patients with type-1 diabetes. We are assessing whether the immuno-regulatory mechanism of action of ToleraCyte is dependent on the use of immunologically matched $CD34^+$ cells, or whether $CD34^+$ cells from healthy donors or $CD34^+$ cells created from iPSCs can regulate autoreactive T cells and induce immune tolerance. This assessment includes the conduct of side-by-side in vivo preclinical studies in several different models of T-cell mediated autoimmune diseases and inflammatory disorders using immunologically matched $CD34^+$ cells, immunologically mismatched $CD34^+$ cells and immunologically mismatched $CD34^+$ cells created from iPSCs.

FT300 iPSC-derived Myeloid Derived Suppressor Cell Product Candidate

Myeloid-derived suppressor cells (MDSCs) are a naturally occurring population of immune regulatory cells. These cells can function to inhibit antigen-specific and non-specific T-cell activation and proliferation through a diverse set of mechanisms. MDSCs often associate with tumors in the microenvironment, promoting escape from T-cell immunity, and are being targeted clinically to promote tumor regression.

Although MDSCs can impede T-cell responses against cancer, the cells' potent suppressive properties may be therapeutically beneficial for treating autoimmune diseases. However, MDSCs are rare in healthy donors and, although abundant in tumor-bearing patients, repurposing tumor-derived MDSCs for therapeutic purposes may pose undesirable risks. As a result, a need exists to generate MDSCs in large quantities, particularly from healthy sources that are relatively accessible in order to explore the therapeutic potential of MDSCs.

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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 and which can be banked for off-the-shelf use. Preclinical studies of iPSC-derived MDSCs have shown that the cells suppress T-cell proliferation and activity independent of antigen recognition, and that these immunoregulatory properties are maintained across immunologically mismatched systems. We are developing FT300 as an off-the-shelf cellular immunotherapy for the treatment of autoimmune diseases.

Our Cell Programming Partnerships

Juno Therapeutics

T-cell immunotherapies commonly use a patient's own T cells as the starting cell source to manufacture a personalized cell therapy. T cells sourced from patients require in vitro culturing, engineering, activation and expansion, usually over a period of days to weeks, to generate the number of cells that are therapeutically necessary for use as an immunotherapy. Significant challenges associated with this therapeutic paradigm include a high degree of patient-to-patient variability in the ability to harvest, engineer and expand T cells and the propensity for T cells to become exhausted during in vitro processing. These challenges can negatively affect T-cell function in vivo upon administration to a patient. In fact, clinical studies have shown that the anti-tumor properties of exhausted T cells are less durable and efficacious.

In May 2015, we entered into a strategic research collaboration and license agreement with Juno Therapeutics, Inc. (Juno) bringing together our expertise in hematopoietic cell biology and cell programming with Juno's scientific and development leadership in CAR and T-cell receptor (TCR) immunotherapy. Under the collaboration, we screen for and seek to identify small molecule modulators that improve the function of T cells, including for molecules that enhance the therapeutic properties of CAR T-cell and TCR immunotherapies. Juno has the right to incorporate such modulators in their development and commercialization of genetically engineered CAR T-cell and TCR immunotherapies directed against certain tumor-associated antigen targets designated by Juno. Juno is responsible for the development and commercialization of genetically engineered CAR T-cell and TCR immunotherapies incorporating such modulators against such targets.

Pursuant to the terms of the agreement, Juno paid us an upfront payment of $5.0 million, and purchased one million shares of our common stock, at $8.00 per share, for an aggregate purchase price of $8.0 million. Additionally, Juno agreed to fund all of our collaboration research activities during the research term of the agreement with minimum annual research payments of $2.0 million to us. The initial research term of the agreement is four years ending in May 2019. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of a one-time, non-refundable extension fee of $3.0 million and the continued funding of our activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to us during the two-year extension period. Additionally, if Juno elects to exercise its extension option, we then have the option to require Juno to purchase up to $10.0 million of our common stock at a premium equal to 120% of the then thirty-day trailing volume weighted average trading price. Juno may terminate the agreement upon six (6) months' written notice to us.

We are eligible under the agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. Additionally, in connection with each Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million, in the aggregate, per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones.

Beginning on the date of the first commercial sale (in each country) for each Juno therapy that uses or incorporates our small molecule modulators, and continuing until the later of i) the expiration of the last valid patent claim, ii) ten years after such first commercial sale, or iii) the expiration of all data and other regulatory exclusivity periods afforded each therapy, Juno has agreed to pay us royalties in the low single-digits on net sales of each Juno therapy that uses or incorporates our small molecule modulators.

Under the agreement, we have granted Juno an exclusive worldwide license to certain of our intellectual property, including our intellectual property arising under the collaboration, to make, use, sell and otherwise exploit genetically-engineered CAR T cell and TCR immunotherapies (excluding those derived from iPSCs) using or incorporating small molecule modulators directed against certain designated tumor-associated antigen targets, subject to the selection of such target by Juno. We have retained exclusive rights to such intellectual property, including our intellectual property arising under the collaboration, for all other purposes.

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During the term of our research activities under the agreement, we have agreed to collaborate exclusively with Juno on the research and development of small molecule modulators with respect to CAR T-cell and TCR immunotherapies (excluding those derived from iPSCs) against certain tumor-associated antigen targets designated by Juno. Furthermore, during the term of the agreement, we will be unable to conduct, or enable third parties to conduct, research, development and commercialization activities using small molecule modulators to enhance the therapeutic properties of CAR T-cell and TCR immunotherapies against certain tumor-associated antigen targets selected by Juno.

In January 2018, Juno announced its entry into a merger agreement with Celgene Corporation (Celgene), pursuant to which Celgene has agreed to acquire all of the outstanding shares of common stock of Juno through a tender offer.

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 we are prepared to file additional patent applications if 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 March 2, 2018, our intellectual property portfolio is composed of over 190 issued patents and 140 patent applications that we license from academic and research institutions, and over 90 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 immunotherapeutics, including ProTmune, 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 the Programming of Hematopoietic and Immune Cells

As of March 2, 2018, we own 11 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 47 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 2038.

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 March 2, 2018, we currently have exclusive rights to 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

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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.

We also have licensed exclusive rights to three families of patent applications from the University of Minnesota. This portfolio includes 14 patent applications pending 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 chimeric antigen receptors on NK cells. Any patents that may issue from patent applications pending in this portfolio will expire in 2035 or 2036.

Intellectual Property Relating to iPSC Technology

As of March 2, 2018, we own 10 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 2038.

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 induced pluripotent cells from somatic cells and, as of March 2, 2018, includes 12 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.

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We also have an exclusive license to a patent family relating to the creation of off-the-shelf T and CAR-T cell immunotherapies, and their use in adoptive immunotherapy, from The Memorial Sloan-Kettering Cancer Center. This portfolio covers compositions of T cells and NK cells derived from pluripotent cells which are engineered with chimeric antigen receptors for enhanced antigen specificity and functionality, as well as methods of engineering pluripotent cell lines, and methods of deriving CAR-T cells from CAR expressing pluripotent stem cells. Any patents that may issue from patent applications pending in the U.S. and internationally in this portfolio will have expiration dates around 2034.

Our Material Technology License Agreements

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.

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 chimeric antigen receptors 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.

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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.

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

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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.

Manufacturing

We are responsible for ensuring consistent manufacture of our product candidates in compliance with regulatory requirements as necessary for marketing approval of these candidates. We do not own or operate any of our own manufacturing facilities. Other than small amounts of materials that we may synthesize ourselves for preclinical testing, we currently rely, and expect to continue to rely, on third parties for the manufacture of our required materials, including our clinical materials and 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 from a 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 from 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.

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FATE-NK100

FATE-NK100 is a first-in-class NK cell cancer immunotherapy comprised of adaptive memory NK cells. The cell therapy product candidate is manufactured using peripheral blood (PB) leukocytes from a CMV seropositive donor, where the donor is typically a HLA haplo-identical donor, and is depleted of CD3+ (T-lymphocytes) and CD19+ (B-lymphocytes). This starting cell population is cultured for seven days in a feeder-free environment and in a media containing a proprietary pharmacologic modulator combination, including a cytokine and a small molecule GSK3 inhibitor, to expand and enrich for NK cells that phenotypically have been associated with the adaptive memory phenotype.

For the conduct of Phase 1 clinical trials, FATE-NK100 is being manufactured at each participating clinical site by a clinical cell processing facility operated by or affiliated with such clinical site. Each clinical cell processing facility will be trained and qualified to manufacture FATE-NK100 by our technical staff prior to manufacture of FATE-NK100 for clinical use. We may in the future qualify additional medical center cell therapy facilities, contract with third-party manufacturers, or operate our own facilities for the manufacture of FATE-NK100 for use in clinical trials or for commercial therapeutic use.

Other reagents and excipients used in the manufacture of FATE-NK100 include the pharmacologic modulators used in programming FATE-NK100 as well as the culture media used in the seven-day manufacturing process. All of these reagents and excipients required for the manufacture of FATE-NK100 are obtained today from third-party manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain these components used in the manufacture of FATE-NK100.

Off-the-Shelf Cellular Immunotherapies Created from Master Pluripotent Cell Lines

We expect that the manufacture of our off-the-shelf cellular immunotherapy product candidates created from iPSCs will involve 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 normal human donor cells, such as fibroblasts or $CD34^+$ cells, and conduct transfusion transmissible disease testing on the donor cells; (ii) induction of pluripotency in the donor cells using a proprietary transgene-free and footprint-free method of reprogramming; (iii) genetic engineering, where applicable, of iPSCs; (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 candidate 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. At this stage, we anticipate cryopreserving individual aliquots from this cell product population and banking these aliquots in single vials, where each vial contains cells sufficient to constitute a single

dose.

