FATE THERAPEUTICS INC
Form 10-K
March 05, 2019
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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, 2018

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $488,652,000 as of June 30, 2018 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 1, 2019 was 64,999,547.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, on or before the date 120 days after the conclusion of the registrant's fiscal year ended December 31, 2018 pursuant to Regulation 14A in connection with the registrant's 2019 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, 2018

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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:

- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and product development activities;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- our ability and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;
- the timing and likelihood of, and our ability to obtain and maintain, regulatory clearance of our IND applications for and regulatory approval of our product candidates;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- our ability to source clinical and, if approved, commercial materials and supplies used to manufacture our product candidates;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- the potential of our technology platform, including our induced pluripotent stem cell (iPSC) product platform, and our plans to apply our platform to research, develop and commercialize our product candidates;
- our ability to attract and retain strategic collaborators with development, regulatory and commercialization expertise;
- the potential benefits of strategic collaboration agreements and our ability, and the ability of our collaborators, to successfully develop product candidates under the respective collaborations;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with actual or potential collaborators, to commercialize our product candidates, if approved;
- our ability to successfully commercialize our product candidates, if approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;

- the potential scope and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- our ability to obtain funding for our operations;

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- the accuracy of our projections and estimates regarding our revenues, expenses, capital requirements, cash utilization and need for additional financing;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those described under Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K.

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

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

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

ITEM 1. Business

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 a therapeutic approach that we generally refer to as cell programming. For certain of our cell therapy product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of healthy donor cells ex vivo before our product candidates are administered to a patient. In other cases, we use human iPSCs to generate a clonal master iPSC line having preferred biological properties, and direct the fate of the clonal master iPSC line to create our cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be made and used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients.

Utilizing these therapeutic approaches, we program cells of the blood and immune system, including natural killer (NK) cells, T cells and $CD34^+$ cells, and are advancing a pipeline of programmed cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation.

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

Product Candidate	Cell Type	Stage of Development	Therapeutic Area	Commercial Rights
Immuno-Oncology				
FATE-NK100	Donor NK	Phase 1	Relapsed / Refractory AML [1]	Worldwide
FATE-NK100	Donor NK	Phase 1	Recurrent Ovarian Cancer [1]	Worldwide
FATE-NK100	Donor NK	Phase 1	Advanced Solid Tumors	Worldwide
FT500	iPSC-NK	IND Allowed	Advanced Solid Tumors	Worldwide
FT516	iPSC-NK	IND Allowed	Hematologic Malignancies	Worldwide
FT596	iPSC-NK	Preclinical	Hematologic Malignancies	Worldwide
FT538	iPSC NK	Preclinical	Hematologic Malignancies	Worldwide
FT819	iPSC-T	Preclinical	Hematologic Malignancies	Worldwide
FT-ONO1	iPSC-T	Research	Hematologic Malignancies	Joint [2]
FT-ONO2	iPSC-T	Research	Advanced Solid Tumors	Joint [2]
Immuno-Regulation				
ProTmune™	Donor cell graft	Phase 2	Prevention of Acute GvHD	Worldwide
FT301	iPSC-MDSC	Preclinical	Immune Disorders	Worldwide
Cell Programming Partnership				
Engineered T Cells [3]		Preclinical	Hematologic / Solid Tumors	Juno Therapeutics

Notes:

[1] Clinical trial is being conducted as an investigator-initiated study at the Masonic Cancer Center, University of Minnesota.

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

[3] Collaboration excludes all cell types derived from iPSCs 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.

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. One particular form of cancer immunotherapy, chimeric antigen receptor (CAR) T-cell therapy, has recently emerged as a revolutionary and potentially curative therapy for patients with certain hematologic malignancies; in fact, in 2017, two CAR T-cell therapies were approved by the U.S. Food and Drug Administration (FDA). While advancements in the sourcing, engineering and expansion of cells have opened new avenues for their use as therapeutic entities, we believe the biological properties and therapeutic function of cells 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

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

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

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

Rather than rely on the use of a patient's own cells, we seek to use healthy donor cells and clonal master iPSC lines to manufacture, develop and commercialize first-in-class cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation. We believe our approach has the potential to improve cell product consistency and potency, reduce manufacturing costs, shorten time to treatment and reach more patients. The key pillars of our business strategy are to:

- Efficiently develop and commercialize first-in-class allogeneic cellular immunotherapies for severe, life-threatening diseases where treatment options are limited. We are clinically developing first-in-class allogeneic cellular immunotherapies for cancer and immune disorders. We are advancing our product candidates to improve the lives of patients with severe, life-threatening diseases, where the unmet need is significant and where regulatory agencies offer efficient and expedited development and review programs. For example, we are developing our product candidate ProTmune as a first-in-class hematopoietic cell graft for the prevention of life-threatening complications, including graft-versus-host disease (GvHD), in patients undergoing allogeneic HCT. GvHD is a leading cause of morbidity and mortality in patients undergoing allogeneic HCT, and there are currently no therapies approved by the FDA for the prevention of GvHD. The FDA has granted Fast Track designation, and the FDA and the European

Commission have granted Orphan Drug Designation and Orphan Medicinal Product Designation, respectively, for ProTmune. We are also developing our product candidate FATE-NK100, which is manufactured using healthy donor cells, as a first-in-class, adaptive memory NK cell cancer immunotherapy. FATE-NK100 is currently being clinically investigated in three Phase 1 studies for the treatment of patients with relapsed/refractory hematologic malignancies and advanced solid tumors. 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.

- Exploit our dominant leadership position in iPSC technology to develop and commercialize universal, off-the-shelf cell products for the treatment of hematologic malignancies and solid tumors. We have developed an industry-leading iPSC product platform, and we believe the manufacture of cell products using clonal master iPSC lines has the potential to revolutionize the field of cancer immunotherapy. Our first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event, and selecting a single iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients.

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We have amassed unrivaled expertise in the manufacture of NK cells and T cells from clonal master iPSC lines. Our expertise includes: generating, engineering, isolating and characterizing single-cell iPSC clones; creating and cryopreserving clonal master iPSC lines; differentiating these clonal master cell lines to produce NK cells and T cells; and regulatory affairs to enable clinical investigation of iPSC-derived cell products. We believe our iPSC-derived NK cell and T-cell product candidates have the potential to be administered in multi-dose, multi-cycle treatment regimens, including in combination with cycles of other cancer treatments, to drive deeper and more durable responses. In November 2018, the FDA cleared our IND application for FT500, a universal, off-the-shelf, iPSC-derived NK cell product candidate for use in combination with checkpoint blockade therapy for the treatment of solid tumors; and in February 2019, the FDA cleared our IND application for FT516, a universal, off-the-shelf, iPSC-derived NK cell product candidate that expresses a high-affinity, non-cleavable CD16 Fc receptor for use in combination with monoclonal antibody therapy for the treatment of hematologic malignancies. FT500 is the first-ever iPSC-derived cell therapy, and FT516 is the first-ever engineered iPSC-derived cell therapy, allowed to proceed to clinical investigation in the United States by the FDA.

