FATE THERAPEUTICS INC
Form 10-K
March 03, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

o 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<br>(State or other jurisdiction of<br>incorporation or organization) | 65 1311552<br>(I.R.S. Employer<br>Identification No.) |
| 3535 General Atomics Court, Suite 200, San Diego, CA<br>(Address of principal executive offices) | 92121<br>(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 o or No x

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 o or No x

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 x or No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

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

| | |
|---|---|
| Large accelerated filer o | Accelerated filer x |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |

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

The aggregate market value of the common stock held by non affiliates of the registrant was approximately $166,230,000 as of June 30, 2015 based upon the closing sale price on the NASDAQ Global Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 2, 2016 was 28,861,711.

INCORPORATION BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the registrant's 2016 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this annual report on Form 10 K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2015.

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FATE THERAPEUTICS, INC.

Annual Report on Form 10 K

For the Fiscal Year Ended December 31, 2015

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## FORWARD–LOOKING STATEMENTS

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

- the initiation, timing, progress and results of our preclinical studies and planned clinical trials, and our research and development programs;
- our ability to advance our product candidates into, and successfully complete, clinical studies;
- the timing and likelihood of, and our ability to obtain and maintain regulatory approval of our product candidates;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain strategic arrangements;
- our ability to enroll patients in our planned clinical trials at the pace we project;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third party suppliers and manufacturers;
- our ability to develop sales and marketing capabilities, whether alone or with actual or potential collaborators, to commercialize our product candidates, if approved;
- our ability to successfully manufacture and commercialize our product candidates;
- the pricing and reimbursement, and the degree of market acceptance, of 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;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to retain and recruit key personnel;
- our ability to obtain funding for our operations;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the accuracy of our estimates regarding our expenses, ongoing losses, capital requirements and revenues;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those described under Part I, Item 1-A. 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

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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 our product candidates based on a simple notion: we believe that better cell therapies start with better cells. Our therapeutic approach, which we refer to as cell programming, utilizes pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of cells ex vivo, or outside the body. These programmed cells are then adoptively transferred to patients as therapies. We believe that this highly-differentiated therapeutic paradigm – systematically and precisely programming the biological properties and therapeutic function of cells ex vivo prior to adoptive transfer – is an elegant, cost-effective and scalable approach for maximizing the safety and efficacy of cell therapies. Utilizing our cell programming approach, we program immune cells, such as CD34+ cells, Natural Killer (NK) cells and T cells.

We are advancing a pipeline of programmed cellular immunotherapies, including both donor-sourced and off-the-shelf, pluripotent cell-derived immune cell therapies, in the fields of immuno-oncology and immuno-regulation. Our clinical program is ProTmune™, a programmed immuno-regulatory cell therapy consisting of donor-sourced mobilized peripheral blood cells which have been modulated using two small molecules, for the prevention of acute graft-versus-host disease (GvHD) and cytomegalovirus (CMV) infection in immunocompromised patients undergoing allogeneic hematopoietic cell transplantation (HCT). Our preclinical programs include NK- and T-cell cancer immunotherapies, including off-the-shelf therapies derived from engineered induced pluripotent cells (denoted as an iNK Cell Therapy and an iT Cell Therapy, respectively), and a CD34+ cell immuno-regulatory therapy to suppress aberrant auto-reactive effector cells for autoimmune diseases.

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

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA.

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Our Product Pipeline & Partnerships

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

| Programmed Cellular Immunotherapy Programs | Development Stage | Therapeutic Area | Commercial Rights |
|---|---|---|---|
| Immuno-Regulatory Therapies | | | |
| ProTmune™ | Phase 1/2 | Prevention of acute GvHD and CMV infection post-HCT | Worldwide |
| Programmed CD34+ Cell Therapy | Preclinical | Autoimmune / Inflammatory Diseases | Worldwide |
| | | | |
| Immuno-Oncology Therapies | | | |
| Adaptive NK Cell Therapy | Preclinical | Solid Tumors | Worldwide |
| Programmed iNK Cell Therapy | Preclinical | Hematologic / Solid Tumors | Worldwide |
| Programmed iT Cell Therapy | Preclinical | Hematologic / Solid Tumors | Worldwide |
| | | | |
| Cell Programming Partnerships | | | |
| CAR / TCR T Cell Therapies | Preclinical | Hematologic / Solid Tumors | Juno Therapeutics |

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, or 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 CD34+ cells, NK cells and T cells, as therapies for the treatment of human diseases is rapidly expanding. In fact, over 150 clinical trials using hematopoietic cells as therapeutic entities are currently being conducted. Many of these clinical trials are investigating transformative applications of hematopoietic cells, including for the treatment of hematologic malignancies and solid tumors, genetic disorders and immunological diseases. While advancements in the isolation, expansion and manufacture of hematopoietic cells have opened new avenues for their use as therapeutic entities, we believe hematopoietic cells can also be programmed to maximize therapeutic benefit.

Since our founding, we have been dedicated to programming the biological properties and therapeutic function of immune cells ex vivo, and we believe immune cells can be systematically and precisely modulated outside the body to impart profound therapeutic effects inside the body upon their administration to a patient. Using advanced molecular characterization tools and technologies, we identify small molecule or 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 T cells and NK cells. We apply our deep understanding of the hematopoietic system to rapidly assess and quantify the therapeutic benefit of programmed immune cells in vivo. Applying these capabilities in the settings of cancer and immune disorders, we aim to develop programmed cellular immunotherapies with disease transforming potential.

Additionally, we have worked closely with our scientific founders to pioneer the derivation and differentiation of induced pluripotent stem cells, or iPSCs, a potentially disruptive technology for engineering and programming the fate of cells ex vivo. iPSCs are pluripotent cells, which are generated through the expression of certain genes and factors, that have cellular and physiological traits similar to those of an embryonic stem cell. We believe our iPSC platform, which combines genetic engineering with rapid and efficient generation of immune cells, has the potential to create large quantities of homogeneous, engineered cell populations in the hematopoietic lineage, such as CD34+ cells, NK cells and T cells, which can otherwise be limited in quantity, difficult to manufacture,

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heterogeneous in composition and unoptimized for efficacy. Specifically, our iPSC platform is designed to enable the generation of highly-stable, genetically-modified, clonal pluripotent cell lines and to utilize these lines for the unlimited production of engineered CD34+ cells, NK cells and T cells without requiring patient-sourced cells. We believe our approach has the potential to overcome key limitations of patient-sourced cell therapies, such as the requirement to source, isolate, engineer and expand cells for each individual patient, and may prove to be the cornerstone of off-the-shelf cellular immunotherapy.