- The third stage is intended to derive the final cell product candidate and generally consists of the following steps: thawing and washing a single vial of the cell product population, and formulating the cells in an infusion media for intravenous administration of the cell therapy product candidate.

We are manufacturing certain of our iPSC-derived product candidates for use in research and preclinical development. As we expand our research activities and prepare for clinical translation of our iPSC-derived product candidates, we may continue to manufacture our iPSC-derived product candidates at facilities operated by us, or we may contract with third parties, including medical center cell therapy facilities, for the conduct of some or all of the activities required for manufacturing our iPSC-derived product candidates. As part of our manufacturing process, we endeavor to utilize cGMP grade materials and reagents, if commercially available; however, certain critical materials and reagents are currently qualified for research use only.

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.

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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, suspension or revocation of an approval, clinical hold, warning or untitled letters, 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 current 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

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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.

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

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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) which was signed into law in December 2016, 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 later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

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 beginning on October 1, 2017 and in effect through September 30, 2018, the user fee for an application requiring clinical data, such as a BLA and an NDA, will be $2,421,495 for fiscal year 2018. PDUFA also imposes an annual prescription drug product program fee for biologics and drugs ($304,162 for fiscal year 2018). Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs 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.

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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.

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

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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.

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.

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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 if the company with the orphan product exclusivity is unable to meet market demand. 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), 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. By its terms, PREA does not apply to any biological product or drug for an indication for which

orphan designation has been granted, unless the FDA issues regulations stating otherwise. Because the FDA has not issued any such regulations, submission of a pediatric assessment is not required for an application to market a product for an orphan-designated indication.

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.

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Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, 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. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We are developing ProTmune as a next-generation mobilized peripheral blood graft for patients undergoing allogeneic HCT. The product candidate is intended to prevent GvHD and other life-threatening complications that compromise the procedure's curative potential. While ProTmune is designed to replace a standard-of-care mobilized peripheral blood graft to improve patient outcomes, we are aware of other companies and medical centers that are developing adjunct therapies, such as Bellicum Pharmaceuticals, Inc. and Kiadis Pharma Netherlands B.V., or treatments for GvHD and other life-threatening complications of HCT, such as AbbVie Inc., Incyte Corporation, Bristol-Myers Squibb, and Alexion Pharmaceuticals, Inc.

We are developing FATE-NK100 as a cancer immunotherapy. Additionally, we are utilizing our iPSC platform to develop off-the-shelf NK- and T-cell cancer immunotherapies. Cellular immunotherapies for the treatment of cancer have recently been an area of significant research and development by academic institutions and biopharmaceutical companies. While we believe our focus on NK cells, as well as our use of master pluripotent cell lines to create our 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, bluebird bio, Inc., Celgene Corporation, Cellectis SA, Celyad SA, CRISPR Therapeutics AG, Green Cross Corporation, Intrexon Corporation, Juno Therapeutics, Inc., Kite Pharma, Inc. (a wholly-owned subsidiary of Gilead Sciences, Inc.), Mustang Bio, Inc., NantKwest, Inc., Novartis AG, Pfizer 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 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 strategic 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, 2017, we employed 80 employees, all of whom are full-time employees, including 44 in research and development, 25 in clinical development and regulatory affairs and 11 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.

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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 the following marks referred to in this document: Fate Therapeutics®, our corporate logo, ProTmune™ and ToleraCyte™. 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.

On October 4, 2013, we completed our initial public offering. We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. We would cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Information about Segments and Geographic Areas

In accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC), Topic 280, Segment Reporting, we have determined that we operate as one operating segment. Decisions regarding our overall operating performance and allocation of our resources are assessed on a consolidated basis. Our operations and assets are predominantly located in the United States.

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. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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.

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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 have not completed the clinical trials necessary to support an application for approval to market ProTmune or FATE-NK100. Furthermore, we have not initiated or conducted any clinical trials necessary to support an application for approval to market any of our product candidates created from master pluripotent cell lines 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 to our focus on the development of 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 relating to patients enrolling in studies of therapeutics sponsored by our competitors;
- difficulties in obtaining agreement from regulatory authorities on study endpoints, achieving study endpoints, 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 approval of an IND application to initiate and conduct clinical trials for any of our product candidates;
- the occurrence of unexpected safety issues or adverse events in any current or subsequent 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 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 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;
- obtaining sufficient quantities of critical reagents and other materials and equipment necessary for the manufacture of any product candidate;
- 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 to be enrolled in our clinical trials, who may die or suffer adverse medical events 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.

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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 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 criteria, in a timely manner. For example, with respect to the development of ProTmune, there are currently only a limited number of specialized transplant centers that perform hematopoietic stem cell transplants (HSCTs) and among physicians who perform HSCTs, some may not choose to perform these procedures under conditions that fall within our protocols, which would have an adverse effect on our ability to develop ProTmune. Our ability, and the ability of investigators, to enroll patients in clinical trials that we are conducting or supporting, including in our current Phase 1/2 PROTECT clinical trial of ProTmune and our clinical trials of FATE-NK100, certain of which are investigator-sponsored, 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 the trials in question;
- eligibility criteria for the trials in question;
- perceived risks and benefits of the product candidate under study;
- 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;
- 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.

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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.

Developing therapeutic products, including conducting preclinical studies, process development and manufacturing activities, and clinical trials of cellular immunotherapies, is expensive. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations for at least the next twelve months. However, our resources will likely be insufficient to conduct research and development programs, process development and manufacturing activities, and clinical development of our product candidates to the full extent currently planned. We will require substantial additional capital to conduct the research and development, process development, manufacturing, and clinical and regulatory activities necessary to bring any of our product candidates to market. 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, the Phase 1 clinical trials of FATE-NK100, certain of which are being conducted under an investigator-sponsored clinical trial agreement with the University of Minnesota, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing, and 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, including ProTmune and FATE-NK100, 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 product candidates, including ProTmune and FATE-NK100, 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 and commercialization activities and arrangements, including the manufacturing 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 Juno, the University of Minnesota and Memorial Sloan Kettering Cancer Center, to advance the research, development and commercialization of therapeutic products.

We cannot guarantee that additional capital will be available in sufficient amounts or on terms acceptable to us, if at all. We intend to seek additional funding through the public or private sales of our securities, including equity securities. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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.

Our clinical development of ProTmune and FATE-NK100, and the initiation of clinical development of our other 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 of ProTmune or FATE-NK100, or initiating and conducting any future clinical trials of ProTmune, FATE-NK100 or our other product candidates, including our iPSC-derived cell product candidates. Additionally, the FDA may in the future have comments, or impose requirements, on the conduct of our clinical trials of ProTmune, FATE-NK100, or our iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or

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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 ProTmune, FATE-NK100, our iPSC-derived cell 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.

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, including ProTmune, FATE-NK100, and our iPSC-derived cell product candidates. 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 and 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, including ProTmune, FATE-NK100, and our iPSC-derived cell 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;
- 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;
- difficulties in manufacturing a product candidate, including the inability to manufacture 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;
- 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 adequate reimbursement;
- our inability to secure strategic partners which may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization; or
- our prioritization of other product candidates for advancement.

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 and 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

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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, which will harm our business, prospects, financial condition and results of operations.

Our product candidates are cellular therapeutics, and the manufacture of our cell product candidates, particularly our iPSC-derived cell product candidates, is complex and subject to a multitude of risks. These manufacturing risks could substantially increase our costs and limit supply of our product candidates for clinical 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.

Manufacture of our cell product candidates involves novel manufacturing processes that present significant challenges and are subject to multiple risks. The manufacture of our cell product candidates also requires processing steps that are more complex than those required for most small molecule drugs and other cellular immunotherapies including, for our iPSC-derived product candidates, reprogramming human fibroblasts to obtain iPSCs, genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics, the cost to manufacture biologics in general, and our cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing processes are less reliable and are more difficult to reproduce. 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. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials.

We may make changes as we continue to evolve the manufacturing 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 clinical trials, future 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.

We also will need 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 contract manufacturing organization (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. The inability to manufacture comparable drug product by us or our CMO could delay the continued development of our product candidates.

In addition, the manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval process, 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, and to manufacture FATE-NK100 within a short period of time before administration to a patient, may present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. While our clinical product candidates ProTmune and FATE-NK100 are currently manufactured by third-party cell processing facilities, including third-party facilities operated by or affiliated with our clinical sites, we may be required to identify alternative protocols, processes, materials or facilities for the manufacture of ProTmune or FATE-NK100 in compliance with applicable regulatory requirements. Any requirements to

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modify our manufacturing protocols, processes, materials or facilities, and any delays in, or inability to, establish manufacturing operations acceptable to the FDA for ProTmune, FATE-NK100, or any of our iPSC-derived cell 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 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 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 candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Even if we are successful in developing our manufacturing capabilities sufficient for clinical and commercial supply, problems with our manufacturing operations, even minor deviations from the normal protocols, processes or materials, 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 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. Any such events could delay or prevent our ability to obtain regulatory approval or commercialize ProTmune, FATE-NK100 or our other product candidates, which would adversely affect our business, financial condition and results of operations.