- Forge collaborations with leading researchers and top medical centers to accelerate development of and rapidly translate our iPSC-derived cell product candidates into first-in-human clinical trials. The research and development of iPSC-derived cell product candidates requires an exceptional team of people and scientific, manufacturing and clinical expertise across a range of disciplines. We have and will continue to seek collaborations with leading researchers, investigators and top medical centers for the research, development, manufacture and clinical translation of our iPSC-derived cell product candidates. Among our collaborations is a partnership with the University of Minnesota, led by Dr. Jeffrey S. Miller, a renowned NK cell biologist and clinical investigator, to support the development of FT500 and FT516 product candidates, and a partnership with Memorial Sloan Kettering Cancer Center, led by Dr. Michel Sadelain, a renowned T-cell biologist and a recognized founder of CAR T-cell therapy, to support the development of engineered iPSC-derived CAR T-cell immunotherapies, including FT819. We believe this approach to research and development will maximize our potential to successfully build our iPSC product platform, accelerate the clinical translation and clinical investigation of our iPSC-derived cell product candidates, and efficiently establish clinical proof-of-concept for our iPSC-derived cell product candidates.
- Selectively share our iPSC product platform with industry-leading strategic partners for the development of highly differentiated cellular immunotherapies. The research, development and clinical investigation of cell therapies for the treatment of human diseases is rapidly expanding. We believe we are uniquely positioned as an expert partner of choice for industry-leading developers seeking to maximize the therapeutic potential of cell therapies for the treatment of cancer. Additionally, since iPSCs have the unique capacity to be genetically engineered, indefinitely expanded and differentiated in culture into any type of cell in the body, we believe there is significant opportunity to broadly exploit our industry-leading iPSC product platform and intellectual property position into other disease areas. We will continue to seek partnerships with institutions and companies for the research, development and commercialization of iPSC-derived cell product candidates for the treatment of human diseases.

Our Product Pipeline & Partnerships

Immuno-Oncology Product Candidates

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

known as antibody-dependent cellular cytotoxicity (ADCC).

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

We are developing NK cell and T-cell cancer immunotherapies with a focus on developing next-generation cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens.

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FATE-NK100 Adaptive Memory Natural Killer Cell Product Candidate

Adaptive memory NK cells are a highly specialized and functionally distinct subset of NK cells. In July 2015, we entered into a research collaboration with the University of Minnesota led by Dr. Jeffrey S. Miller, Professor of Medicine at the University of Minnesota and Deputy Director of the University of Minnesota Masonic Comprehensive Cancer Center, to develop an 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 NK 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. 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 as a monotherapy in subjects with refractory or relapsed acute myelogenous lymphoma (AML). The clinical trial is designed 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, a cohort of three subjects will be enrolled 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.

In November 2018, we reported initial clinical data from the ongoing VOYAGE study as of an October 22, 2018 data cutoff. As of that date, a total of four subjects, each with refractory or relapsed disease at the time of enrollment, were

treated with a single infusion of FATE-NK100 as monotherapy. All three subjects treated at the second dose level ($1\text{-}3x10^7$ cells per kg) achieved a morphologic leukemia-free state at Day 14 as assessed by bone marrow biopsy; however, the anti-leukemic activity in each of these three subjects was transient, and each of these three subjects subsequently had progressive disease. No subjects treated at the first two dose levels achieved a complete response. No DLTs or serious adverse events related to FATE-NK100 were reported. A DLT unrelated to FATE-NK100 was reported in one subject at the second dose level.

The Phase 1 clinical trial is currently being conducted at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study.

The APOLLO Study. APOLLO is an ongoing open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 as a monotherapy in women with ovarian, fallopian tube or primary peritoneal cancer resistant to, or recurrent on, platinum-based treatment. The clinical trial is designed 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, 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.

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In November 2018, we reported initial clinical data from the ongoing APOLLO study as of an October 22, 2018 data cutoff. As of that date, a total of four subjects, each with progressive disease at the time of enrollment, were treated with a single infusion of FATE-NK100 as monotherapy. One subject at the second dose level (1-3x10^7 cells per kg) had stable disease at one-month follow-up, was treated with a second dose of FATE-NK100, and remained on study and maintained disease control for 6.2 months. Three other subjects, one each at the first dose level (1x10^7 cells per kg), the second dose level and the third dose level (3-10x10^7 cells per kg) had progressive disease at one-month follow-up. No DLTs were reported. One serious adverse event related to FATE-NK100 was reported (Grade 3: abdominal pain).

The Phase 1 clinical trial is currently being conducted at the Masonic Cancer Center, University of Minnesota as an investigator-sponsored study.

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 clinical trial is designed 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. The DIMENSION study is designed with three treatment regimens:

- Regimen A: FATE-NK100 as a monotherapy in subjects with advanced solid tumor malignancies. Up to three dose levels of FATE-NK100 are intended to be assessed using an accelerated dose-escalation design. In the event a DLT is observed, the clinical trial will convert immediately to a traditional 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. Up to four dose levels of FATE-NK100 are intended to be assessed using an accelerated dose-escalation design. In the event a DLT is observed, the clinical trial will convert immediately to a traditional 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. Up to four dose levels of FATE-NK100 are intended to be assessed using an accelerated dose-escalation design. In the event a DLT is observed, the clinical trial will convert immediately to a traditional 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.

In November 2018, we reported initial clinical data from the ongoing DIMENSION study as of an October 22, 2018 data cutoff. As of that date, one-month follow up data were available for seven subjects, each with progressive disease at the time of enrollment following multiple prior lines of therapy. Three of five subjects treated with FATE-NK100 in the monotherapy regimen had stable disease at one-month follow-up: one subject treated at the second dose level (1-3x10^7 cells per kg) and two subjects treated at the third dose level (3-10x10^7 cells per kg). These two subjects at the third dose level each received a second dose of FATE-NK100, and remained on study with ongoing disease control as of the data cutoff (94 and 149 days, respectively). The two other subjects in the monotherapy regimen (one subject at the first dose level (1x10^7 cells per kg) and one subject at the third dose level) had progressive disease at one-month follow-up. Each of the two subjects in the cetuximab combination regimen had progressive disease at one-month follow-up: one subject at the run-in dose level (1x10^6 cells per kg) and one subject at the first dose level (1x10^7 cells per kg). No DLTs were reported, and no serious adverse events related to FATE-NK100 were reported.

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

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

We are developing FT500 as a universal, off-the-shelf NK cell cancer immunotherapy for the treatment of advanced solid tumors, both as a monotherapy and in combination with FDA-approved checkpoint inhibitor therapy. We isolated and selected a single iPSC, and clonally-expanded this single iPSC to generate the clonal master iPSC line for production of FT500. 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 particular, in an in vitro three-dimensional tumor spheroid model, FT500 in combination with activated T cells and an anti-PD1 antibody significantly enhanced the elimination of target cancer cells, as compared to FT500 alone, activated T cells alone and activated T cells in combination with anti-PD1 antibody.

In November 2018, the FDA issued a letter informing us that our FT500 IND application was allowed and that we can proceed with human clinical investigation of FT500. To our knowledge, FT500 is the first-ever iPSC-derived cell therapy cleared by the FDA for clinical investigation in the United States.