Our Business Strategy

We seek to develop and commercialize programmed cellular immunotherapies for cancer and immune disorders based on our cell programming approach. The key pillars of our strategy are to:

- Efficiently develop and commercialize programmed cellular immunotherapies for the prevention of life-threatening complications in immunocompromised patients undergoing allogeneic HCT.

Allogeneic HCT involves the adoptive transfer of donor-sourced hematopoietic cells to reconstitute the blood and immune system of an immunocompromised patient following receipt of chemotherapy and/or radiation therapy for the treatment of hematologic malignancies and other rare disorders. We believe donor-sourced hematopoietic cells administered to a patient can be programmed to maximize therapeutic benefit and more effectively enable the curative potential of allogeneic HCT. Using our cell programming approach, we modulate the biological properties and therapeutic function of donor-sourced hematopoietic cells ex vivo prior to adoptive transfer, and we are developing a programmed cellular immunotherapy for use as a hematopoietic cell graft for allogeneic HCT.

We believe the use of our programmed cellular immunotherapy as a hematopoietic cell graft for allogeneic HCT may significantly improve the procedure’s curative potential by preventing a multitude of life-threatening complications, including acute GvHD and severe infections, that currently contribute to high rates of patient morbidity and mortality. We are developing our immunotherapies to serve patients across a wide range of ages and a broad spectrum of hematologic malignancies. Due to the rare disease nature of our target indications and the high incidences of life-threatening complications, we believe clinical trials that we conduct will generally require relatively small numbers of subjects. Additionally, because HCT is a highly specialized procedure performed at a limited number of centers, we intend to build our own sales and marketing capabilities to commercialize any immunotherapies that we may successfully develop in a cost efficient manner.

- Leverage our deep understanding of hematopoietic cell biology and our clinical and regulatory expertise in cell therapy to advance a pipeline of donor-sourced and off-the-shelf programmed cellular immunotherapies for cancer and immune disorders.

In developing a programmed cellular immunotherapy for use as a hematopoietic cell graft for allogeneic HCT, we have gained a deep understanding of and novel insights into the biological properties and therapeutic function of the key cell types that comprise a hematopoietic cell graft including CD34+ cells, NK cells and T cells. We have also built research, clinical and regulatory affairs teams that are experienced and skilled in the development of hematopoietic cell therapies. Additionally, we have complemented our internal efforts by forming collaborations with renowned scientists, top clinical investigators and prominent medical centers to accelerate the preclinical development and clinical translation. We seek to leverage these advantages to advance a portfolio of programmed hematopoietic cell therapies for cancer and immune disorders.

Most hematopoietic cell therapies under development today utilize hematopoietic cells sourced from patients and, therefore, share a number of features that may limit their therapeutic potential and commercial viability. For example, the overall safety and efficacy of these cell therapies may be limited by the inherent qualities, quantities and properties of the patient's cells; the manufacture of these cell therapies in therapeutically-relevant amounts involves resource-intensive sourcing, culturing, activation and expansion of patient cells; the incorporation of multiple therapeutic mechanisms through genetic engineering may be restricted by the inherent nature of hematopoietic cells to become exhausted during manufacture; and the overall therapeutic paradigm, from cell sourcing to cell therapy manufacture to therapy delivery, is patient-specific. In collaboration with two of our scientific founders, Dr. Rudolf Jaenisch of the Whitehead Institute for Biomedical Research and Dr. Sheng Ding of the Gladstone Institute at UCSF, we have built a proprietary, small molecule enhanced iPSC platform. Our patent protected iPSC platform enables the isolation, genetic engineering, selection and characterization of pluripotent cells, at a single cell level, for stable clonal expansion. We seek to utilize our iPSC platform to develop off-the-shelf, engineered NK- and T-cell cancer immunotherapies having multi-pronged therapeutic functionality and scalability, and which overcome many of the key limitations of patient-sourced cell therapies.

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· Selectively share our cell programming expertise with industry-leading strategic partners for the development of highly-differentiated cellular immunotherapies.

Over 150 clinical trials using hematopoietic cells as therapeutic entities are currently being conducted, and hundreds of hematopoietic cell therapies are currently being advanced through preclinical development. We believe a tremendous opportunity exists to program the biological properties and therapeutic function of hematopoietic cells to create better cells and better cell therapies, and we seek to apply our expertise in hematopoietic cell biology and cell programming in collaboration with industry-leading companies and academic investigators engaged in the development of hematopoietic cell therapies. Through the establishment of collaborative arrangements, we seek to expand our ability to identify pharmacologic modulators, increase our understanding of the immune system and enable us to participate in the research and development of highly-differentiated cellular immunotherapies.

We believe we are uniquely positioned as an expert partner of choice for industry-leading developers seeking to maximize the therapeutic benefit of hematopoietic cell therapies through pharmacologic modulation. For example, we entered into a multi-year collaboration with Juno Therapeutics, Inc., or Juno, a leading developer of genetically-engineered CAR T-cell and TCR immunotherapies, in May 2015. Under the collaboration, we screen for and identify small molecule modulators that improve the function of T cells, including modulators that enhance the therapeutic properties of CAR T-cell and TCR immunotherapies. Juno has exclusive rights to incorporate such modulators in its development and commercialization of genetically-engineered CAR T-cell and TCR immunotherapies directed against certain tumor-associated antigen targets selected by Juno, and we have retained exclusive rights to such modulators for all other purposes. For each Juno therapy that uses or incorporates our small molecule modulators, we are eligible to receive clinical, regulatory and commercial milestones as well as low single-digit royalties on sales. We believe our collaboration with Juno has the potential to lead to the development and commercialization of multiple programmed CAR T-cell and TCR immunotherapies.

Our Programed Cellular Immunotherapies

We are developing a highly-differentiated pipeline of programmed cellular immunotherapies based on a simple notion: we believe better cell therapies start with better cells. We believe that enhancing the biological properties and therapeutic function of cells ex vivo prior to adoptive transfer is an elegant, cost effective and scalable approach for maximizing the safety and efficacy of cell therapies. Utilizing our cell programming approach, we seek to program immune cells, including CD34+ cells, NK cells and T cells, and are advancing a pipeline of donor-sourced and off-the-shelf, pluripotent cell-derived immune cell therapies in the fields of immuno-oncology and immuno-regulation.