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 ProTmune or FATE-NK100 in our ongoing clinical trials, as well as patients who may undergo treatment with 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 ProTmune, FATE-NK100, or other product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance ProTmune, FATE-NK100, 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 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 approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the research or preclinical stage, we have not yet been able to assess safety in humans or 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 any iPSC-derived cell product candidates we develop, as required by the FDA and other regulatory authorities for product 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.

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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 products will likely be reviewed by the FDA’s 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.

Results from earlier studies may not be predictive of the results 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. Results from preclinical testing, process development and manufacturing activities, and earlier clinical studies, including clinical studies with similar product candidates, are not necessarily predictive of future results, including 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 29, 2017 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 of our product candidates, including ProTmune and FATE-NK100, and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency 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.

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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. Our failure to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and 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. 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, 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

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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 currently depend on third-party cell processing facilities for the manufacture of ProTmune and FATE-NK100 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.

We do not currently operate our own facilities for the manufacture of our product candidates. Clinical cell processing facilities operated by or affiliated with our clinical sites currently manufacture ProTmune and FATE-NK100 for use in our clinical trials of these product candidates. We will be required by the FDA to standardize the manufacture of ProTmune and FATE-NK100, 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 and FATE-NK100 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 and FATE-NK100 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 and FATE-NK100, 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 or FATE-NK100 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 or FATE-NK100 in both the clinical and the commercial setting, which would have an adverse effect on our business.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment, which 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 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 ProTmune and FATE-NK100 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.

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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, including ProTmune and FATE-NK100. Additionally, any such change or modification may adversely affect the safety, efficacy 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 certain of our product candidates, including ProTmune and FATE-NK100.

Certain of our product candidates, including ProTmune and FATE-NK100, are manufactured from the blood of third-party donors, which subjects the manufacture of such product candidates to the availability and quality of the third-party donor material. The selection of the appropriate donor material for manufacture of our ProTmune and FATE-NK100 product candidates requires close coordination between clinical and manufacturing personnel.

ProTmune is manufactured using 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 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.

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 mobilized peripheral blood 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 our ProTmune and FATE-NK100 product candidates from donor material involves complex processes, with specialized equipment and highly skilled and trained personnel. The processes for manufacturing these product candidates 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 could result in delays in the development of our product candidates. Such contaminations could also increase the risk of adverse side effects.

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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.

Our collaborators and strategic partners may control aspects of our clinical trials, which 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 will 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.

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 for use in conducting clinical trials and for commercial sale upon approval of any of our product candidates. In some cases these third parties are academic, research or similar institutions that may not apply the same quality control protocols utilized in certain commercial settings. 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.

In addition, we do not currently operate our own facilities for the manufacture of our product candidates. The facilities used to manufacture our product candidates must be approved 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 does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which 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 entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations, the possibility that the

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third party fails to manufacture 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 to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of 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.

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 products. 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

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such proceedings. In addition, 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.

We also rely upon unpatented trade secrets and improvements, unpatented 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 commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial 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 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, FATE-NK100, 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 and FATE-NK100, 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.

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

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

We cannot guarantee that the manufacture, use or marketing of ProTmune, FATE-NK100, our iPSC-derived cell 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.

As is common in the biotechnology and pharmaceutical industries, 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. 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.

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.

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Risks Related to the Commercialization of Our Product Candidates

We do not have experience marketing our 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.

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 ProTmune, FATE-NK100, 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. 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.

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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 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.

Risks Related to Our Business and Industry

The success of our product candidates, including ProTmune and FATE-NK100, is substantially dependent on developments within the field of HSCT and cellular immunotherapy, some of which are beyond our control.

Our product candidates, including ProTmune and FATE-NK100, 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.

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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.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities.

In July 2014, we entered into an amended and restated loan and security agreement with Silicon Valley Bank (SVB) pursuant to which we were extended term loans in the aggregate principal amount of $20.0 million. In July 2017, we entered into an amendment to the loan and security agreement, pursuant to which SVB extended an additional term loan to us in the aggregate principal amount of $15.0 million, a portion of which was applied to repay in full our previously outstanding debt to SVB under the agreement. Borrowings under the loan and security agreement, as amended, are secured by substantially all of our assets, excluding certain intellectual property rights. The loan and security agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business or property, subject to limited exceptions;
- make material changes to our business or management;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in shares of our common stock, or make distributions on and, in certain cases, repurchase our stock;
- enter into transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our loan agreement to maintain our deposit and securities accounts with SVB and to comply with various operating covenants and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

If we are unable to generate sufficient cash to repay our debt obligations when they become due and payable, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively affect our

business operations and financial condition.

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We have entered into a strategic research collaboration and license agreement with Juno Therapeutics, Inc. to pursue the identification and application of small molecule modulators to program certain genetically-engineered T cells. Our collaboration may be terminated, or may not be successful, due to a number of factors, which could have a material adverse effect on our business and operating results.

We are party to a strategic research collaboration and license agreement with Juno Therapeutics, Inc. (Juno) for the identification and application of small molecule modulators for programming the therapeutic properties of genetically engineered chimeric antigen receptor (CAR) and T-cell receptor (TCR) based cellular immunotherapies directed against certain targets designated by Juno. Under the agreement, Juno has agreed to fund our collaboration research activities for an initial research term ending in May 2019, subject to a two-year extension under certain circumstances, and we are eligible to receive target selection fees and clinical, regulatory, and commercial milestones, as well as royalties on sales, should any therapies using our modulators be developed and commercialized. Our collaboration with Juno may be terminated, or may not be successful, due to a number of factors. For example, we may be unable to identify small molecule modulators that are effective in modulating genetically engineered T-cell therapies, or Juno may elect not to develop any genetically engineered T-cell therapies incorporating any modulators that are identified through the collaboration. Additionally, Juno may terminate the agreement upon six (6) months' written notice to us. If the collaboration is unsuccessful for these or other reasons, or is otherwise terminated for any reason, we may not receive all or any of the research program funding, target selection fees, milestone payments or royalties under the agreement. Any of the foregoing could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

In addition, during the term of our research activities under the agreement, we have agreed to collaborate exclusively with Juno on the research and development of small molecule modulators with respect to T cells (other than T cells derived from iPSCs) that have been genetically engineered to express chimeric antigen receptors or T-cell receptors against certain targets designated by Juno. Furthermore, during the term of the agreement, we will be unable to conduct, or enable third parties to conduct, research, development and commercialization activities using small molecule modulators to program T-cell therapies that have been genetically engineered to express chimeric antigen receptors or T-cell receptors directed against certain targets selected by Juno, unless such T cells are derived from iPSCs. These restrictions may prevent us from exploiting our small molecule modulators or impair our ability to pursue research, development and commercialization opportunities that we would otherwise deem to be beneficial to our business.

In January 2018, Juno announced its entry into a merger agreement with Celgene Corporation (Celgene), pursuant to which Celgene has agreed to acquire all of the outstanding shares of common stock of Juno through a tender offer. The acquisition of Juno by Celgene may result in organizational and personnel changes, shifts in business focus or other developments that may have a material adverse effect on our collaboration agreement with Juno.

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.

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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.

We use hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development and manufacturing operations involve the controlled use of hazardous materials including chemicals, biological materials and infectious disease agents. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets.

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.

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, 2017, we had an accumulated deficit of $218.8 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of

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ProTmune and FATE-NK100 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.

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Our principal stockholders exercise significant control over our company.

As of March 2, 2018, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 47.6% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 6 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 6 of the Notes to the Consolidated Financial Statements herewith) elects to remove certain limitations on the percentage of the Company's outstanding common stock that it may own such that the 2,819,549 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 14,097,745 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 58.4%. 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 or affecting the liquidity and volatility of our common stock, and might affect the market price of our common stock.

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. In addition, a shelf registration statement declared effective by the SEC in August 2017 provides for the sale by us of up to $100 million in the aggregate of shares of our common stock, preferred stock, debt securities, warrants and/or units, and 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. 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, we are party to an amended and restated loan and security agreement, as amended, with SVB, which imposes restrictive covenants on our operations. Any future debt financings may impose additional 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 and cash equivalents and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents 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;

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- 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.

As a result, these provisions could limit the price that investors are willing to pay in the future for shares of our common stock. These provisions might also discourage a potential acquisition proposal or tender offer, even if the acquisition proposal or tender offer is at a premium over the then-current market price for 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.

Generally, a change of more than 50% 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. An ownership change may limit a company's ability to use its net operating loss carryforwards (NOLs) and other pre-change tax benefits (such as research tax credits) attributable to the period prior to such change. We triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that there were no ownership changes from May 2015 through December 2017. We may experience ownership changes as a result of shifts in our stock ownership in the future or subsequent to ownership change analyses. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us. In addition, under the Tax Cuts and Jobs Act (the Tax Act), the amount of post 2017 NOLs 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. There is a risk that due to changes under the Tax Act, regulatory changes or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, our ability to realize a tax benefit from the use of our NOLs may be further limited.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Facilities

As of December 31, 2017, we occupied approximately 48,000 square feet of office and laboratory space in San Diego, California under a non-cancelable operating lease through June 2023. We believe that our 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.

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PART II

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

Market Information

The table below provides the high and low intra-day sales prices of our common stock for the periods indicated, as reported by The NASDAQ Global Market.

	High	Low
Year ended December 31, 2017		
Fourth quarter	$6.75	$3.50
Third quarter	4.43	2.52
Second quarter	4.77	2.92
First quarter	5.68	2.44
Year ended December 31, 2016		
Fourth quarter	$3.35	$1.80
Third quarter	3.82	1.55
Second quarter	2.37	1.47
First quarter	3.54	1.46

Holders of Common Stock

As of March 2, 2018, there were approximately 44 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.