Our clinical trial of FT500 is expected to be the first-ever clinical investigation in the U.S. of an iPSC-derived cell product. The open-label, multi-center, repeat-dose, multi-cycle, dose-escalation Phase 1 clinical trial is designed to assess the safety and determine the maximum dose of FT500 when administered after outpatient lymphoconditioning chemotherapy in up to 64 subjects with advanced solid tumors. The study includes two treatment regimens: FT500 as a monotherapy in subjects that are candidates for salvage therapy; and, in subjects who have failed or progressed on checkpoint inhibitor therapy (nivolumab, pembrolizumab or atezolizumab), FT500 in combination with the checkpoint inhibitor on which the subject has failed or progressed. The study will assess three once weekly doses of FT500 (Day 1, Day 8, Day 15); a second treatment cycle of three once weekly doses of FT500 may be administered for certain subjects who are clinically stable at Day 29. In the checkpoint inhibitor treatment regimen, subjects will receive treatment with the checkpoint inhibitor on which the subject had most recently progressed at the respective FDA-approved dose beginning on Day 8. Up to two dose levels of FT500 are intended to be assessed (1×10^8 cells per dose and 3×10^8 cells per dose) with the potential for higher doses to be defined by protocol amendment. In February 2019, the first subject was treated with FT500, and the clinical trial is now open for enrollment at two top cancer treatment centers.

FT516: iPSC-derived, hnCD16 Engineered NK Cell Product Candidate for 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 and potentiate 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 FT516, 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. Our novel hnCD16 Fc receptor 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 the clonal master engineered iPSC line for production of FT516. 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.

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We are developing FT516 as a monotherapy and in combination with tumor-antigen targeting monoclonal antibody therapy for the treatment of hematologic malignancies and solid tumors. 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;
- 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; and
- FT516 augments anti-tumor activity and promotes prolonged survival in combination with rituximab in vivo, as compared to expanded peripheral blood NK cells in combination with rituximab, in a human lymphoma cancer model, where FT516 in combination with rituximab supported a survival rate of 50% at Day 200.

In April 2018, we executed an award agreement with the California Institute of Regenerative Medicine (CIRM) pursuant to which CIRM awarded us up to $4.0 million to advance our FT516 product candidate into a first-in-human clinical trial for the treatment of subjects with advanced solid tumors, including in combination with monoclonal antibody therapy (the Award). Pursuant to the terms of the Award, we are eligible to receive five disbursements in varying amounts throughout the project period of the Award, which was estimated to be from April 1, 2018 to June 30, 2019. The Award is subject to certain co-funding requirements by us, and we are required to provide progress and financial update reports to CIRM. We, in our sole discretion, have the option to treat the Award either as a loan or as a grant. If we do not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant.

In December 2018, we discussed with CIRM our intent to pursue the clinical development of FT516 in relapsed / refractory hematologic malignancies in addition to advanced solid tumors, and our preference to first submit an IND application for FT516 in relapsed / refractory hematologic malignancies rather than in advanced solid tumors. In January 2019, we submitted our IND application for FT516 in relapsed / refractory hematologic malignancies, the second product candidate intended for clinical investigation emerging from our iPSC product platform, which IND submission was allowed by the FDA in a letter from February 2019. Such letter from the FDA also informed us that we could proceed with human clinical investigation of FT516. We are currently developing a clinical protocol to support a potential submission of an IND application for FT516 in advanced solid tumors. We agreed with CIRM to suspend the Award until such time as we elect to proceed with our submission of an IND application for FT516 in advanced solid tumors. At the time of suspension, an additional $0.5 million was available for funding under the Award.

Our clinical trial of FT516 is expected to be the first-ever clinical investigation of an engineered iPSC-derived cell product. The open-label, multi-center, repeat-dose, multi-cycle, dose-escalation Phase 1 clinical trial is designed to assess the safety and determine the maximum dose of FT516 when administered after outpatient lymphoconditioning chemotherapy followed by a short course of sub-cutaneous IL-2 administration in up to 99 subjects with relapsed/refractory hematologic malignancies. The study includes three treatment regimens: FT516 as a monotherapy in subjects with AML; FT516 in combination with rituximab in subjects with non-Hodgkin's lymphoma (NHL); and

FT516 in combination with elotuzumab in subjects with multiple myeloma (MM). The study will assess three once weekly doses of FT516 (Day 1, Day 8, Day 15); a second treatment cycle of three once weekly doses of FT516 may be administered for certain subjects who are clinically stable at Day 29. In the monoclonal antibody treatment regimens, subjects will receive treatment with the monoclonal antibody beginning four days prior to the first administration of FT500. Up to four dose levels of FT516 are intended to be assessed (0.3×10^8 cells per dose (monoclonal antibody regimens only); 1×10^8 cells per dose; 3×10^8 cells per dose; 9×10^8 cells per dose).

Additional iPSC-derived Cell Product Candidates for Cancer

We are applying our iPSC product platform to develop other clonal master engineered iPSC lines and additional engineered iPSC-derived cell product candidates, including in collaboration with leading researchers and top medical centers. For example, we entered into a multi-year research collaboration with the University of California, San Diego to develop off-the-shelf, CAR-NK cell cancer immunotherapies. The 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. We also entered into a multi-year partnership with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf engineered T-cell product candidates using clonal master iPSC lines. The research and development activities under the collaboration are being led by Dr. Michel Sadelain, Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center.

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FT596. CAR T-cell therapy has recently emerged as a revolutionary and potentially curative therapy for patients with hematologic malignancies, including refractory cancers. In 2017, two autologous CD19-specific CAR T-cell therapies were approved by the FDA for the treatment of certain relapsed/refractory leukemias and lymphomas. While most researchers and clinical investigators continue to focus on the development of autologous CAR T-cell therapies, we are developing CAR NK cell product candidates created from clonal master engineered iPSC lines as off-the-shelf cancer immunotherapies for the treatment of hematologic malignancies and solid tumors.

We are developing FT596, a universal, off-the-shelf CAR NK cell product candidate derived from a clonal master engineered iPSC line incorporating "CAR4", a novel CAR construct specifically designed to augment NK cell signaling. CAR4 was developed by our collaborator Dr. Kaufman, and contains the transmembrane domain of NKG2D, the 2B4 co-stimulatory domain, and the CD3 signaling domain and mediates strong antigen-specific NK cell signaling in vitro. In preclinical studies using an ovarian cancer xenograft model, Dr. Kaufman has shown that iPSC-derived CAR4 NK cells markedly inhibit tumor growth and significantly prolong survival as compared to iPSC-derived NK cells containing a CAR construct commonly used with CAR T-cell therapy.

FT596 is derived from a clonal master iPSC line engineered to include the expression of CD19-specific CAR4 to convey antigen specificity, a high-affinity, non-cleavable CD16 (hnCD16) Fc receptor to enhance ADCC, and a novel IL-15 receptor fusion for cytokine-independent persistence. Using a research iPSC line for production of FT596, we have shown in preclinical studies that FT596:

- shows cytokine-free expansion in vitro and extended persistence in vivo in various immunocompromised mouse strains;
- mediates CAR-directed specificity and cytotoxicity against multiple CD19-positive target cell lines in vitro;
- mediates rituximab-induced ADCC against CD20-positive, CD19-negative ARH-77 and Raji target cell lines in vitro;
- promotes enhanced and extended survival in vivo compared to control groups in a CD19-positive Nalm6 xenograft model of leukemia; and
- completely eradicates, in combination with rituximab, CD19+ and CD19- target cell lines in vitro in a mixed-culture cytotoxicity assay.