Programmed Cellular Immunotherapies for Allogeneic HCT

Allogeneic HCT is a well established procedure that 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 each 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 result in 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, there are approximately 30,000 allogeneic HCT procedures 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 35-50% of patients undergoing mPB HCT develop acute GvHD and 70-80% of patients undergoing mPB HCT experience at least one severe infection, such as CMV infection, within the first 180 days following HCT. We believe our cell programming approach has the potential to prevent severe, life-threatening complications and improve outcomes in patients undergoing HCT.

ProTmune™. We are developing ProTmune as an investigational programmed cellular immunotherapy for use as an allogeneic HCT cell source. ProTmune is produced by modulating donor-sourced, human mPB ex vivo with two small molecules, 16,16-dimethyl

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prostaglandin E2 (FT1050) and dexamethasone (FT4145), to enhance the biological properties and therapeutic function of the hematopoietic cells. The programmed mPB cells are adoptively transferred and administered to a patient as a one-time intravenous therapy.

In January 2016, the U.S. Food and Drug Administration (FDA) cleared the Company's investigational new drug (IND) application for ProTmune. We plan to initiate a multi-center, randomized, controlled Phase 1/2 clinical trial of ProTmune in adult subjects with hematologic malignancies undergoing mPB HCT in mid-2016. The primary objectives of the Phase 1/2 clinical trial are to evaluate safety and tolerability, and to assess the potential of ProTmune to prevent acute GvHD and CMV infection, both of which are leading causes of morbidity and mortality in patients undergoing HCT. There are currently no approved therapies for the prevention of GvHD or CMV infection in patients undergoing allogeneic HCT, giving rise to a significant unmet medical need.

The Phase 1 stage of the clinical trial is a non-randomized, open-label, single-arm study that is intended to enroll approximately 10 subjects, all of whom must have an available matched unrelated peripheral blood cell donor and must be at high risk of CMV infection in the post-HCT period based on antibody evidence of a prior infection with CMV, designated as CMV seropositive, with no evidence of detectable CMV replication at baseline. All eligible patients enrolled in the Phase 1 stage of the study will be administered ProTmune as the hematopoietic cell source for the HCT procedure following myeloablative conditioning. After administering ProTmune to the first three subjects in the Phase 1 stage of the clinical trial, no further subjects will be enrolled until at least two of these first three subjects demonstrate neutrophil engraftment.

An independent data monitoring committee will conduct a safety review of data from the Phase 1 stage, and pending the committee’s recommendation, a 60-subject, randomized, controlled Phase 2 stage is expected to enroll, during which subjects undergoing mPB HCT following myeloablative conditioning will be assigned in a 1:1 ratio to be administered either ProTmune or unmanipulated mPB cells as the hematopoietic cell source for HCT. Two Endpoint Adjudication Committees are expected to evaluate the efficacy of ProTmune in the clinical trial, one through assessing the incidence of acute GvHD and the other through assessing the incidence of CMV tissue-invasive disease, viremia and additional clinical outcomes.

The efficacy endpoints for the Phase 1/2 clinical trial are: cumulative incidence of Grades B through D acute GvHD at Day 100 based on EAC-adjudicated results (where Day 0 is defined as the day of HCT), where acute GvHD maximum severity will be graded according to the CIBMTR acute GvHD Grading Scale; cumulative incidence of subjects with CMV viremia by Day 100 (defined as CMV plasma viral load of ≥1000 IU/mL), as determined by central laboratory testing; and cumulative incidence of CMV tissue-invasive disease by Day 100, based on EAC-adjudicated results. We also plan to assess numerous exploratory endpoints, including cumulative incidence of confirmed bacterial, fungal, viral, and parasitic infections by Day 100 and by Day 180, cumulative incidence of GvHD-free and relapse-free survival and cumulative incidence of GvHD-free, infection-free and relapse-free survival.

Based on preclinical data, we believe ProTmune has the potential to suppress the GvHD response and maintain the anti-viral and 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. In December 2015, we presented data at the American Society of Hematology 2015 Annual Meeting demonstrating that a single administration of FT1050-FT4145 programmed mPB cells result in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, in a murine model of allogeneic HCT. Additionally, in February 2016, we presented data at the 2016 BMT Tandem

Meetings defining the impact of FT1050-FT4145 modulation on the anti-tumor effector properties of donor T cells in a murine model of leukemia and demonstrating that ex vivo programmed donor T cells retain GvL activity.

ProHema®. On December 7, 2015, we announced interim data from our Phase 2 PUMA clinical trial of ProHema, a programmed hematopoietic cell therapy produced by modulating umbilical cord blood ex vivo with FT1050. Concurrently, we announced our election to discontinue all further clinical development of ProHema in umbilical cord blood HCT and focus our resources on the clinical development of ProTmune in mPB HCT.

The open-label, randomized, controlled PUMA study was designed to assess ProHema in adult subjects with hematologic malignancies undergoing double umbilical cord blood HCT (dUCBT). The PUMA study was intended to enroll 60 subjects, age 15 to 65 years, and was conducted at 11 leading allogeneic HCT centers in the United States. Eligible subjects were randomized, at a ratio of 2:1, with approximately 40 subjects expected to receive ProHema plus an unmanipulated cord blood unit, and approximately 20 concurrent control subjects expected to receive a standard dUCBT. Based upon physician choice, subjects were treated with one of two conditioning regimens, an intense myeloablative regimen (MAC) or a reduced intensity regimen (RIC), to destroy malignant cells and to prevent rejection of the donor hematopoietic cells. Randomization was stratified by conditioning regimen. An independent Data Monitoring Committee (iDMC) provided safety oversight during the conduct of the PUMA study.