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Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a $100 investment in the Company's common stock, the NASDAQ Composite® (US) Index and the NASDAQ Biotechnology Index commencing on October 1, 2013 (the date our common stock began trading on the NASDAQ Global Market) and continuing through December 31, 2017. 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, 2017, 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, 2017.

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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 and as of December 31,				
	2017	2016	2015	2014	2013
Consolidated Statements of Operations Data (in thousands, except share and per share data):					
Revenue:					
Collaboration revenue	$4,106	$4,402	$2,431	$—	$626
Grant revenue	—	—	—	—	345
Total revenue	4,106	4,402	2,431	—	971
Operating expenses:					
Research and development	34,358	26,452	19,861	16,435	12,007
General and administrative	11,873	9,913	10,352	8,469	6,639
Total operating expenses	46,231	36,365	30,213	24,904	18,646
Loss from operations	(42,125)	(31,963)	(27,782)	(24,904)	(17,675)
Total other expense, net	(827)	(1,499)	(2,210)	(979)	(3,219)
Net loss	(42,952)	(33,462)	(29,992)	(25,883)	(20,894)
Other comprehensive loss	(2)	(1)	—	—	—
Comprehensive loss	$(42,954)	$(33,463)	$(29,992)	$(25,883)	$(20,894)
Net loss per common share, basic and diluted	$(1.02)	$(1.05)	$(1.18)	$(1.27)	$(3.54)
Weighted-average common shares used to compute basic and diluted net loss per share	41,982,167	31,754,140	25,484,262	20,451,840	5,896,171
Consolidated Balance Sheet Data (in thousands):					
Cash and cash equivalents	$88,952	$88,609	$64,809	$49,101	$54,036
Short-term investments and related maturity receivables	11,997	3,503	—	—	—
Working capital	91,547	78,136	52,211	45,291	50,051
Total assets	105,292	95,048	67,958	51,183	55,583
Long-term debt, current portion	—	8,187	7,550	1,535	1,732
Long-term debt, net of current portion	14,808	2,501	10,688	18,073	—
Deferred revenue, non-current portion	724	2,829	4,934	—	—
Convertible preferred stock	36,289	36,289	—	—	—
Accumulated deficit	(218,798)	(175,846)	(142,384)	(112,392)	(86,509)
Total stockholders’ equity	$77,189	$73,154	$38,038	$28,340	$50,848

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."

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 an 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 cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs) generate a clonal master iPSC line having preferred biological properties and direct the fate of the clonal master iPSC line to create a homogeneous population of our cell therapy product candidate. We believe the use of clonal master iPSC lines may

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enable the creation of cell therapy product candidates that are well-defined and uniform in composition; that can be reproducibly manufactured at significant scale; and that can be effectively used to treat a large number of patients in an off-the-shelf manner. Utilizing these therapeutic approaches, we program cells of the immune system, including natural killer cells (NK) cells, T cells and $CD34^+$ cells, and are advancing a pipeline of programmed cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation.

We have entered into a research collaboration and license agreement with the Regents of the University of Minnesota to develop off-the-shelf 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 to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines.

We have also entered into a research collaboration and license agreement with Juno Therapeutics, Inc. to identify and apply small molecule modulators to enhance the therapeutic function of genetically-engineered CAR (chimeric antigen receptor) T-cell and TCR (T-cell receptor) immunotherapies.

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 Phase 1/2 clinical trial of ProTmune, and initiate and conduct any additional clinical trials of ProTmune;
- conduct our clinical trials of FATE-NK100, including under investigator-sponsored clinical trial agreements with the University of Minnesota and under our own Investigational New Drug application;
- conduct preclinical research, process development, manufacturing and development activities to support the clinical translation of our first-in-class product candidates derived from master iPSC lines, and conduct first-in-human clinical trials of such product candidates;
- continue our research and development activities, including under our research collaboration agreements;
- continue process development for, and manufacture of, preclinical study and clinical trial materials, including our product candidates;
- 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;
- hire additional clinical, 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.

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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. owned 100% of the voting shares of Fate Therapeutics (Canada) Inc. (Fate Canada) which was dissolved in November 2016 and directed all of its operational activities, which were insignificant. Fate Therapeutics, Inc. owns 100% of the voting shares of Fate Therapeutics Ltd., or Fate Ltd., incorporated in the United Kingdom, whose operations have not been material to date. Fate Therapeutics, Inc. owns the majority of the voting shares of Tfinity Therapeutics, Inc. (Tfinity) and controls Tfinity for consolidation purposes. To date, Tfinity has not had any material operations. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc., Tfinity, Fate Ltd., and Fate Canada. All intercompany transactions and balances are eliminated in consolidation.

Revenue

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

On May 4, 2015, we entered into a strategic research collaboration and license agreement (the 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 Agreement, we received an upfront, non-refundable payment of $5.0 million and $8.0 million for the purchase of 1,000,000 shares of our common stock at $8.00 per share. Based on the upfront payment and the premium paid on the share purchase, we recorded $8.4 million of deferred revenue to be recognized ratably as revenue over the initial four-year research term. Additionally, we have received and are entitled to receive a minimum of $2.0 million in research funding annually during the initial four-year term. We account for the research funding as revenue using the gross method and record such amounts received from Juno as revenue when earned.

Pursuant to the Agreement, Juno has the option to extend the research term an additional two years subject to payment of a one-time, non-refundable extension fee of $3.0 million and minimum research funding of $4.0 million per year during the extended two-year research term. Additionally, if Juno elects to exercise its extension option, we then have the option to require Juno to purchase up to $10.0 million of our common stock at a premium equal to 120% of the then thirty-day trailing volume weighted average trading price.

Additionally, we are eligible to receive certain contingent payments under the Agreement, including selection fees for each tumor-associated antigen target selected by Juno and clinical, regulatory, and commercial milestones, and royalties on commercial sales, in connection with each Juno immunotherapy that uses or incorporates our small molecule modulators. To date, no such payments have been received by us.

In connection with the Agreement, we have recognized $4.1 million and $4.4 million, respectively, during the years ended December 31, 2017 and 2016, as collaboration revenue in the consolidated statements of operations. As of December 31, 2017, aggregate deferred revenue related to the Agreement was $2.8 million.

Research and Development Expenses

Research and development expenses consist of costs associated with the research and development of our product candidates and cell programming technology, and the performance of research activities under our collaboration agreements. These costs are expensed as incurred and include:

- salaries and employee-related costs, including stock-based compensation;
- costs associated with conducting our preclinical, process development, manufacturing, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs incurred under clinical trial agreements with investigative sites;
- costs incurred under our collaboration agreements;
- costs for laboratory supplies;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials, including our product candidates; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

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We plan to increase our current level of research and development expenses for the foreseeable future as we continue the development of our product candidates and cell programming technology, and as we perform research activities under our sponsored research and collaboration agreements, including our agreements with the University of Minnesota, Memorial Sloan Kettering and Juno. Our current planned research and development activities over the next twelve months consist primarily of the following:

- conducting our Phase 1/2 clinical trial of ProTmune, and initiating and conducting any additional clinical trials for ProTmune, to examine its safety and efficacy in adult patients with hematologic malignancies undergoing allogeneic HCT;
- conducting our clinical trials of FATE-NK100, including under investigator-sponsored clinical trial agreements with the University of Minnesota and under our own Investigational New Drug application, to examine its safety and efficacy in various forms of cancer;
- conducting preclinical research, process development, manufacturing and clinical translation activities to investigate the therapeutic potential of our immuno-oncology programs, including our off-the-shelf NK- and T-cell cancer immunotherapies derived from clonal master iPSC lines, and conduct first-in-human clinical trials of such product candidates;
- conducting preclinical activities to investigate the therapeutic potential of our immuno-regulatory programs, including a hematopoietic cell therapy for regulating auto-reactive T cells of patients with autoimmune disorders; and
- performing research, preclinical development, process development, manufacturing and clinical translation activities under our sponsored research and collaboration agreements, including our agreements with the University of Minnesota, Memorial Sloan Kettering and Juno.

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, including ProTmune, FATE-NK100 and our product candidates derived from clonal master iPSC lines. 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 short-term investments (including the amortization of discounts and premiums), interest expense, and debt extinguishment losses on amounts outstanding under our credit facilities.

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.

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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

Our revenues have principally consisted of license fees, research and development funding, and milestone payments under collaboration agreements, including our May 2015 license and collaboration agreement with Juno, as well as funding received under government grants. Our license and collaboration agreement with Juno contains multiple elements, all of which are accounted for as collaboration revenue. We recognize revenues when all four of the following criteria are met: (i) persuasive evidence that an agreement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured.

Pending Adoption of Accounting Standards Update 2014-09 (ASU 2014-09)

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, which created a single, principle-based revenue recognition model that will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the consideration that the entity expects to be entitled to receive in exchange for those goods or services. The model provides that entities follow five steps: (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. For public business entities, ASU 2014-09 is effective beginning in the first quarter of 2018 using one of two prescribed transition methods: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). The Company will adopt ASU 2014-09 in the first quarter of 2018 using the full retrospective method. The Company has evaluated the effect that the updated standard will have on its internal processes, financial statements and related disclosures, and has determined that the adoption will not have a material impact on the Company’s historical Consolidated Financial Statements.