FT538. We are developing FT538, a universal, off-the-shelf NK cell product candidate derived from a clonal master engineered iPSC line, for use in combination with anti-CD38 monoclonal antibody therapy for the treatment of multiple myeloma (MM). CD38 is highly and uniformly expressed on MM cells. Daratumumab, which is the only FDA-approved monoclonal antibody that has demonstrated single agent efficacy in relapsed/refractory MM, effectively targets CD38 and induces MM cell death through multiple mechanisms, including ADCC. However, because CD38 is also expressed on the surface of activated NK cells, daratumumab treatment can induce NK cell fratricide, which likely impairs the effectiveness of ADCC-mediated targeting and elimination of MM cells. In addition, NK cell function is often suppressed or absent in patients with MM as a result of the cancer itself and/or from cancer therapy, further reducing the effectiveness of daratumumab. Collectively, preclinical and clinical observations suggest a potential therapeutic benefit of maintaining NK cell numbers and function in patients to support daratumumab-mediated ADCC and augment the treatment of MM.

FT538 is derived from a clonal master iPSC line engineered to include the expression of a hnCD16 Fc receptor to enhance ADCC and a novel IL-15 receptor fusion for cytokine-independent persistence, and to completely eliminate CD38 expression to mitigate NK cell fratricide. We have generated NK cells from master engineered iPSC lines, and have shown in preclinical studies that:

- CD38 deficiency protected NK cells from fratricide mediated by daratumumab in vitro;

- hnCD16 iPSC-derived NK cells mediate robust anti-myeloma activity with daratumumab in vitro, which is further augmented by elimination of CD38 expression;
- hnCD16, CD38-null iPSC-derived NK cells demonstrate more durable ADCC with increased serial killing potential in combination with daratumumab in vitro; and
- there is no significant difference in NK cell differentiation, expansion, activation or ability to mediate natural cytotoxicity between hnCD16, CD38-null iPSC-derived NK cells and hnCD16 iPSC-derived NK cells.

FT819. We are developing CAR T-cell product candidates created from clonal master engineered iPSC lines as off-the-shelf cancer immunotherapies for the treatment of liquid and solid tumors. In September 2016, we announced a multi-year partnership with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf engineered T-cell product candidates using clonal master iPSC lines. Research and development activities under the collaboration are being led by Dr. Michel Sadelain, Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center.

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In connection with the formation of our partnership with Memorial Sloan Kettering Cancer Center, we exclusively licensed from Memorial Sloan Kettering foundational intellectual property covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs, for human therapeutic use. We also secured an exclusive option to exclusively license intellectual property arising from all research and development activities under the partnership. In May 2018, we licensed from Memorial Sloan Kettering Cancer Center additional intellectual property covering compositions of novel CAR constructs, including the 1XX CAR construct, and of genetically-engineered CAR T cells, including methods of making these cells using CRISPR for certain targeted gene modifications. Embodiments of this additional intellectual property include preclinical data published by Dr. Sadelain in March 2017 demonstrating that directing a CD19-specific CAR to the T-cell receptor constant (TRAC) locus results in uniform CAR expression in human peripheral blood T cells, enhances T-cell potency, and delays effector T-cell differentiation and exhaustion, and in November 2018 demonstrating that CAR T cells utilizing a novel 1XX CAR signaling domain exhibited enhanced antitumor efficacy, persistence and long-term cytotoxicity as well as a decrease in T-cell exhaustion.

We are developing FT819, a first-of-kind CD19-specific CAR T-cell product candidate derived from a clonal master engineered iPSC line. The engineered features of the clonal master iPSC line include the targeted integration of a CD19-specific 1XX CAR into the TRAC locus to convey antigen specificity, promote TRAC-regulated CAR expression and completely eliminate TCR expression to mitigate GvHD. We have generated CD8 + T cells from master engineered iPSC lines, and have shown in preclinical studies that CD8 + TCR-null, CD19-specific CAR T cells derived from master engineered iPSC lines:

- consist of bi-allelic disruption of TCR expression at the genetic level and demonstrate regulated expression of 1XX CAR under the control of the endogenous TRAC promoter;
- display antigen-specific anti-tumor potency in vitro, including cytokine release and targeted cellular cytotoxicity, comparable to peripheral blood CD19-specific CAR T cells;
- do not respond or proliferate against HLA-mismatched (CD19-) peripheral blood mononuclear cells as targets in a mixed lymphocyte reaction, indicating the risk of GvHD is alleviated; and
- effectively control tumor progression in vivo comparable to peripheral blood CD19-specific CAR T cells in a preclinical mouse model of acute lymphoblastic leukemia.

Other Immuno-Oncology Product Candidates. We are applying our iPSC product platform to research and develop additional off-the-shelf, iPSC-derived cell product candidates. In November 2018, we entered into an exclusive option agreement with the Max Delbrück Center for Molecular Medicine (MDC) to obtain rights to intellectual property covering novel humanized CAR constructs that uniquely and specifically bind B-cell Maturation Antigen (BCMA). Under the agreement with MDC, we have the right to exclusively license the portfolio for all cell products, including CAR NK- and T-cell products, derived from iPSCs. In data published by MDC scientists, anti-BCMA CAR T cells equipped with its unique humanized extracellular antigen-binding domains show higher affinity and greater specificity than other anti-BCMA antigen-binding domains. These differentiated properties conveyed both greater selectivity in recognizing target B cells and more robust killing of target B cells in vitro, including malignant B cells with low expression levels of BCMA. Additionally, in in vivo proof-of-concept studies, MDC scientists demonstrated that anti-BCMA CAR T cells mediated anti-tumor activity in xenotransplant mouse models of multiple myeloma and of mature B-cell non-Hodgkin lymphoma, where BCMA surface expression is up to 4-fold lower as compared to mouse models of multiple myeloma.

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

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mPB HCT develop acute GvHD and 70-80% of patients undergoing mPB HCT experience at least one severe infection within the first 180 days following HCT. Additionally, approximately 50% of patients undergoing HCT experience cancer relapse or die within the first two years following HCT. We believe our cell programming approach has the potential to reduce the three leading causes of morbidity and mortality associated with allogeneic HCT – namely, graft-versus-host disease, severe infections and disease relapse – and to improve outcomes in patients undergoing allogeneic HCT.

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

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

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

- ProTmune was well-tolerated. There were no events of graft failure and no serious adverse events related to ProTmune reported by investigators.
- There were no reported events of cancer relapse.
- At Day 100, all seven subjects receiving ProTmune were alive and relapse-free; and three subjects experienced acute GvHD during the first 100 days following HCT, all of whom responded to standard-of-care steroid treatment. The median time to resolution of the maximum GvHD grade was 7 days [range: 5-8 days].
- At Day 365, five of seven subjects receiving ProTmune were alive and relapse-free, with non-relapse mortality occurring in two subjects (Subject 1 on Day 228; Subject 3 on Day 151); and three of seven subjects were alive, relapse-free and without moderate-to-severe chronic GvHD.

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

PROTECT Phase 1 Clinical Data (as of November 26, 2018 data cut-off)							
Subject	1	2	3	4	5	6	7

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

[1] As measured from the day following HCT

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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, overall survival and overall survival with freedom from cancer relapse and from moderate-to-severe chronic GvHD, are also being assessed. Fifteen U.S. centers are currently open for enrollment in the Phase 2 stage of PROTECT. In December 2018, we reported that over 30 subjects had been treated in the randomized, controlled and double-blinded Phase 2 PROTECT study.