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The primary endpoint of the PUMA study was based on a categorical analysis of neutrophil engraftment, and was powered to show with statistical significance that 70% of subjects with neutrophil engraftment in the ProHema treatment arm engraft prior to a pre specified control day of neutrophil engraftment, which was established as 26 days for subjects receiving MAC and 21 days for subjects receiving RIC. Based on an October 15, 2015 data cut-off, the interim analysis of the PUMA study showed that subjects administered ProHema had an increase in the incidence of early neutrophil engraftment and a reduction in the incidence of severe viral infection-related adverse events (Grade 3-5) following HCT. Specifically, the analysis showed:

- 24 of 28 subjects administered ProHema achieved neutrophil engraftment. 16 of these 24 subjects (67%) achieved early neutrophil engraftment prior to a pre-specified historical control median time of engraftment (which had been established as Day 26 for subjects receiving MAC and Day 21 for subjects receiving RIC). The overall reduction in the median time to neutrophil engraftment was 4.5 days, as compared to the applicable pre-specified historical control value. Two early deaths prior to engraftment, which were both attributed to the toxicity of the conditioning regimen received by the subjects, were reported in the ProHema arm. Two subjects administered ProHema failed to achieve neutrophil engraftment.
- 14 of 15 concurrent control subjects achieved neutrophil engraftment. Eight of these 14 subjects (57%) achieved early neutrophil engraftment prior to the applicable pre-specified historical control median. The overall reduction in the median time to neutrophil engraftment was 2 days, as compared to the applicable pre-specified historical control value. One subject failed to achieve neutrophil engraftment.
- 32% of subjects administered ProHema (9 of 28), as compared to 60% of concurrent control subjects (9 of 15), experienced one or more severe viral infection-related adverse events (Grade 3-5) following HCT; and, of the subjects who were CMV-seropositive at the time of HCT, 11% of subjects administered ProHema (2 of 18), as compared to 30% of concurrent control subjects (3 of 10), experienced one or more severe CMV-related adverse events (Grade 3-5) following HCT.

In connection with our election to discontinue all further clinical development of ProHema in umbilical cord blood HCT, two additional clinical trials of ProHema were also discontinued: the PROMPT study, an open label Phase 1b clinical trial in pediatric subjects undergoing single umbilical cord blood transplantation (sUCBT) for the treatment of hematologic malignancies; and the PROVIDE study, an open label Phase 1b clinical trial in pediatric subjects undergoing sUCBT for the treatment of inherited metabolic disorders. At the time of announcement of our election, two subjects had been administered ProHema in the PROMPT study and one subject had been administered ProHema in the PROVIDE study.

Adaptive NK Cell Therapy

Natural Killer, or 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 potential to protect healthy cells and induce death of abnormal cells through multiple mechanisms. These mechanisms include direct killing, by binding to stress ligands expressed by cells and releasing toxic granules, and antibody-mediated targeted killing, by binding to and enhancing the cancer-killing effect of antibodies through a process known as antibody-dependent cellular cytotoxicity, or ADCC.

Recent breakthroughs in cell-based cancer immunotherapy have been achieved by harnessing and optimizing the anti-tumor activity of T cells. NK cells, like T cells, have significant anti-tumor activity. Additionally, NK cells offer several unique advantages over T cells for use in cancer immunotherapy: the anti-tumor activity of NK cells is independent of tumor antigen exposure; the inhibitory mechanisms of NK cells prevent the killing of normal cells and

tissue; and the synergistic interaction between NK cells and antibodies enables efficient and highly-targeted killing. To date, however, the isolation and administration of homogenous populations of persistent and potent NK cells has been challenging.

In July 2015, we entered into a collaboration to advance the development of a NK-cell cancer immunotherapy program with the University of Minnesota, whose investigators have identified a distinct class of NK cells, referred to as “adaptive” NK cells. Adaptive NK cells have an epigenetic profile similar to that of cytotoxic T lymphocytes and express a unique metabolic profile that promotes long-term persistence in vivo. We have identified small molecule modulators that induce high levels of CD16 expression on adaptive NK cells. CD16 is a cell-surface protein that allows NK cells to bind to and synergize with monoclonal antibodies to efficiently destroy cancer cells.

In collaboration with Dr. Jeffrey Miller, M.D., Professor of Medicine and Deputy Director, University of Minnesota Cancer Center, we are advancing our programmed adaptive NK cell therapy through clinical translation. We intend to develop our adaptive NK cell therapy for the treatment of solid tumors in combination with widely-used, FDA-approved monoclonal antibodies, such as Herceptin, Erbitux and Rituxan. Monoclonal antibodies are prevalently used to treat cancer and generate over $50.0 billion in reported

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annual sales. We believe our programmed adaptive NK cell therapy may enhance targeted cancer cell-killing in combination with monoclonal antibodies through ADCC and has the potential to serve a large number of patients who respond poorly to single-agent treatment with monoclonal antibodies.

Programmed CD34+ Cell Therapy

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 activation of T cells in the presence of tumor cells, can be exploited to suppress auto-reactive T-cell destruction of normal tissues. Cancerous cells often evade the immune system by expressing programmed cell death ligand-1 (PD-L1), a ligand that binds to the cell-surface receptor PD-1 on T lymphocytes and prevents T-cell activation. The PD-1 / PD-L1 biological axis has been clinically-validated as a potent immuno-suppressive pathway, and certain monoclonal antibodies, commonly referred to as immune checkpoint inhibitors, have been shown to block the interaction between PD-L1 and PD-1, boosting the immune system and enhancing T-cell killing of cancer cells.

We believe CD34+ cells possess intrinsic immuno-regulatory properties that are triggered under certain physiological conditions and, once triggered, have the potential to suppress activated T cells through the cell-surface expression of PD-L1 and the expression of potent immuno-modulatory enzymes. We seek to exploit these immuno-regulatory properties of CD34+ cells to down-regulate and suppress the body's attack on its own tissues. We are advancing the development of a pharmacologically-programmed CD34+ cell therapy with enhanced immuno-regulatory potential for the treatment of autoimmune and inflammatory diseases. We are currently investigating our programmed CD34+ cell therapy in several preclinical models of T cell-mediated immune dysfunction.

In June 2015, we entered into a collaboration with Boston Children's Hospital and its investigator, Paolo Fiorina, M.D., Ph.D., Assistant Professor of Pediatrics at Boston Children's Hospital and Harvard Medical School, to accelerate the development of our programmed CD34+ cell therapy. Dr. Fiorina and his team have extensively studied the cellular mechanisms and molecular pathways involved in the autoimmune-mediated destruction of pancreatic beta cells that result in insulin deficiency and onset of type 1 diabetes. Preclinical data from the Fiorina laboratory, which was presented at the American Diabetes Association's 75th Scientific Sessions in June 2015, show that genetically-engineered PD-L1+ hematopoietic cells adoptively transferred into hyperglycemic mice traffic to the pancreas, reduce aberrant T-cell activity and revert hyperglycemia in a well-established murine model of type 1 diabetes.