Collaboration Revenues

In October 2009, FASB issued a new accounting standard which amended the guidance on accounting for arrangements involving the delivery of more than one element. This standard addresses the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement’s consideration should be allocated to each unit of accounting. In January 2011, we adopted new authoritative guidance on revenue recognition for milestone payments related to agreements under which we have continuing performance obligations. As required under the new literature, we evaluate all milestones at the beginning of the agreement to determine if they meet the definition of a substantive milestone.

We recognize revenue from milestone payments when earned, provided that (i) the milestone event is substantive in that it can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance and its achievability was not reasonably assured at the inception of the agreement; (ii) we do not have ongoing performance obligations related to the achievement of the milestone; and (iii) it would result in the receipt of additional payments. A milestone payment is considered substantive if all of the following conditions are met: (i) the milestone payment is non-refundable; (ii) achievement of the milestone was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved to achieve the milestone;

and (iv) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone.

Collaboration arrangements providing for payments to us upon the achievement of research and development milestones generally involve substantial uncertainty as to whether any such milestone would be achieved. In the event a milestone is considered to be substantive, we expect to recognize future payments as revenue in connection with the milestone as it is achieved. Collaboration arrangements providing for payments to us upon the achievement of milestones that are solely contingent upon the performance of a collaborator also involve substantial uncertainty as to whether any such milestone would be achieved. For such contingent milestones, even if they do not meet the definition of a substantive milestone, since they are based solely upon a collaborator's effort, we expect to recognize future payments as revenue when earned under the applicable arrangement, provided that collection is reasonably assured.

Government Grant Revenue

Revenue from government grants is recorded when reimbursable expenses are incurred under the grant in accordance with the terms of the grant award.

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Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue. Amounts not expected to be recognized within the next 12 months are classified as non-current deferred revenue on our consolidated balance sheets.

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 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. 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.

We account for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms. For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the performance condition is determined to be probable of achievement or when it has been achieved.

We generally estimate the fair value of our stock option awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (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

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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 6 of the Notes to the Consolidated Financial Statements for additional information.

Total stock-based compensation expense for the years ended December 31, 2017, 2016, and 2015, was $3.6 million, $3.2 million, and $2.4 million, respectively. Expense related to unvested employee stock option grants not yet recognized (excluding those with performance-based conditions which are unachieved or determined not to be probable of achievement) as of December 31, 2017 was approximately $5.8 million and the weighted-average period over which these grants are expected to vest is 2.6 years. As of December 31, 2017, the unrecognized compensation cost related to outstanding restricted stock units was $0.9 million, which is expected to be recognized as expense over approximately 1.8 years.

Other Company Information

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (b) December 31, 2018, (c) the date on which we have issued more than $1 billion in non-convertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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, 2017 and 2016

The following table summarizes the results of our operations for the years ended December 31, 2017 and 2016:

	Years Ended December 31,		Increase/ (Decrease)
	2017	2016	
	(in thousands)		
Collaboration revenue	$4,106	$4,402	$ (296)
Research and development expenses	34,358	26,452	7,906
General and administrative expenses	11,873	9,913	1,960
Total other expense, net	827	1,499	(672)

Revenue. During the years ended December 31, 2017 and 2016, we recognized revenue of $4.1 million and $4.4 million, respectively, under the Agreement with Juno, which we entered into in May 2015.

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Research and development expenses. Research and development expenses were $34.4 million for the year ended December 31, 2017, compared to $26.5 million for the year ended December 31, 2016. The increase in research and development expenses includes the following changes:

- $4.1 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 research collaboration agreements;
- $1.7 million increase in employee compensation and benefits expense, including employee-stock based compensation expense, relating to employee headcount costs to support our clinical development, manufacturing and research activities;
- $1.4 million increase in facility rent expense due to an office and lab space expansion in January 2017; and
- $0.5 million increase in expenditures for laboratory equipment, materials and supplies relating to the conduct of our clinical trials and research activities and the manufacture of our product candidates.

General and administrative expenses. General and administrative expenses were $11.9 million for the year ended December 31, 2017, compared to $9.9 million for the year ended December 31, 2016. The increase in general and administrative expenses includes the following changes:

- $1.2 million increase in intellectual property-related expenses;
- $0.3 million increase in third-party professional consultant and service provider expenses; and
- $0.2 million increase in facility rent expense due to an office and lab space expansion in January 2017.

Other expense, net. Other expense, net, was $0.8 million and $1.5 million for the years ended December 31, 2017 and 2016, respectively. Other expense, net for each period consisted primarily of interest expense relating to our term loans with Silicon Valley Bank, interest income earned on cash and cash equivalents, and interest income from short-term investments (including the amortization of discounts and premiums). The year ended December 31, 2017 also included a $0.1 million loss on debt extinguishment related to the amendment of our loan agreement with Silicon Valley Bank.

Comparison of Years Ended December 31, 2016 and 2015

The following table summarizes the results of our operations for the years ended December 31, 2016 and 2015:

	Years Ended December 31,		Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Collaboration revenue	$4,402	$2,431	$ 1,971
Research and development expenses	26,452	19,861	6,591
General and administrative expenses	9,913	10,352	(439)
Total other expense, net	1,499	2,210	(711)

Revenue. During the years ended December 31, 2016 and 2015, we recognized revenue of $4.4 million and $2.4 million, respectively, under the Agreement with Juno, which we entered into in May 2015. The increase was driven by an increase in our research activities.

Research and development expenses. Research and development expenses were $26.5 million for the year ended December 31, 2016, compared to $19.9 million for the year ended December 31, 2015. The increase in research and development expenses includes the following changes:

- $2.7 million increase in third-party professional consultant and service provider expenses relating to the clinical development of our product candidates and the conduct of our research activities, including under our research collaboration agreement with the University of Minnesota;
- $2.1 million increase in employee compensation and benefits expense, including employee-stock based compensation expense, relating to employee headcount costs to support our research activities; and
- $1.2 million increase in expenditures for laboratory equipment, materials and supplies relating to the conduct of our research activities, including our activities under our collaboration with Juno.

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General and administrative expenses. General and administrative expenses were $9.9 million for the year ended December 31, 2016, compared to $10.4 million for the year ended December 31, 2015. The decrease in general and administrative expenses includes the following changes:

- $0.3 million decrease in intellectual property-related expenses;
- $0.3 million decrease in third-party service fees, including accounting and legal professional services fees to support our operations as a public company; partially offset by a
- $0.3 million increase in employee compensation and benefits expense, including stock-based compensation expense.

Other expense, net. Other expense, net, was $1.5 million and $2.2 million for the years ended December 31, 2016 and 2015, respectively. Other expense, net for each period consisted primarily of interest expense related to our term loans with Silicon Valley Bank.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of December 31, 2017, we had an accumulated deficit of $218.8 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:

	2017	2016	2015
	(in thousands)		
Net cash used in operating activities	$(36,905)	$(29,823)	$(18,397)
Net cash used in investing activities	(10,196)	(4,114)	(1,498)
Net cash provided by financing activities	47,444	57,737	35,603
Net increase in cash, cash equivalents and restricted cash	$343	$23,800	$15,708

Operating Activities

Cash used in operating activities increased from $29.8 million for the year ended December 31, 2016 to $36.9 million for the year ended December 31, 2017. The primary driver of this change in cash used in operating activities was our increase in net loss from 2016 to 2017 partially offset by a change of $1.0 million in deferred rent resulting from the office and lab expansion in January 2017 and a change of $1.0 million in accounts payable and accrued expenses.

Cash used in operating activities increased from $18.4 million for the year ended December 31, 2015 to $29.8 million for the year ended December 31, 2016. The primary driver of this change in cash used in operating activities was a change of $9.7 million in deferred revenue resulting from the Agreement with Juno in May 2015 and our increase in net loss from 2015 to 2016.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement with Juno to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno’s genetically-engineered T-cell immunotherapies. Pursuant to the terms of the Agreement, Juno paid us an upfront payment of $5.0 million, and

purchased one million shares of our common stock, at $8.00 per share, for an aggregate purchase price of $8.0 million. Additionally, Juno agreed to fund all of our collaboration research activities for an initial four-year research term beginning on the effective date of the Agreement, with minimum annual research payments of $2.0 million to us. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of an extension fee of $3.0 million and the continued funding of our activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to us during the two-year extension period. As of December 31, 2017, we have received a total of $5.3 million of such research payments.

We are eligible under the Agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. Additionally, in connection with each Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million, in the aggregate, per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones. As of December 31, 2017, no selection fees or milestone payments have been received by us.

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Beginning on the date of the first commercial sale (in each country) for each Juno therapy that uses or incorporates our small molecule modulators, and continuing until the later of i) the expiration of the last valid patent claim, ii) ten years after such first commercial sale, or iii) the expiration of all data and other regulatory exclusivity periods afforded each therapy, Juno has agreed to pay us royalties in the low single-digits on net sales of each Juno therapy that uses or incorporates our small molecule modulators. As of December 31, 2017, no royalties have been received by us.

In January 2018, Juno announced its entry into a merger agreement with Celgene, pursuant to which Celgene has agreed to acquire all of the outstanding shares of common stock of Juno through a tender offer.

Investing Activities

During the years ended December 31, 2017, 2016, and 2015, investing activities used cash of $10.2 million, $4.1 million, and $1.5 million, respectively. During the year ended December 31, 2017 we purchased $40.0 million in U.S. Treasuries as short-term investments, offset by $31.5 million in maturities of these short-term investments. During the year ended December 31, 2016 we purchased $19.7 million in U.S. Treasuries as short-term investments, offset by $16.0 million in maturities of these short-term 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 $47.4 million for the year ended December 31, 2017, which primarily consisted of $43.2 million of net proceeds from our December 2017 public offering of common stock and $15.0 million of proceeds from the July 14, 2017 amendment to our loan agreement with Silicon Valley Bank, offset by $10.8 million of principal payments on our term loans outstanding with Silicon Valley Bank.