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.

FT301

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

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

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

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

graft-versus-host disease, multiple sclerosis, ulcerative colitis and others.

Our Cell Programming Partnerships

Ono Pharmaceutical

In September 2018, we entered into a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates. The first off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 1) targets an antigen expressed on certain lymphoblastic leukemias, and the second off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 2) targets a novel antigen identified by Ono expressed on certain solid tumors (each a Candidate and, collectively, the Candidates). Pursuant to the agreement, we are jointly conducting research and development activities under a joint development plan with Ono, with the goal of advancing each Candidate to a pre-defined preclinical milestone.

We have granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize (a) Candidate 1 in Asia, where we retain rights for development and commercialization in all other territories of the world and (b) Candidate 2 in all territories of the world, where we retain rights to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share

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at least 50% of the profits and losses. For each Candidate, the option will expire upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for the Candidate and (c) the date that is the later of (i) four years after the Effective Date and (ii) completion of all applicable activities contemplated under the joint development plan. We maintain worldwide rights of manufacture for both Candidates.

Under the terms of the agreement, Ono paid us an upfront, non-refundable and non-creditable payment of $10.0 million in connection with entering into the agreement. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be $20.0 million in aggregate over the course of the joint development plan. Further, Ono has agreed to pay us up to an additional $40.0 million, subject to the achievement of a preclinical milestone and the exercise by Ono of its options to develop and commercialize Candidate 1 and Candidate 2. Such fees are in addition to the upfront payment and research and development fees.

Subject to Ono's exercise of the options and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, we are entitled to receive an aggregate of up to $285.0 million in milestone payments for Candidate 1 and an aggregate of up to $895.0 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize Candidate 2 as described above. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono of each Candidate in specified territories, with such royalties subject to certain reductions.

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

Juno Therapeutics

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 is responsible for the development and commercialization of genetically engineered CAR T-cell and TCR immunotherapies incorporating our modulators.

Under the agreement, subject to the selection by Juno of designated tumor-associated antigen targets which selection may be made by Juno on a target-by-target basis, we agreed to grant 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 such designated tumor-associated antigen targets. We have retained exclusive rights to such intellectual property, including our intellectual property arising under the collaboration, for all other purposes.

Pursuant to the terms of the agreement, Juno paid us an upfront, non-refundable and non-creditable 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

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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.

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 March 2018, Juno was acquired by Celgene Corporation (Celgene). This acquisition did not affect the terms of the Juno Agreement. On January 3, 2019, Celgene announced that it had entered into a definitive merger agreement with Bristol-Myers Squibb Company (BMS), under which BMS will acquire Celgene.

Additional iPSC Platform Technologies

In September 2018, we entered into an exclusive license agreement with the J. David Gladstone Institutes (Gladstone) under which we obtained an exclusive license to certain patents and patent applications for the research, development, manufacturing, and commercialization of human therapeutics derived from iPSCs (the Gladstone License Agreement). The licensed patent rights cover the generation of iPSCs using CRISPR-mediated gene activation. This new approach for inducing pluripotency uses CRISPR to directly target a specific location of the genome and activate endogenous gene expression, and does not rely on established methods of cellular reprogramming that require the transduction of multiple transcription factors. The discovery was made by a team of scientists led by Sheng Ding, Ph.D., a senior investigator at Gladstone and one of our scientific founders.

In consideration for the rights granted under the Gladstone License Agreement, we issued to Gladstone 100,000 shares of our common stock pursuant to an exemption from registration under the Securities Act of 1933, as amended (the Securities Act), in reliance on Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering.

Additionally, we paid Gladstone an upfront fee of $0.1 million and are obligated to pay Gladstone milestone payments in an aggregate amount of up to approximately $1.9 million upon the achievement of specified clinical and regulatory milestones and tiered royalties in the low single digits on net sales of licensed products developed using the licensed intellectual property rights. We are also obligated to pay Gladstone a tiered percentage in the low to mid-single digits of certain income received by us in connection with the sublicense of the licensed patent rights.

Our Intellectual Property

Overview

We seek to protect our product candidates and our cell programming technology through a variety of methods, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the United States, we typically file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Europe, Japan, Canada, Australia and China. We continually assess and refine our intellectual property strategy in order to best fortify our position, and file additional patent applications when our intellectual property strategy warrants such filings. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We have entered into exclusive license agreements with various academic and research institutions to obtain the rights to use certain patents for the development and commercialization of our product candidates.

As of March 1, 2019, our intellectual property portfolio is composed of over 200 issued patents and 150 patent applications that we license from academic and research institutions, and over 100 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

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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 1, 2019, we own 12 families of U.S. and foreign patents and pending patent applications covering our cell programming technology and compositions of programmed cellular immunotherapies. This portfolio includes 70 issued patents or pending patent applications relating to methods of programming the biological properties and therapeutic function of cells ex vivo, and the resulting therapeutic compositions of hematopoietic and immune cells. Patents and patent applications in this portfolio include claims covering (i) therapeutic compositions of hematopoietic and immune cells, including T cells, NK cells, and $CD34^+$ cells, that have been programmed ex vivo with one or more agents to optimize their therapeutic function for application in oncology and immune disorders and (ii) methods of programming cells including by the activation or inhibition of therapeutically-relevant genes and cell-surface proteins, such as those involved in the homing, proliferation and survival of hematopoietic cells or those involved in the persistence, proliferation and reactivity of immune cells. Any U.S. patents within this portfolio that have issued or may yet issue from pending patent applications will have statutory expiration dates between 2030 and 2039.

Additionally, we have an exclusive license to an intellectual property portfolio consisting of two families of issued patents and pending patent applications co-owned by the Children's Medical Center Corporation and The General Hospital Corporation. As of March 1, 2019, 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 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 20 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 CARs 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 1, 2019, 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

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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 iPSCs from somatic cells and, as of March 1, 2019, 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.

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

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

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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 CARs for expression on NK cells. Under our agreement with the University of Minnesota, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell licensed products in all fields for commercial purposes. The licensed patent rights are described in more detail above under “Intellectual Property Relating to the Programming of Hematopoietic Cells.” The University of Minnesota retains the right to practice the patent rights for research, teaching and educational purposes, including in corporate-sponsored research subject to certain limitations during the initial three years of the license agreement. The University of Minnesota also retains the right to license other academic and non-profit research institutes to practice the patent rights for research, teaching and educational purposes, but not for corporate-sponsored research. Our license is also subject to pre-existing rights of the U.S. government.

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

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

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

Memorial Sloan Kettering Cancer Center

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

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

Under the terms of the amended and restated agreement, we are required to pay Memorial Sloan Kettering Cancer Center an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $12.5 million for development, regulatory and commercial milestones achieved with respect to each licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates up to the high-single digits on net sales of licensed

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products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, Memorial Sloan Kettering Cancer Center is also entitled to receive a percentage of the sublicensing income received by us. Additionally, in the event a licensed product achieves a specified clinical milestone, Memorial Sloan Kettering Cancer Center is then eligible to receive additional milestone payments, where the amount of such payments owed to Memorial Sloan Kettering Cancer Center are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone.

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

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

Whitehead Institute for Biomedical Research

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

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

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

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

The Scripps Research Institute

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

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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

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.

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 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 is 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.