Programmed iPSC-derived Immunotherapies

We believe induced pluripotent stem cells, or iPSCs, have the potential to enable the next frontier in the development of cell therapy. The seminal discovery that it is possible to reprogram the fate of fully differentiated human cells ex vivo through the expression of certain genes and factors, such that the reprogrammed cell's cellular and physiological traits are similar to those of an embryonic stem cell, is one of the most remarkable scientific breakthroughs of the past decade and was recognized with the 2012 Nobel Prize in Science and Medicine. In collaboration with two of our Scientific Founders, Dr. Rudolf Jaenisch of the Whitehead Institute for Biomedical Research and Dr. Sheng Ding of

the Gladstone Institute at UCSF, we have developed a proprietary, small molecule enhanced iPSC platform for the generation and maintenance of pluripotent cells in a consistent, scalable and highly efficient manner. Our iPSC platform is supported by an intellectual property portfolio of over 60 issued patents and 90 pending patent applications that we own or license.

Since induced pluripotent cells are capable of long-term self-renewal and can be used to generate almost any functional cell, we believe iPSCs are an ideal source for the development of disruptive off-the-shelf adoptive immunotherapies. Our patent-protected iPSC platform has the potential to consistently create large quantities of homogeneous hematopoietic cell populations, which would otherwise be limited in quantity, difficult to manufacture, heterogeneous in composition and unoptimized for efficacy. Specifically, our iPSC platform, which combines genetic engineering with rapid and efficient generation of immune cells, is designed to enable the generation of highly-stable, genetically-modified, clonal pluripotent cell lines and to utilize these lines for the unlimited production of engineered CD34+ cell-, NK cell- and T cell-based therapies without requiring patient-sourced cells.

We believe our pluripotent cell line approach is disruptive and has the potential to overcome key limitations of patient-sourced cell therapies, such as the requirement to source, isolate, engineer and expand cells for each individual patient, and may prove to be

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the cornerstone of off-the-shelf cellular immunotherapy. We are extensively characterizing the properties of pluripotent cell line-derived immune cells, including CD34+ cells, NK cells and progenitor T cells, and evaluating their functionality in vitro and in vivo.

In July 2015, we entered into a collaboration with the University of Minnesota to advance the development of a pluripotent cell-derived, engineered, NK-cell cancer immunotherapy. In published findings, our collaborators have shown that a standardized, homogenous NK-cell population can be produced efficiently and in large quantities from a human pluripotent cell line, and NK cells derived from a pluripotent cell line have potent anti-tumor activity in vivo in two different preclinical models of ovarian cancer. We believe these findings demonstrate that pluripotent cells have promising potential to be effectively utilized as a source for off-the-shelf NK-cell cancer immunotherapy.

Our Cell Programming Partnerships

Juno Therapeutics

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

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

Pursuant to the terms of the agreement, Juno paid us an upfront payment of $5.0 million, and purchased one million shares of our common stock, at $8.00 per share, for an aggregate purchase price of $8.0 million. Additionally, Juno agreed to fund all of our collaboration research activities for an initial four-year research term ending in May 2019, with minimum annual research payments of $2.0 million to us. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of 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, Fate then has 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.

We are eligible under the agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. Additionally, in connection with each Juno therapy that uses or incorporates our small molecule modulators, Juno has

agreed to pay us non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million, in the aggregate, per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones.

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

Under the agreement, we have granted Juno an exclusive worldwide license to certain of our intellectual property, including our intellectual property arising under the collaboration, to make, use, sell and otherwise exploit genetically-engineered CAR T cell and TCR immunotherapies using or incorporating small molecule modulators directed against certain designated tumor-associated antigen

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targets, subject to the selection of such target by Juno. We have retained exclusive rights to such intellectual property, including our intellectual property arising under the collaboration, for all other purposes.

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 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.

Our Intellectual Property

Overview

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

As of March 2, 2016, our intellectual property portfolio is composed of 114 issued patents and 150 patent applications that we license from academic and research institutions, and 76 issued patents or pending patent applications that we own. These patents and patent applications generally provide us with the rights to develop our product candidates in the United States and worldwide. This portfolio covers compositions of programmed cellular immunotherapeutics, including ProTmune, our cell programming approach for enhancing the therapeutic function of cells ex vivo, and our platform for industrial scale iPSC generation and engineering. We believe that we have a significant intellectual property position and substantial know how relating to the programming of hematopoietic and immune cells and to the derivation, genetic engineering, and differentiation of iPSCs.

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

Intellectual Property Relating to the Programming of Hematopoietic and Immune Cells

As of March 2, 2016, we own 13 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 41 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 2037.

Additionally, we have an exclusive license to an intellectual property portfolio consisting of two families of issued patents and pending patent applications co owned by the Children's Medical Center Corporation and The General Hospital Corporation. As of March 2, 2016, we currently have exclusive rights to 54 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,

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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 the exclusive right to negotiate licenses to obtain exclusive worldwide rights to certain intellectual property portfolios directed to NK cells, including adaptive NK cells and genetically-engineered NK cells, and therapeutic strategies for the treatment of cancer using these NK cells, pursuant to exclusive option agreements that we have entered into with the University of Minnesota.

Intellectual Property Relating to iPSC Technology

As of March 2, 2016, we own six patent families directed to programming the fate of somatic cells ex vivo, including patent applications pending in the U.S. and internationally related to our platform for industrial scale iPSC generation and applications related to differentiation of iPSCs into specialized cells with therapeutic potential. These patent applications cover our proprietary small molecule enhanced iPSC platform, including novel reprogramming factors and methods of reprogramming to obtain iPSCs. Our intellectual property portfolio also includes gene editing compositions and methods of genetic engineering, as well as methods of directing the fate of cells to obtain homogenous cell populations in the hematopoietic lineage, including CD34+ cells, T cells and NK cells. Our proprietary intellectual property enables highly efficient iPSC derivation, selection, engineering, and clonal expansion while maintaining high quality, homogeneous cells. Any patents issued from these patent applications will expire on dates ranging from 2031 to 2037.

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 pluripotent cells from somatic cells and, as of March 2, 2016, includes eight issued U.S. patents (including U.S. Patents 8,071,369 and 7,682,828) 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 human 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 (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 are 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.

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, or 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.

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CMCC retains a non exclusive right to practice and use the patent rights for research, educational, clinical or charitable purposes, and also to license other academic and nonprofit organizations to practice the patent rights for research, educational, and charitable purposes (but excluding any clinical use and commercialization of the patent rights to the extent granted to us under the license agreement). Our license is also subject to pre existing rights of the U.S. government and rights retained by the Howard Hughes Medical Institute and the General Hospital Corporation to use the patent rights for research purposes. Additionally, if we make any discovery or invention that is described in a patent application and is not within the scope of the licensed patent rights but would not have been made but for the licensed patent rights, we are required to disclose the invention to CMCC and enter into a non exclusive license agreement with CMCC, for no more than a nominal fee, for CMCC to practice the invention solely for internal research purposes or clinical purposes and not for commercial purposes.