Financing activities provided cash of $57.7 million for the year ended December 31, 2016, which primarily consisted of $36.4 million of net proceeds from our November 2016 private placement issuance of Class A convertible preferred stock, $18.6 million of net proceeds from our November 2016 private placement issuance of common stock and $10.2 million of net proceeds from our August 2016 private placement issuance of common stock, offset by $7.7 million of principal payments on our term loans outstanding with Silicon Valley Bank.

Financing activities provided cash of $35.6 million for the year ended December 31, 2015, which primarily consisted of $32.1 million of net proceeds from our May 2015 follow-on public offering of our common stock and $4.6 million from our May 2015 collaboration agreement with Juno, which amount represents the fair value of the equity component from Juno’s common stock purchase under the agreement, offset by $1.5 million of principal payments on our term loans outstanding with Silicon Valley Bank.

From our inception through December 31, 2017 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, 2017, we had aggregate cash and cash equivalents and short-term investments of $100.9 million.

Public Offering of Common Stock

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 our shelf registration statement. Gross proceeds from the offering were $46.0 million. After giving effect to an estimated $3.0 million of costs related to the offering (of which

$0.2 million was not paid as of December 31, 2017), net proceeds are estimated to be $43.0 million.

Private Placements of Common and Convertible Preferred Stock

In August 2016, we completed a private placement of common stock in which investors purchased 5,250,000 shares of our common stock at a price of $1.96 per share. Gross proceeds from the private placement were $10.3 million, and after giving effect to costs related to the private placement, net proceeds were $10.2 million.

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In November 2016, we completed a private placement of stock in which investors purchased shares of our Class A convertible Preferred Stock and common stock. We issued 2,819,549 shares of non-voting Class A Preferred Stock at $13.30 per share, each of which is convertible into five shares of common stock upon certain conditions. We also issued 7,236,837 shares of common stock at $2.66 per share. Gross proceeds from the private placement were $56.7 million. After giving effect to costs related to the private placement, net proceeds were $54.9 million.

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 (SVB), 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 SVB (the Loan Agreement). Pursuant to the Restated LSA, SVB 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 (Term B Loan). On December 24, 2014, we elected to draw $10.0 million under the Term B Loan.

On July 14, 2017, we and SVB entered into an amendment (the SVB Loan Amendment) of the Restated LSA where SVB extended an additional term loan to us in the principal amount of $15.0 million (the 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 SVB under the Restated LSA, cash proceeds to us from the remaining portion of the Term Loan were $7.5 million.

The 2017 Term Loan matures on January 1, 2022 (Term Loan Maturity Date). The 2017 Term Loan bears 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 shall such interest rate exceed 8.25%. Interest is payable on a monthly basis on the first day of each month. From August 1, 2017 through January 1, 2019 (the Interest-only Period), we are required to make monthly payments of interest only. Thereafter, we are required to repay the principal, plus monthly payments of accrued interest, in 36 equal monthly installments based on a 36-month amortization schedule. Notwithstanding the foregoing, subject to the achievement of a product development milestone by us before the expiration of the above-described Interest-only Period, (i) the Interest-only Period shall be extended from January 1, 2019 through and including to July 1, 2019 and (ii) we shall thereafter repay the principal, plus monthly payments of accrued interest, in 30 equal monthly installments based on a 30-month amortization schedule. Our final payment, due on the Term Loan Maturity Date, shall include all outstanding principal and accrued and unpaid interest under the 2017 Term Loan, plus a 7.5% final payment fee.

Subject to certain conditions, including the payment of a prepayment fee in the amount of (x) 3% of the principal amount of the Term Loan for any prepayment made through July 14, 2018 or (y) 1% of the principal amount of the Term Loan for any prepayment made after July 14, 2018 and on or before July 14, 2019, we may voluntarily prepay all, but not less than all, of the 2017 Term Loan.

In connection with the SVB Loan Amendment, we issued to SVB 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.

We are required under the Loan Agreement, as amended by the SVB Loan Amendment, to maintain our deposit and securities accounts with SVB and to comply with various default clauses and operating covenants that may restrict our

ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

Registration Statements on Form S-3

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, 2017, 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 as described below.

In October 2017, a shelf registration statement filed by us in October 2014 (File No. 333-199107) expired.

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Agreement with Juno Therapeutics, Inc.

Under the Agreement with Juno, Juno purchased one million shares of our common stock, at $8.00 per share, for an aggregate purchase price of $8.0 million in May 2015, $4.6 million of which was considered an equity component of the transaction. Juno has the option to extend the exclusive research term under the Agreement for an additional two years beyond the initial four-year term, subject to the payment of an extension fee of $3.0 million and the continued funding of our activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to us during the two-year extension period. Upon exercise of the research term extension, we have the option to require Juno to purchase up to $10.0 million of our common stock at a premium equal to 120% of the then thirty-day trailing volume weighted average trading price of our common stock.

See the Operating Activities in the “Liquidity and Capital Resources” section above for further discussion on the 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. 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 short-term investments as of December 31, 2017 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 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 short-term 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 preclinical studies and clinical trials for our product candidates;
- the number and the nature of product candidates that we pursue;
- the cost of process development and manufacturing of our product candidates, including the cost of supplies and materials 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 in-license agreements and the timing of such payments;

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- the extent to which milestones are achieved under our collaboration agreement with Juno, and the time to achievement of such milestones;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the expansion 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, 2017 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
Long-term debt (including interest and fees)	$19,319	$1,215	$11,306	$6,798	$—
Operating lease obligations	12,928	2,116	4,624	4,906	1,282
Total	$32,247	$3,331	$15,930	$11,704	$1,282

Our long-term debt bears 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 shall such interest rate exceed 8.25%. The amounts in the table above assume payment at our current interest rate, which is subject to change. The amounts in the above table also assume the Interest-only Period to be from August 1, 2017 through January 1, 2019.

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 an exclusive 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 an exclusive license agreement with the Whitehead Institute for Biomedical Research, pursuant to which we license certain patents relating to the reprogramming of somatic cells, 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.

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- We are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by various exclusive license agreements with The Scripps Research Institute (TSRI) pursuant to which we license certain patents relating to the use of small molecules in the reprogramming of somatic cells. 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, but will be required to pay a percentage of any sublicense income.
- Under an exclusive 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 an exclusive 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 induced pluripotent stem cells, including engineered induced pluripotent stem cells, 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 $3.8 million in the United States, plus an additional $1.0 million in the event of approval in each of certain other foreign territories. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the 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.

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 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 related to changes in interest rates. As of December 31, 2017, our cash and cash equivalents consisted of cash and money market mutual funds, and our short-term investments consisted of United States treasuries with maturities ranging from six to twelve 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 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.

Our outstanding debt under the SVB Loan Amendment bears 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 that in no event shall such interest rate exceed 8.25%. Given the floor and ceiling of the interest rate, the maximum interest expense increase of a 10% change in market interest rates would be $0.1 million annually and would not have a material impact on our financial condition and/or results of operations.

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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. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and shareholders' equity and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young LLP

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

San Diego, California

March 5, 2018

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Fate Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except par value and share data)

	December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$88,952	$88,609
Short-term investments and related maturity receivables	11,997	3,503
Prepaid expenses and other current assets	1,647	1,211
Total current assets	102,596	93,323
Property and equipment, net	2,550	1,579
Restricted cash	122	122
Other assets	24	24
Total assets	$105,292	$95,048
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,678	$934
Accrued expenses	7,254	3,957
Current portion of deferred rent	12	4
Current portion of deferred revenue	2,105	2,105
Long–term debt, current portion	—	8,187
Total current liabilities	11,049	15,187
Deferred rent	1,347	101
Deferred revenue	724	2,829
Accrued expenses	175	1,276
Long–term debt, net of current portion	14,808	2,501
Commitments and contingencies (Note 5)		
Stockholders' Equity:		
Preferred stock, $0.001 par value; authorized shares—5,000,000 at December 31, 2017 and December 31, 2016; 2,819,549 Class A convertible preferred shares issued and outstanding at December 31, 2017 and December 31, 2016	3	3
Common stock, $0.001 par value; authorized shares—150,000,000 at December 31, 2017 and December 31, 2016; issued and outstanding—52,648,601 at December 31, 2017 and 41,386,506 at	53	41

December 31, 2016		
Additional paid–in capital	295,934	248,957
Accumulated other comprehensive loss	(3)	(1)
Accumulated deficit	(218,798)	(175,846)
Total stockholders' equity	77,189	73,154
Total liabilities and stockholders' equity	$105,292	$95,048

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	For the Years Ended December 31,		
	2017	2016	2015
Collaboration revenue	$4,106	$4,402	$2,431
Operating expenses:			
Research and development	34,358	26,452	19,861
General and administrative	11,873	9,913	10,352
Total operating expenses	46,231	36,365	30,213
Loss from operations	(42,125)	(31,963)	(27,782)
Other income (expense):			
Interest income	559	138	10
Interest expense	(1,268)	(1,637)	(2,220)
Loss on extinguishment of debt	(118)	—	—
Total other expense, net	(827)	(1,499)	(2,210)
Net loss	$(42,952)	$(33,462)	$(29,992)
Other comprehensive loss:			
Unrealized loss on available-for-sale securities, net	(2)	(1)	—
Comprehensive loss	$(42,954)	$(33,463)	$(29,992)
Net loss per common share, basic and diluted	$(1.02)	$(1.05)	$(1.18)
Weighted–average common shares used to compute basic and diluted net loss per share	41,982,167	31,754,140	25,484,262

See accompanying notes.