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

The manufacture of our off-the-shelf cellular immunotherapy product candidates created from iPSCs involves a three-stage process:

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

We are manufacturing our iPSC-derived cell product candidates for use in research and preclinical development, and manufacturing certain elements used to produce clinical supplies of our product candidates. Currently, we contract with third parties, including medical center cell therapy facilities and contract manufacturing organizations (CMOs), for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates for use in clinical investigation. We expect that we will continue to contract with third parties, including medical center cell therapy facilities and CMOs, for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates. Additionally, we have initiated build out of our own GMP manufacturing facility, and plan to continue investing in our manufacturing capabilities and technology. In the future we may manufacture our iPSC-derived cell product candidates for clinical or commercial supply at facilities we own or operate.

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. Additionally, we obtain key components required for the manufacture of our iPSC-derived cell product candidates from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain certain key components used in the manufacture of our iPSC-derived cell product candidates.

Marketing & Sales

We currently intend to commercialize any products that we may successfully develop. We currently have no experience in marketing or selling therapeutic products. To market any of our products independently would require us to develop a sales force with technical expertise along with establishing commercial infrastructure and capabilities. Our commercial strategy for marketing our product candidates also may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial infrastructure. We plan to further evaluate these alternatives as we approach approval for the first of our product candidates.

Government Regulation

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (the FDCA) and the Public Health Service Act (the PHS Act) and related regulations, and drugs under the FDCA and related regulations. Biological products and drugs are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products and drugs. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval or licensing, advertising and promotion, and import and export of our products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process or after approval may subject an applicant to administrative or judicial sanctions. FDA sanctions include refusal to approve pending applications, suspension or revocation of an approval or license, 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.

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Marketing Approval

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

- completion of nonclinical laboratory and animal tests according to good laboratory practices (GLPs) and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product or drug for its intended use or uses;
- for a biological product, submission to the FDA of a Biologics License Application (BLA) for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials, and, for a drug, submission of a New Drug Application (NDA) that includes substantive evidence of the product's safety and efficacy;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate, and, if applicable, the FDA's current good tissue practices (cGTPs) for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;
- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval, or licensure, of the BLA and review and approval of the NDA which must occur before a biological product and a drug can be marketed or sold.

U.S. Biological Products and Drug Development Process

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

Prior to commencing the first clinical trial, the trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND application. Some nonclinical testing may continue even after the IND application is submitted. The IND application automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the trial on a clinical hold. In such case, the sponsor of the IND application must resolve any outstanding concerns with the FDA before the clinical trial may begin. The FDA also may impose a clinical hold on ongoing clinical trials due to safety concerns or non-compliance. If a clinical hold is imposed, a trial may not recommence without FDA authorization and then only under terms authorized by the FDA. Further, an independent institutional review board (IRB) for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA and to the IRB. Information about certain clinical studies must be submitted with specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

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

- Phase 1—The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.

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- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and physician labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended indication, particularly for long-term safety follow-up. The FDA has statutory authority to require post-market clinical trials to address safety issues. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Within 15 calendar days after the sponsor determines that the information qualifies for reporting, written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the investigated product has been associated with unexpected serious harm to patients, and the trial may not recommence without the IRB's authorization.

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

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

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (the Cures Act), as amended, the manufacturer of an investigational drug for a serious

disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug, or as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy.

U.S. Review and Approval Processes

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

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA and NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective beginning on October 1, 2018 the user fee for an application requiring clinical data, such as a BLA and an NDA, will be $2,588,478 for fiscal year 2019. PDUFA

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also imposes an annual prescription drug product program fee for biologics and drugs ($309,915 for fiscal year 2019). 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.

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

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

the BLA or NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the applicant in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA or NDA to address all of the deficiencies identified in the letter, or withdraw the application, or request a hearing.

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

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require Phase 4 post-marketing clinical trials and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or complete withdrawal of the product from the market.

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Expedited Development and Review Programs

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

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product or drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product or drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

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

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

Accelerated Approval for Regenerative Advanced Therapies

As part of the Cures Act, Congress amended the FDCA to create an accelerated approval program for regenerative advanced therapies, which include cell therapies, therapeutic tissue engineering products, human cell and tissue

products, and combination products using any such therapies or products. Regenerative advanced therapies do not include those human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the PHS Act and 21 CFR Part 1271. The new program is intended to facilitate efficient development and expedite review of regenerative advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A drug sponsor may request that FDA designate a drug as a regenerative advanced therapy concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA or NDA for a regenerative advanced therapy may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative advanced therapy that is granted accelerated approval and is subject to post approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post approval monitoring of all patients treated with such therapy prior to its approval.

U.S. Patent Term Restoration and Marketing Exclusivity

Under certain circumstances, U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for

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a patent that covers a new product or its use. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The period of patent term restoration is generally one-half the time between the effective date of an IND application (falling after issuance of the patent) and the submission date of a BLA or NDA, plus the time between the submission date of the BLA or NDA and the approval of that application, provided the sponsor acted with diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in consultation with the FDA. A patent term extension is only available when the FDA approves a biological product or drug for the first time.

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

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

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

A biological product or drug can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Orphan Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to biological products and drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation

that the cost of developing and making a biological product or drug in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA or NDA. After the FDA grants orphan designation, the identity of the applicant, the name of the therapeutic agent and its designated orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a biological product or drug that receives orphan designation is the first such product approved by FDA for the orphan indication, it receives orphan product exclusivity, which for seven years prohibits the FDA from approving another application to market the same product for the same indication. Orphan product exclusivity will not bar approval of another product under certain circumstances, including if the new product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or a demonstration that the new product otherwise makes a major contribution to patient care. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different. If a biological product or drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act (PREA), as amended, a BLA or NDA or supplement must contain data to assess the safety and effectiveness of the biological product or drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The intent of PREA is

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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.

Competition

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

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 and our off-the-shelf NK- and T-cell product candidates, including FT500 and FT516, as 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, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., bluebird bio, Inc., Celgene Corporation (pending acquisition by Bristol-Myers Squibb Company), Cellectis SA, Celyad SA, CRISPR Therapeutics AG, Gilead Sciences, Inc., Green Cross Corporation, Intrexon Corporation, Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), NantKwest, Inc., Novartis AG, 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.

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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, 2018, we employed 104 employees, all of whom are full-time employees, including 57 in research and development, 33 in clinical development and regulatory affairs and 14 in general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good.

Corporate Information

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Our principal executive office is located at 3535 General Atomics Court, Suite 200, San Diego, CA 92121, and our telephone number is (858) 875-1800. Our website address is www.fatetherapeutics.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website a part of this Annual Report on Form 10-K.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks, including 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. As of December 31, 2018, we no longer qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). As such, we are no longer eligible to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies.