Under the terms of the license agreement, we are required to pay to CMCC an annual license maintenance fee during the term of the agreement. We also are required to make payments to CMCC of up to $5.0 million per product in development, regulatory and sales milestones. If commercial sales of a licensed product commence, we will pay CMCC royalties at percentage rates ranging in the low to mid single digits on net sales of licensed products in countries where such product is protected by patent rights. Our obligation to pay royalties continues on a country by country basis until the expiration of all licensed patent rights covering licensed products in such country, and our royalty payments will be reduced by other payments we are required to make to third parties until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, CMCC is also entitled to receive a percentage of the sublicensing income received by us.

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

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

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.

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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, or 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, or the TSRI License Agreements, we acquired exclusive royalty bearing, sublicensable, worldwide licenses to make, use and sell products covered by the licensed patent rights, and to perform licensed processes, in each case, in all fields. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” TSRI retains a non exclusive right to practice and use the patent rights for non commercial educational and research purposes, and to license other academic and non profit research institutions to practice the patent rights for internal basic research and education purposes. Under certain of our TSRI License Agreements, other third parties maintain a right to practice the patent rights for their internal use only. Our license is also subject to pre existing rights of the U.S. government.

Under the terms of the TSRI License Agreements, we are required to pay to TSRI annual minimum fees during the term of each agreement. Additionally, upon the achievement of specific regulatory and commercial milestones, we are required to make payments to TSRI of up to approximately $1.75 million under each of the TSRI License Agreements. We will also be required to pay TSRI royalties at percentage rates ranging in the low to mid single digits on net sales of licensed products. In the event that we sublicense the patent rights, TSRI is also entitled to receive a percentage of the sublicensing income received by us.

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

Manufacturing

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

ProTmune 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.

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

Marketing & Sales

We currently intend to commercialize any products that we may successfully develop. We currently have limited 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 products 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 one of our product candidates.

Government Regulation

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or 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. In addition, government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities.

Marketing Approval

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

- completion of nonclinical laboratory and animal tests according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug, or 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, or 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, or 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, or 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 good manufacturing practices, or GMPs, to assure that the facilities, methods and controls are adequate, and, if applicable, the FDA's current good tissue practices, or GTPs, 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.

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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, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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

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

- Phase 1—The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.
- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit risk relationship of the investigational product, and to provide an adequate basis for product approval and 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.

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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 GMP 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.

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, or 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, 2015 and in effect through September 30, 2016, the user fee for an application requiring clinical data, such as a BLA and an NDA, will be $2,374,200 for fiscal year 2016. PDUFA also imposes an annual product fee for biologics and drugs ($114,450 for fiscal year 2016), and an annual establishment fee ($585,200 for fiscal year 2016) on facilities used to manufacture prescription biologics or drugs. 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 GMPs 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 GMP 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 GTPs. FDA regulations also require tissue establishments to register and list their human cells, tissues, and cellular and tissue based products, or 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

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

After the FDA completes its initial review of a BLA or NDA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA or NDA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA or NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the applicant in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA or NDA to address all of the deficiencies identified in the letter, or withdraw the application.

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

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

Expedited Development and Review Programs

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

and the sponsor pays any required user fees upon submission of the first section of the application.

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

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FDA may require that a sponsor of a biological product or drug receiving accelerated approval perform adequate and well controlled post marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre approval of promotional materials. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, also amended the FDCA to require 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.

U.S. Patent Term Restoration and Marketing Exclusivity

Under certain circumstances, U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The period of patent term restoration is generally one half the time between the effective date of an IND application (falling after issuance of the patent) and the submission date of a BLA or NDA, plus the time between the submission date of the BLA or NDA and the approval of that application, provided the sponsor acted with diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office, or USPTO, 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, or ANDA, which relies on the preclinical and clinical testing previously conducted for a drug approved under an NDA, known as the reference listed drug, or 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 similar 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, or 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.

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FDA Post Approval Requirements

FDA regulation of biological products and drugs continues after approval, particularly with respect to GMP. Other post approval requirements applicable to biological products and drugs include record keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the BLA holder must report GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, and the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. FDA sanctions include refusal to approve pending applications, suspension or revocation of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Biological product and drug manufacturers and other entities involved in the manufacture and distribution of approved biological products and drugs are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of biological products and drugs, including direct to consumer advertising, promotional activities involving the internet, and industry sponsored scientific and educational activities that are not independent of the influence of the supporting company. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a biological product or drug that are consistent with FDA approval, and the company is allowed to market a biological product or drug only for the particular use and treatment approved by the FDA. In addition, any claims in product advertising or promotion must be appropriately balanced with important safety and risk information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, untitled or warning letters, corrective advertising, injunctions, potential civil and criminal penalties and exclusion from government healthcare programs.

Orphan Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to biological products and drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the

United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product or drug in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA or NDA. After the FDA grants orphan designation, the identity of the applicant, the name of the therapeutic agent and its designated orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

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Pediatric Research Equity Act

Under the Pediatric Research Equity Act, or PREA, a BLA or NDA or supplement must contain data to assess the safety and effectiveness of the biological product or drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations. FDASIA 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 saying 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.

Anti Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of biological products and drugs are potentially subject to regulation by various federal, state and local authorities in addition to the FDA. For example, sales, marketing and scientific/educational grant programs must comply with the Anti Kickback Statute, as amended, the federal False Claims Act, as amended (the False Claims Act), the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

In the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including, but not limited to, the Anti Kickback Statute, the False Claims Act, and other state and federal laws and regulations. The Anti Kickback Statute makes it illegal for any person, including a biological product or drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices or our future relationships with physicians might be challenged under anti kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including biological products and drugs, that are false or fraudulent. Manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off label. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, and the potential for exclusion from participation in federal healthcare programs. A False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the False Claims Act and certain states have enacted laws modeled after the False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. In addition, a federal law requires manufacturers of biological products and drugs that are reimbursable under Medicare, Medicaid, and the Children's Health Insurance Program to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. Many of these laws are evolving and may contain ambiguities as to what is required for compliance or the penalties for non compliance.