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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 Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2014	—	$ —	20,569,399	$ 21	$ 140,711	$ —	$ (112,392)	$ 28,340
Exercise of stock options, net of issuance costs	—	—	227,215	—	420	—	—	420
Repurchase liability for unvested equity awards	—	—	—	—	44	—	—	44
Stock–based compensation	—	—	—	—	2,400	—	—	2,400
Senior executive incentive bonuses paid in common stock	—	—	19,956	—	97	—	—	97
Public offering of common stock, net of offering costs	—	—	6,900,000	7	32,142	—	—	32,149
Issuance of common stock to collaboration partner	—	—	1,000,000	1	4,579	—	—	4,580
Net loss	—	—	—	—	—	—	(29,992)	(29,992)
Balance at December 31, 2015	—	$ —	28,716,570	$ 29	$ 180,393	$ —	$ (142,384)	$ 38,038
Exercise of stock options, net of issuance costs	—	—	136,368	—	187	—	—	187
Repurchase liability for unvested	—	—	—	—	1	—	—	1

equity awards								
Stock–based compensation	—	—	—	—	3,184	—	—	3,184
Private placement issuances of common stock, net of offering costs	—	—	12,486,837	12	28,785	—	—	28,797
Private placement issuance of Series A convertible preferred stock, net of offering costs	2,819,549	3	—	—	36,286	—	—	36,289
Senior executive incentive bonuses paid in common stock	—	—	46,731	—	121	—	—	121
Unrealized loss on short-term investments	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(33,462)	(33,462)
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
Issuance of warrants for common stock	—	—	—	—	217	—	—	217
Public offering of common stock, net of offering costs	—	—	10,953,750	11	42,968	—	—	42,979
Private placement issuances of	—	—	—	—	(13)	—	—	(13)

common stock, net of offering costs								
Private placement issuance of Series A convertible preferred stock, net of offering costs	—	—	—	—	(26)	—	—	(26)
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Unrealized loss on short-term 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

See accompanying notes

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Fate Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2017	2016	2015
Cash flows from operating activities			
Net loss	$(42,952)	$(33,462)	$(29,992)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	971	881	687
Stock–based compensation	3,606	3,184	2,400
Amortization of debt discounts and debt issuance costs	81	139	176
Amortization of premiums and discounts on investments, net	(25)	171	—
Noncash interest expense	321	492	651
Deferred rent	1,085	(7)	(24)
Deferred revenue	(2,105)	(2,401)	7,335
Loss on extinguishment of debt	30	—	—
Changes in assets and liabilities:			
Prepaid expenses and other assets	(428)	(381)	(107)
Accounts payable and accrued expenses	2,511	1,561	477
Net cash used in operating activities	(36,905)	(29,823)	(18,397)
Cash flows from investing activities			
Proceeds from sale of property and equipment	—	18	—
Purchase of property and equipment	(1,725)	(457)	(1,498)
Purchases of short-term investments	(39,971)	(19,675)	—
Maturities of short-term investments	31,500	16,000	—
Net cash used in investing activities	(10,196)	(4,114)	(1,498)
Cash flows from financing activities			
Issuance of common stock from equity incentive plans, net of repurchases and issuance costs	205	186	420
Proceeds from public offering of common stock, net of issuance costs	43,206	—	32,149
Proceeds from private placement issuances of common stock, net of issuance costs	(65)	28,849	—
Proceeds from private placement issuance of preferred stock, net of issuance costs	(128)	36,391	—
Proceeds from sale of common stock to collaboration partner	—	—	4,580
Proceeds from long–term debt	15,000	—	—
Payments on long–term debt	(10,764)	(7,689)	(1,546)
Payments for the issuance of debt	(10)	—	—
Net cash provided by financing activities	47,444	57,737	35,603

Net change in cash, cash equivalents and restricted cash	343	23,800	15,708
Cash, cash equivalents and restricted cash at beginning of the period	88,731	64,931	49,223
Cash, cash equivalents and restricted cash at end of the period	$89,074	$88,731	$64,931
Supplemental disclosure of cash flow information			
Interest paid	$2,314	$1,067	$1,353
Supplemental schedule of noncash investing and financing activities			
Issuance of warrants for common stock in connection with long–term debt	$217	$—	$—

See accompanying notes.

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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 cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf engineered product candidates derived from clonal master iPSC lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel ex vivo cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of December 31, 2017, 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 May 2015, the Company completed a public offering of common stock in which investors purchased 6,900,000 shares of its common stock at an offering price of $5.00 per share. Gross proceeds from the offering were $34.5 million. After giving effect to costs related to the offering, total net proceeds from the offering were $32.1 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 the Company's shelf registration statement. Gross proceeds from the offering were $46.0 million, and after giving effect to an estimated $3.0 million of costs related to the offering (of which $0.2 million was not paid as of December 31, 2017), net proceeds are estimated to be $43.0 million.

Private Placements of Common Stock and Convertible Preferred Stock

In August 2016, the Company completed a private placement of common stock in which investors purchased 5,250,000 shares of the Company's common stock at a price of $1.96 per share. Gross proceeds from the private placement were $10.3 million. After giving effect to costs related to the private placement, net proceeds were $10.2 million. The Company also registered all of the shares issued in the private placement transaction for resale on a Form S-3 filed with the Securities and Exchange Commission (the SEC), as required under a registration rights agreement entered into by the Company with the purchasers of the common stock, and the registration statement was declared effective in September 2016.

In November 2016, the Company completed a private placement of common and preferred stock in which investors, including investors affiliated with the Company's directors and officers, purchased convertible preferred stock and common stock of the Company. The Company issued 2,819,549 shares of non-voting Class A Preferred Stock at

$13.30 per share, each of which is convertible into five shares of common stock upon certain conditions. The Company also issued 7,236,837 shares of common stock at $2.66 per share. Gross proceeds from the private placement were $56.7 million. After giving effect to costs related to the private placement, net proceeds were $54.9 million. The Company also entered into a registration rights agreement (the Registration Rights Agreement) with certain of the purchasers in the November 2016 placement, excluding those purchasers affiliated with the Company's directors and officers, requiring the Company to register for the resale of the relevant shares. The Company registered all of the relevant shares issued in the placement for resale on a Form S-3 filed with the SEC, as required under the Registration Rights Agreement, and the registration statement was declared effective in January 2017. See Note 6 to the Consolidated Financial Statements for additional information related to this offering.

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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 (Canada), Inc. or Fate Canada, incorporated in Canada and which was dissolved in November 2016, Fate Therapeutics Ltd., incorporated in the United Kingdom, 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 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 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, and because of the relatively recent financing date, 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.

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Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and short-term investments. Cash equivalents consisted of money market funds and short-term investments consisted of U.S. treasuries. The following table presents the Company's assets which were measured at fair value on a recurring basis as of December 31, 2017 and 2016 (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, 2017:				
Cash equivalents	$88,952	$88,952	$ —	$ —
U.S. Treasury debt securities	11,997	11,997	—	—
Total assets	$100,949	$100,949	$ —	$ —
As of December 31, 2016:				
Cash equivalents	$88,609	$88,609	$ —	$ —
U.S. Treasury debt securities	3,503	3,503	—	—
Total assets	$92,112	$92,112	$ —	$ —

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 is recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

As of December 31, 2017 and 2016, 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, 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, 2017 (in thousands):

	December 31, 2017	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 88,952	$ 88,609	$ 64,809
Restricted cash	122	122	122
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 89,074	$ 88,731	$ 64,931

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

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Short-Term Investments

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on 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 short-term 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, and scientific and office equipment. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. 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. 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.

Deferred Rent

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company occupies. The Company’s lease for its facilities provides for fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease term are charged to rent expense ratably over the life of the lease.

Revenue Recognition

The Company recognizes revenues when all four of the following criteria are met: (i) persuasive evidence that an agreement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured.

Revenue arrangements with multiple elements are analyzed to determine whether the elements can be divided into separate units of accounting or whether the elements must be accounted for as a single unit of accounting. The

Company divides the elements into separate units of accounting and applies the applicable revenue recognition criteria to each of the elements, if the delivered elements have value to the customer on a stand-alone basis, if the arrangement includes a general right of return relative to the delivered elements, and if the delivery or performance of the undelivered elements is considered probable and substantially within the Company's control.

Revenue has been allocated to each element at the inception of the arrangement using the relative selling price method that is based on a three-tier hierarchy. The relative selling price method requires that the estimated selling price for each element be based on vendor-specific objective evidence (VSOE) of fair value, which represents the price charged for each element when it is sold separately or, for an element not yet being sold separately, the price established by management. When VSOE of fair value is not available, third-party evidence (TPE) of fair value is acceptable, or a best estimate of selling price is used if neither VSOE nor TPE is available. A best estimate of selling price should be consistent with the objective of determining the price at which the Company would transact if the element were sold regularly on a stand-alone basis and should also take into account market conditions and company-specific factors.