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 any of our product candidates, including ProTmune, FATE-NK100, or FT500. Furthermore, we have not initiated or conducted any clinical trials necessary to support an application for approval to market FT516 or any other product candidates that we may identify. We, or any investigators who initiate or conduct clinical trials of our product candidates, may experience delays in our current or future clinical trials, and we do not know whether we or our investigators will be able to initiate, enroll patients in, or complete, clinical trials of our product candidates on time, if at all. Current and future clinical trials of our product candidates may be delayed, unsuccessful or terminated, or not initiated at all, as a result of many factors, including factors related to:

- difficulties in identifying eligible patients for participation in clinical trials of our product candidates, due in part to our focus on the development of certain of our product candidates for the treatment of rare diseases;
- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties relating to patients enrolling in studies of therapeutic product candidates sponsored by our competitors;
- difficulties determining suitable doses of our novel cell product candidates for evaluation in clinical trials;
- difficulties in obtaining agreement from regulatory authorities on study endpoints, achieving study endpoints, the amount and sufficiency of data, demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- difficulties in obtaining agreement from regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for an IND application to go into effect to initiate and conduct clinical trials for any of our product candidates, including FT819 and any other product candidates that we may identify;
- the occurrence of unexpected safety issues or adverse events in any 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, and in sufficient quantities, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct of and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators and IRBs;
- failure or delays in obtaining sufficient quantities of suitable raw materials and equipment necessary for the manufacture of any product candidate;
-

the costs of conducting clinical trials or manufacturing of our product candidates being greater than we anticipate or the timelines for these activities being longer than we anticipate;

- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;
- the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;
- failure of patients to complete clinical trials due to safety issues, side effects, or other reasons; and
- approval of competitive agents that may materially alter the standard of care or otherwise render our product candidates or clinical trial designs obsolete.

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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 who meet certain 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. In addition, we will be competing with other clinical trials for product candidates being developed by our competitors in the same therapeutic areas, and potential patients who might be eligible for enrollment in one of our clinical trials may instead choose to enroll in a trial being conducted by one of our competitors.

Our ability, and the ability of investigators, to enroll patients in clinical trials that we are conducting or supporting, including in our current Phase 1/2 PROTECT clinical trial of ProTmune, our clinical trial of FT500, 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 certain of our clinical trials;
- eligibility criteria for the trials in question;
- perceived risks and benefits of the product candidate under study, including any perceived risks associated with iPSC-derived product candidates such as FT500, which we believe is the first ever iPSC-derived cell therapy cleared by the FDA for clinical investigation in the United States;
- the availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates, including ProTmune and FATE-NK100;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

Development of our product candidates will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates.

We are currently advancing ProTmune, FATE-NK100, and FT500 through clinical development, and conducting preclinical research and development activities in our other programs. Drug development is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

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As of December 31, 2018, our cash and cash equivalents and short-term investments were $201.0 million. We intend to use our cash and cash equivalents to fund the advancement of ProTmune, FATE-NK100, our iPSC-derived cell product candidates, including FT500 and FT516, and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, ProTmune, FATE-NK100, FT500 and FT516, and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our current Phase 1/2 PROTECT clinical trial of ProTmune, the Phase 1 clinical trials of FT500 and 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, including for FT516 and our other iPSC-derived cell product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;
- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates, including ProTmune, FATE-NK100, FT500, and FT516, 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, FATE-NK100, FT500 and FT516, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing 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 Ono Pharmaceutical Ltd., Juno Therapeutics, Inc., the University of Minnesota, and Memorial Sloan Kettering, to advance the research, development and commercialization of therapeutic products.

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

indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

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

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Our clinical development of ProTmune, FATE-NK100, and FT500, and the initiation of clinical development of FT516 and 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, FATE-NK100, or FT500, or initiating and conducting any future clinical trials of ProTmune, FATE-NK100, or FT500, or our other product candidates, including FT516 and our other 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, FT500, or the initiation of clinical trials for FT516 or any of our other iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates and potential future product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or facilities, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development or manufacturing costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with ProTmune, FATE-NK100, our iPSC-derived cell product candidates, including FT500 and FT516, 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 our clinical development activities for any of our product candidates are delayed or suspended, or we fail to obtain or maintain regulatory approvals with an acceptable scope, our business, prospects, financial condition and results of operations will be harmed.

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, FT500 and FT516, and our other 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, purity and potency, or efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

We may delay or cancel our ongoing research and development activities and our current or planned clinical development for any of our product candidates, including ProTmune, FATE-NK100, FT500, FT516, and our other 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;
- 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;
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;
- the proprietary rights of third parties, which may preclude us from developing, manufacturing or commercializing a product candidate;

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- 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 or maintain relationships with strategic partners that may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization in any particular indication(s) or geographic territory(ies); or
- our prioritization of other product candidates for advancement, including a decision to cease research and development of any existing product candidate due to our determination that another of our existing or future product candidates has greater potential for clinical development, regulatory approval, or commercialization, including potentially greater therapeutic benefit, a more favorable safety or efficacy profile, a more consistent or more cost effective manufacturing process, or more favorable marketing exclusivity, including greater market acceptance or commercial potential, or more advantageous intellectual property position.

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

Our product candidates are cellular therapeutics, and the manufacture of our cell product candidates, particularly our iPSC-derived cell product candidates including FT500 and FT516, 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 FT500 and FT516 and our other iPSC-derived product candidates, reprogramming human fibroblasts to obtain iPSCs, in some cases genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics, 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.

We may make changes as we continue to develop and refine 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.

In addition, the manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval requirements, and we will need to meet, and our CMOs or other third party manufacturers will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. The requirements to manufacture ProTmune in

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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 product candidates, including ProTmune, FATE-NK100, FT500, and FT516 are currently manufactured by third-party cell processing facilities, including 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 any of these product candidates in compliance with applicable regulatory requirements. Any requirements to 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, including FT500 and FT516, 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 initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party contract manufacturers, or our or their failure to supply sufficient quantities of our product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

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

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

As we leverage third parties for the manufacture of our product candidates, we also intend to manufacture our product candidates ourselves, including some or all of the clinical supply of FT500 and FT516 for our ongoing and planned clinical trials. To do so, we will need to scale up our own manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture our own product candidates for the conduct of our clinical trials or commercialization. Accordingly, we will be required to make significant investments to establish GMP manufacturing capabilities and facilities, and our efforts to scale our own manufacturing operations may not succeed. For example, we may encounter problems with shortages of qualified personnel, raw materials or key contractors. Further, delays in commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities could delay our development plans, including the conduct of our clinical trials, and thereby limit our opportunities for growth.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with 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 ongoing and planned clinical trials or eventual commercialization. Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA, European Medicines Agency, or other applicable standards or specifications with consistent and acceptable production yields and costs. Any such events could delay or prevent our ability to obtain regulatory approval for or commercialize ProTmune, FATE-NK100, FT500, FT516 or our other product candidates, which would adversely affect our business, financial condition and results of operations.

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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,FATE-NK100, or FT500 in our ongoing clinical trials, including investigator-sponsored trials of our product candidates, as well as patients who may undergo treatment with FT516 and other product candidates that we may develop, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing ProTmune, FATE-NK100, FT500, 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, FT500, FT516, or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

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

Our cell programming technology and platform for generating cell therapy products using iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges we may incur during development of our product candidates, and we face uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the early clinical or preclinical stage, we are currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidates in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of our product candidates, particularly FT500 and FT516, and any other iPSC-derived cell product candidates we develop, as required by the FDA and other regulatory authorities for ongoing clinical development and 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.

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

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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 an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

Preliminary data and interim results we disclose, and results from earlier studies, may not be predictive of the final results, or of later studies or future clinical trials.