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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 rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

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, 2015, we employed 60 full time employees, including 35 in research and development, 16 in clinical development and regulatory affairs and 9 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

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 and ProTmune™. All other trademarks or trade names referred to in this document are the property of their respective owners. Solely for convenience, the trademarks and trade names in this document are referred to without the symbols® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

On October 4, 2013, we completed our initial public offering. We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company,

we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. We would cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Information about Segments and Geographic Areas

In accordance with The Financial Accounting Standards Board (or FASB) Accounting Standards Codification, or 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.

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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.

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PART II. OTHER INFORMATION

Item 1A. Risk Factors

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

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

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

Developing therapeutic products, including conducting preclinical studies and clinical trials of cellular therapeutics, is expensive. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations for at least the next twelve months. However, our resources will likely be insufficient to conduct research and development programs and clinical development to the full extent currently planned. We will require substantial additional capital to conduct the research and development and clinical and regulatory activities necessary to bring our product candidates to market. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, timing and costs of our preclinical studies and planned clinical trials;
- continued progress in our research and development programs, including the preclinical studies and planned clinical trials of our product candidates;
- our ability to initiate, and the progress, results, size, timing and costs of, additional future clinical trials of our product candidates that will be necessary to support any application for regulatory approval;
- 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, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of commercialization activities and arrangements, including the commercial manufacturing of our product candidates; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaboration with Juno, to advance the research, development and commercialization of therapeutic products.

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

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

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

All of our product candidates are currently in research or clinical development, including our lead product candidate, ProTmune, which we plan to advance into Phase 1/2 clinical development during 2016. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety and efficacy profile necessary to support further preclinical study, clinical development or regulatory approval.

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

- determining that a product candidate is ineffective or causes harmful side effects during preclinical studies or clinical trials;
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;
- difficulties in manufacturing a product candidate, including the inability to manufacture a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under processes acceptable to the FDA for marketing approval;
- the proprietary rights of third parties, which may preclude us from developing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop or commercialize, or may fail to achieve market acceptance or adequate reimbursement;
- our inability to secure strategic partners which may be necessary for advancement of a product candidate into clinical development or commercialization; or
- our prioritization of other product candidates for advancement.

Additionally, we will only 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 the product candidate is manufactured in accordance with applicable regulatory requirements, is safe and effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies 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 processes are sufficient to support approval. The final results of our planned 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 processes or facilities are insufficient to support approval. We may need to conduct preclinical studies and clinical trials that we currently do not anticipate. If we fail to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, we will not be able to generate any revenues from product sales, which will harm our business, prospects, financial condition and results of operations.

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

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Results from preclinical testing and earlier clinical studies, including clinical studies with similar product candidates, are not necessarily predictive of future clinical study results. While preclinical studies have shown 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, in preclinical models, we may not observe similar results in future preclinical or clinical studies of ProTmune. Additionally, while subjects treated with ProHema in an earlier clinical trial experienced a reduction in the number of severe viral infection-related adverse events, these results should not be relied upon as predictive of our future clinical study results with ProTmune. Although ProTmune and ProHema are similar compositions of human hematopoietic cells that have been programmed ex vivo with FT1050, ProTmune and ProHema are different products resulting from different manufacturing processes. For example, ProHema consists of umbilical cord blood that is programmed ex vivo with FT1050, while ProTmune consists of mobilized peripheral blood that is programmed ex vivo with FT1050 and a second small molecule, FT4145. Further, earlier clinical trials of ProHema were based on a

different study design and assessed different endpoints than our planned clinical trial of ProTmune.

The results of our planned 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 standardize and automate the manufacture of ProTmune may adversely affect its safety, purity, potency or efficacy;
- deviations in the manufacture of ProTmune by cell processing facilities at clinical centers participating in clinical trials that we conduct;

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- 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 planned clinical trials; and
- safety issues or adverse events in patients that enroll in our planned clinical trials.

Even if our planned clinical trials are successful, we will likely need to conduct additional clinical trials, including registrational trials and trials in additional patient populations or under different treatment 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.

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

We have not initiated the clinical trials necessary to support an application for approval to market ProTmune or any other product candidates that we may identify. We may experience delays in initiating or conducting our planned clinical trials, and we do not know whether we will be able to initiate, enroll patients in, or complete, our planned clinical trials on time, if at all. Our planned clinical trials of our product candidates may be delayed, unsuccessful or terminated as a result of many factors, including factors related to:

- difficulties in identifying eligible patients for participation in our clinical trials due to our focus on the development of product candidates for the treatment of rare diseases;
- difficulties enrolling a sufficient number of suitable patients to conduct our clinical trials, including difficulties relating to patients enrolling in studies of therapeutics sponsored by our competitors;
- difficulties in obtaining agreement from regulatory authorities on study endpoints, achieving study endpoints, demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- the occurrence of unexpected safety issues or adverse events in any clinical trial of our product candidates;
- securing and maintaining the support of clinical investigators and investigational sites, and obtaining institutional review board, or 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 of clinical trial sites to manufacture certain of our product candidates consistently in accordance with our protocol-specified processes at their cell processing facilities for use in our clinical trials;
- our failure, or the failure of third-party service providers or clinical trial sites, to ensure the proper and timely conduct and analysis of our clinical trials;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators and IRBs;
- obtaining sufficient quantities of critical reagents and other materials and equipment necessary for the manufacture and processing of any product candidate;
- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;
- the serious, life-threatening diseases of the patients to be enrolled in our clinical trials, who may die or suffer adverse medical events for reasons that may not be related to our product candidates;
- failure of patients to complete clinical trials due to safety issues, side effects, or other reasons; and
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approval of competitive agents that may materially alter the standard of care or otherwise render our product candidates or clinical trial designs obsolete.

If we experience delays in the initiation or completion of any clinical trial 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

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commencing 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 commencement 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 and results of operations.

Our clinical development of ProTmune could be substantially delayed if the FDA requires us to conduct unanticipated studies or trials or imposes other requirements or restrictions.

The FDA may require us to generate additional preclinical, product or clinical data as a condition to initiating and conducting our planned clinical trials of ProTmune. Additionally, the FDA may in the future have comments, or impose requirements, on our protocols for conducting the clinical trials of ProTmune. Any requirements to generate additional data or redesign or modify our protocols, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the planned clinical trials for ProTmune and subsequent development activities for ProTmune, and could require us to incur additional development costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our clinical development activities for ProTmune, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for ProTmune.

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

- be delayed in obtaining, or unable to obtain, regulatory approval for our product candidates;
- be required to amend the protocols for our clinical trials, perform additional 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
- have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Our plans 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 processes or if we are required to change our manufacturing processes to comply with regulatory requirements.