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Revenue arrangements with multiple elements may include license fees, research and development payments, milestone payments, other contingent payments, and royalties on any product sales derived from collaborations. The Company recognizes nonrefundable license fees with stand-alone value as revenue at the time that the Company has satisfied all performance obligations, and recognizes license fees without stand-alone value as revenue in combination with any undelivered performance obligations. The Company recognizes a research and development payment as revenue over the term of the collaboration agreement as contracted amounts are earned, or reimbursable costs are incurred, under the agreement, where contracted amounts are considered to be earned in relative proportion to the performance required under the applicable agreement. The Company recognizes a milestone payment, which is contingent upon the achievement of a milestone in its entirety, as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. These criteria include the following: (i) the consideration being earned should be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) the consideration being earned should relate solely to past performance; (iii) the consideration being earned should be reasonable relative to all deliverables and payment terms in the arrangement; and (iv) the milestone should be considered in its entirety and cannot be bifurcated into substantive and nonsubstantive components. Any amounts received pursuant to revenue arrangements with multiple elements prior to satisfying the Company's revenue recognition criteria are recorded as deferred revenue on the Company's consolidated balance sheets.

Revenue from government grants is recorded when reimbursable expenses are incurred under the grant in accordance with the terms of the grant award.

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 accounts for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting

terms. 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 performance condition is determined to be probable of achievement or when it has been achieved.

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

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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 losses on 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. Excluded from the weighted-average number of shares outstanding are shares which have been issued upon the early exercise of stock options and are subject to future vesting and unvested restricted stock totaling zero shares, 3,284 shares, and 44,381 shares for the years ended December 31, 2017, 2016, and 2015, respectively. Dilutive common stock equivalents are comprised of 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,		
	2017	2016	2015
Warrants for common stock	225,756	134,113	134,113
Common stock options	5,458,043	3,910,350	2,587,474
Restricted stock units	212,625	525,250	525,250
Series A convertible preferred stock (if converted)	14,097,745	14,097,745	—
	19,994,169	18,667,458	3,246,837

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Recent Accounting Pronouncements

In November 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2016-18 (ASU 2016-18). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017. As early adoption of this amendment is permitted, the Company has adopted the update retrospectively to each period presented. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

In March 2016, the FASB issued ASU 2016-09, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 became effective for the Company on January 1, 2017. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

In February 2016, the FASB issued ASU 2016-02, which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its Consolidated Financial Statements.

In May 2014, the FASB issued ASU 2014-09, which created a single, principle-based revenue recognition model that will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. The model provides that entities follow five steps: (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. For public business entities, ASU 2014-09 is effective beginning in the first quarter of 2018 using one of two prescribed transition methods: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). The Company will adopt ASU 2014-09 in the first quarter of 2018 using the full retrospective method. The Company has evaluated the effect that the updated standard will have on its internal processes, financial statements and related disclosures, and has determined that the adoption will not have a material impact on the Company's historical Consolidated Financial Statements.

Going Concern Assessment

Pursuant to ASU 2014-15, the Company has assessed its ability to continue as a going concern for a period of one year from the date of the issuance of these financial statements. 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.

2. Juno Collaboration and License Agreement

On May 4, 2015, the Company entered into a strategic research collaboration and license agreement (the 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. Pursuant to the terms of the Agreement, Juno paid the Company a non-refundable upfront payment of $5.0 million and purchased 1,000,000 shares of the Company's common stock at a price of $8.00 per share.

Additionally, Juno agreed to fund all of the Company's collaboration research activities for an initial four-year research term beginning on the effective date of the Agreement, with minimum annual research payments of $2.0 million to the Company. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of an extension fee of $3.0 million and the continued funding of the Company's activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to the Company during the two-year extension period. Upon exercise of the research term extension, the Company has the option to require Juno to purchase up to $10.0 million of the Company's common stock at a premium equal to 120% of the then thirty-day trailing volume weighted average trading price of the Company's common stock.

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The Company applied Accounting Standards Codification (ASC) 605-25, Revenue Recognition — Multiple Element Arrangements, to evaluate the appropriate accounting for the Agreement. In accordance with this guidance, the Company assessed the potential deliverables, including an exclusive license granted by the Company to Juno for certain intellectual property and research services to be performed by the Company, and determined that the deliverables did not have stand-alone value. The Company determined that the license deliverable granted under the Agreement does not have standalone value given the highly specific nature of the small molecules to be identified for use with Juno's genetically-engineered T-cell immunotherapies. The Company concluded that there is one single unit of accounting, and the arrangement consideration will be recognized in the same manner as the final deliverable, which is the research services. As such, the upfront payment of $5.0 million was recorded as deferred revenue and is being recognized over the initial four-year research term under the Agreement. With respect to the $8.0 million payment for the Company's common stock, the Company determined that the common stock purchase price of $8.00 per share represented a premium of $3.40 per share. This premium represents arrangement consideration and therefore the aggregate premium of $3.4 million was recorded as deferred revenue and is being recorded as revenue ratably over the initial four-year research term. The remaining $4.6 million consideration that represents the purchase of common stock was recorded as the issuance of common stock in shareholders' equity.

Pursuant to the collaboration's research plan under the Agreement, the Company is responsible for screening and identifying small molecule modulators of immunological cells, while Juno will be responsible for the development and commercialization of engineered T-cell immunotherapies incorporating the Company's modulators. As the Company is principally responsible for the performance of the research services under the Agreement, revenue is recognized on a gross basis for such services when earned. Billings for research services will be recognized as deferred revenue until earned.

Total revenue recognized under the Agreement for the years ended December 31, 2017, 2016, and 2015 was $4.1 million, $4.4 million, and $2.4 million, respectively. As of December 31, 2017, aggregate deferred revenue related to the Agreement was $2.8 million.

Under the Agreement, the Company has granted Juno an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the collaboration, to make, use, sell and otherwise exploit genetically-engineered T-cell immunotherapies using or incorporating small molecule modulators directed against certain designated tumor-associated antigen targets, subject to the selection of a target by Juno. The Company has retained exclusive rights to such intellectual property, including its intellectual property arising under the collaboration, for all other purposes, including its use outside of those targets selected by Juno.

The Company is eligible under the Agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. In accordance with ASC 605-28, Revenue Recognition — Milestone Method, the Company determined that such contingent payments do not constitute milestone payments and will not be accounted for under the milestone method of revenue recognition. The events leading to these payments do not meet the definition of a milestone under ASU 2010-17 because the achievement of these events depends on Juno's performance and selections. Any revenue from these contingent selection payments would be subject to an allocation of arrangement consideration and would be recognized over any remaining period of performance obligation, if any, relating to the collaboration.

In connection with each Juno therapy that uses or incorporates the Company's small molecule modulators, Juno has agreed to pay the Company non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million in the aggregate per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates the

Company’s small molecule modulators, Juno has agreed to pay the Company additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones. In accordance with ASU 2010-17, the Company determined that these contingent payments meet the definition of a milestone under ASU 2010-17, and that the milestones are substantive given that the milestones are commensurate with the Company’s performance, relate solely to the Company’s past performance, and are reasonable relative to other deliverables and payments under the Agreement. Accordingly, the milestones under the Agreement will be accounted for as revenue on the achievement date, if any.

Beginning on the date of the first commercial sale (in each country) for each Juno therapy that uses or incorporates the Company’s small molecule modulators, and continuing until the later of: i) the expiration of the last valid patent claim, ii) ten years after such first commercial sale, or iii) the expiration of all data and other regulatory exclusivity periods afforded each therapy, Juno has agreed to pay the Company royalties in the low single-digits on net sales of each Juno therapy that uses or incorporates the Company’s small molecule modulators.

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The Agreement will end on the date that no further payments are due under the Agreement.

3. Short-term Investments

The Company invests portions of excess cash in United States treasuries with maturities ranging from six to twelve months from the purchase date. These debt securities are classified as short-term investments in the accompanying consolidated balance sheets and are accounted for as available-for-sale securities.

The following table summarizes the Company's short-term investments accounted for as available-for-sale securities as of December 31, 2017 and 2016 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
December 31, 2017					
U.S. Treasury debt securities	1 or less	12,000	(3)	—	11,997
Total		$ 12,000	$ (3)	$ —	$ 11,997
December 31, 2016					
U.S. Treasury debt securities	1 or less	3,504	(1)	—	3,503
Total		$ 3,504	$ (1)	$ —	$ 3,503

The Company reviewed its investment holdings as of December 31, 2017 and determined that the unrealized losses were not other-than-temporary unrealized losses because the Company does not intend to sell the underlying securities prior to maturity and it is not more likely than not that the Company will be required to sell these securities before the recovery of their amortized cost basis. During the years ended December 31, 2017 and 2016, the Company did not recognize any impairment or gains or losses on sales of available-for-sale securities.

4. Property and Equipment

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

	December 31,	
	2017	2016
Furniture and fixtures	$508	$324
Computer and office equipment	527	318
Software	103	103
Leasehold improvements—building	180	180
Scientific equipment	6,371	4,858
Property and equipment, gross	7,689	5,783
Less accumulated depreciation and amortization	(5,139)	(4,204)
Property and equipment, net	$2,550	$1,579

Depreciation expense related to property and equipment was $1.0 million, $0.9 million, and $0.7 million, for the years ended December 31, 2017, 2016, and 2015, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2017, 2016, and 2015.

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5. Accrued Expenses, Long-Term Debt, Commitments and Contingencies

Accrued Expenses

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

	December 31, 2017	December 31, 2016
Accrued payroll and other employee benefits	$ 1,761	$ 1,505
Accrued clinical trial related costs	3,323	1,043
Accrued other	2,170	1,409
Accrued expenses		