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Although we may from time to time disclose results from preclinical testing or preliminary data or interim results from our clinical studies of our product candidates, such 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 26, 2018 data cut-off date may not continue for these subjects or be repeated or observed in ongoing or future studies involving ProTmune, including in the Phase 2 stage of the PROTECT study. It is possible that subjects for whom events of acute GvHD have been reduced or eliminated may experience acute GvHD in the future, as there is limited data concerning long-term safety and efficacy following treatment with ProTmune. Accordingly, ProTmune may not demonstrate in the Phase 2 stage of PROTECT, or in subsequent trials, an adequate safety or efficacy profile to support further development or commercialization.

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

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture of our product candidates, including ProTmune, FATE-NK100, FT500 and FT516, 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.

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.

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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, even if we are the first to obtain marketing approval of our product candidates for the applicable indications, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product. In addition, we may be unable to obtain orphan drug designations for any other product candidates that we are currently developing or may pursue.

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

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws and health information privacy and security laws. Any failure to comply with these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. It is possible that some of our business activities could be subject to challenge under one or more of these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Reliance on Third Parties

We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. We are, and expect to continue to be, dependent on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved. Our business could be harmed if those third parties fail to perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties, including cell processing facilities associated with clinical trial sites, to manufacture our product candidates 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.

The facilities used to manufacture our product candidates must be evaluated by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it later finds deficiencies or withdraws any such approval in the future, we may 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.

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Reliance on third parties for manufacture of our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations, the possibility that the 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.

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.

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.

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

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

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

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

In addition, the termination of the Ono Agreement or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payments, sharing of profits, and other benefits under such agreement. Any of these events could have a material adverse effect on our ability to develop and

commercialize our product candidates, including the two iPSC-derived CAR T cell product candidates being developed under the Ono Agreement, and may adversely impact our results of operations and financial condition.

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) (acquired by Celgene Corporation) for the identification and application of small molecule modulators for programming the therapeutic properties of genetically engineered CAR and 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

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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 CARs 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 CARs 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 March 2018, Juno was acquired by Celgene Corporation (Celgene). This acquisition did not affect the terms of our agreement with Juno Agreement. On January 3, 2019, Celgene announced that it had entered into a definitive merger agreement with Bristol-Myers Squibb Company (BMS), under which BMS will acquire Celgene. The acquisition of Juno by Celgene, and the acquisition of Celgene by BMS, 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.

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

Manufacturing our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our clinical cell processing facilities have purchased equipment, materials and disposables, such as automated cell washing devices, automated cell warming units, commercially available media and cell transfer and wash sets, used for the manufacture of our product candidates, including ProTmune, FATE-NK100, FT500, and FT516 from third-party suppliers. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We rely on the general commercial availability of materials required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components, including our pharmacologic modulators

and components for our cell processing media. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates, including ProTmune, FATE-NK100, FT500, and FT516. 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.

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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 mobilized peripheral blood, or 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 mPB adhere to and meet the standards set forth by the Foundation for Accreditation for Cell Therapy (FACT), the NMDP, and the American Association of Blood Banks (AABB), as applicable. In our current Phase 1/2 PROTECT clinical trial of ProTmune, ProTmune is manufactured using unlicensed mPB units. It may be possible that in the future, regulatory policy could change, and the FDA may later require that mPB units be licensed, and that ProTmune be manufactured using only licensed mPB units. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

Further, manufacture of 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.

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.

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

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

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

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

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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.

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

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

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We cannot guarantee that the manufacture, use or marketing of ProTmune, FATE-NK100, our iPSC-derived cell product candidates, including FT500 and FT516, or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of the manufacture of any of our product candidates, any compositions formed during the manufacture, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all.

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

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

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

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. If we fail in defending any such claims, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. We may also be subject to monetary damages, and any of these outcomes could have a material adverse impact on our business.

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

In addition to the protection afforded by patents, we also rely upon unpatented trade secrets and improvements, proprietary know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our collaborators and consultants. Trade secrets, however, may be difficult to protect, and if our employees, collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors, which would adversely affect our business position.

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

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situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

- the safety and efficacy of the products, and advantages over alternative treatments;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of our marketing strategy; and
- sufficient third-party insurance coverage or governmental reimbursement.

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

We expect to face uncertainty regarding the pricing of our product candidates, including ProTmune, FATE-NK100, FT500, and FT516, 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.

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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.

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.

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

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things:

- established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

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- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted, or injected;
- introduced a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

Since January 2017, the Trump administration has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, or executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year or pay a penalty, which is commonly known as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year or pay a penalty, which is commonly known as the "individual mandate" has been eliminated effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the Affordable Care Act are invalid as well. The Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal.

On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on

certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.”

In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

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Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals aimed at improving the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics. Under the plan, the FDA is directed to issue guidance to address certain practices that aim to delay or block generic competition, while also issuing new policies to bring more biosimilars to market as alternatives to brand-name biologics. More recently, the Trump administration announced a complex proposal to reduce Medicare spending by substantially reducing the price of physician-administered drugs, including biologics such as cellular therapeutics, under Medicare Part B. Under this proposal, pharmacy-benefit managers would have an increased role in managing drugs and pricing in the Part B program, and the price paid by Medicare for drugs under Part B would be linked to the prices paid for such drugs in other industrialized countries as reflected in an International Pricing Index, and in most cases these prices are lower than in the U.S. However, if the International Pricing Index model were adopted as proposed, it would not take effect until 2020 at the earliest and would phase in over five years, and it is therefore difficult to predict the impact it will have on our business. The proposal also includes a new payment model for reimbursing physicians for administering drugs under Part B, and the consequences of this payment model on the prescribing practices of physicians are uncertain. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

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

prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, including implementation of or new guidance regarding the frameworks for compounding under Sections 503A and 503B of the FDCA, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for ProTmune, FATE NK-100 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;

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- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of ProTmune, FATE NK-100 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Risks Related to Our Business and Industry

The success of our product candidates, including ProTmune, FATE-NK100, FT500, and FT516, 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, FATE-NK100, FT500, and FT516, are designed and are being developed as therapeutic entities for use as cellular immunotherapies. Any adverse developments in the field of cellular immunotherapy generally, and in the practice of HSCT in particular, will negatively affect our ability to develop and commercialize our product candidates. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the need for patients to undergo HSCT procedures is obviated due to the development and commercialization of therapeutics targeting the underlying cause of diseases addressed by HSCT, our business prospects will be significantly harmed.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from biotechnology and pharmaceutical companies, universities, and other research institutions, and many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations and facilities. In particular, there are several companies and institutions developing products that may obviate the need for HSCT, may be competitive to product candidates in our research and development pipeline, or may render our product candidates obsolete or noncompetitive. Should one or more of these products be successful, the market for our products may be reduced or eliminated, and we may not achieve commercial success.

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

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles and accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

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

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

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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.

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.

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

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, various federal and state fraud and abuse laws, including, without limitation, physician sunshine laws and regulations, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits improper payments or offers of payments, either directly or indirectly, to foreign governments and their officials and political parties by U.S. persons in order to influence official action, or otherwise obtain or retain business. Additionally, the U.S. federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” created under the Affordable Care Act, and their implementing

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regulations, require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully defrauding any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services. HIPAA also imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. Because of the breadth of these laws and the limited statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws.

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

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

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

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, 2018, we had an accumulated deficit of $285.4 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates, including for ProTmune, FATE-NK100, FT500 and FT516, 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.

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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;
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