Our plans to manufacture ProTmune in close proximity to transplant centers within a short period of time before transplantation may present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. We will need to standardize the process for manufacturing ProTmune, and ProTmune used in registrational clinical trials must be manufactured in compliance with FDA regulatory requirements. In addition, the FDA may impose additional requirements on our processes for the manufacture of ProTmune or our other product candidates.

While we plan to have clinical cell processing facilities operated by or affiliated with our clinical sites manufacture ProTmune prior to transplantation, we may be required to identify alternative processes for the manufacture of ProTmune in compliance with applicable regulatory requirements, and in the future we may manufacture ProTmune at facilities operated by us, by transplant centers, or by third parties. Any requirements to modify our manufacturing processes, and any delays in, or inability to, establish manufacturing processes acceptable to the FDA could require us to incur additional development costs or result in delays to our clinical development plans, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for ProTmune. Any such events could delay or

prevent our ability to obtain regulatory approval or commercialize ProTmune, which would adversely affect our business, financial condition and results of operations.

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

Patients undergoing treatment with certain of our product candidates, including ProTmune, 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

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medications that such patients may be using. Any of these events could prevent us from advancing ProTmune 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 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 applicable regulatory pathway to approval and the time, the cost and our ability to successfully complete clinical development, and to obtain the necessary regulatory and reimbursement approvals required for commercialization, of our product candidates.

ProTmune and other product candidates that we may develop based on our cell programming technology represent novel therapeutics, and we face uncertainties associated with the clinical development, regulatory pathways to approval, and reimbursement required for successful commercialization of these product candidates. The clinical development and regulatory 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 a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the clinical development and the regulatory pathways of our product candidates, we may be required to modify or change our clinical development plans or our regulatory pathways for approval. Any such modification or changes could delay or prevent our ability to develop, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular therapeutics, and stem cell therapies in particular, represent a relatively new therapeutic area, and the FDA has cautioned consumers about potential safety risks associated with these therapies. To date, there are relatively few approved cellular therapeutics. In addition, there are currently no FDA approved products with a label designation that supports the use of a product to prevent acute Graft vs. Host Disease (GvHD) or viral infections in patients undergoing allogeneic HSCT, which makes it difficult to determine the time and cost required to obtain regulatory approvals in the United States or other jurisdictions for ProTmune or any other product candidates that we may develop.

Regulatory requirements governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements for or identify different regulatory pathways for approval for any of our product candidates. For example, the FDA established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review, and it is possible that new or different bodies may be established or be granted the responsibility for regulating pharmacologically modulated cellular therapeutics 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 clinical development 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 costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products will likely be reviewed by the FDA’s advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

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 processes, 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 good manufacturing practices, or 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 products, manufacturing processes, 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 seek and rely on orphan drug status to develop and commercialize certain of our product candidates, but any orphan drug designations that we are granted may not confer marketing exclusivity or other expected commercial benefits.

We expect to seek and rely on orphan drug exclusivity for ProTmune and potential future 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. Although we anticipate that we may apply for orphan designation for ProTmune and other product candidates that we may identify and develop, there is no assurance that the FDA or other comparable foreign regulatory authorities will grant orphan designation for our product candidates in the indications that we pursue. Even if we are granted orphan designations for our product candidates, including ProTmune, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

For any product candidate for which we 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. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Additionally, 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 will depend on facilities operated by transplant centers for the manufacture of ProTmune under specific conditions. Any failure by these facilities to manufacture ProTmune 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, ProTmune.

For the conduct of our planned Phase 1/2 clinical study of ProTmune, we plan to use ProTmune that is manufactured at clinical cell processing facilities operated by or affiliated with our clinical sites in close proximity to the treatment site on the same day as product administration. We will be required by the FDA to standardize the manufacture of ProTmune, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the use of our planned manufacturing processes to manufacture ProTmune for commercialization may require each of the clinical cell processing facilities at which ProTmune is 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 the FDA’s requirements and to properly execute the protocol for the manufacture of ProTmune. 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 ProTmune in a

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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 ProTmune, which may require us to spend significant additional time and resources, and would impair our ability to complete the clinical development of, and to commercialize, ProTmune. To comply with applicable regulatory requirements and our protocols for the manufacture of ProTmune, 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 requirements or with our protocols for the manufacture of ProTmune, it will be restricted or prohibited from manufacturing ProTmune and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of ProTmune or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

We depend on third-party suppliers for various components, materials and equipment required for the manufacture of ProTmune and do not have supply arrangements for certain of these components.

We currently rely, and expect to continue to rely, on third-party suppliers for components necessary for the manufacture of ProTmune. We have not entered into, and may not be able to enter into, agreements for the supply of certain components. Even if we are able to enter into such agreements, we may be limited to a sole third-party for the supply of certain required components, including FT1050 and components for our cell processing media. Additionally, to date, we and our clinical cell processing facilities have purchased equipment, materials and disposables, such as automated cell washing devices, automated cell warming units, commercially available media and cell transfer and wash sets, used for the manufacture of ProTmune from third parties. We rely on the general commercial availability of these materials, and we do not have any current contractual relationships for the supply of these materials. Accordingly, we may incur delays or increased costs due to any interruption in supply, and we cannot guarantee that we will have an adequate supply of components, equipment, materials and disposables to complete our planned clinical development and commercialization of ProTmune.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of ProTmune, we may be required to change our manufacturing processes 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 delay, or increase the costs required to complete, our clinical development and commercialization of ProTmune. Additionally, any such change or modification may adversely affect the safety, efficacy or potency of ProTmune, and could adversely affect our clinical development of ProTmune and harm our business.

We face a variety of challenges and uncertainties associated with our dependence on human mobilized peripheral blood, or mPB, for the manufacture of ProTmune.

ProTmune is manufactured using mPB, which will be procured directly by the clinical cell processing facilities from blood banks for our planned Phase 1/2 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;
- the availability of government funding for blood banks;

- 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 mPB for transplantation; and
- methods for the procurement and shipment of mPB and their 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 from blood banks that are compliant 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.

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In the United States, the banking and use of mobilized peripheral blood does not require a biologics license application, or BLA, and mobilized peripheral blood is not an FDA licensed product. However, the FDA does require that units of mobilized peripheral blood adhere to and meet the standards set forth by the Food & Drug Administration, Foundation for Accreditation for Cell Therapy (FACT) and the National Marrow Donor Program (NMDP). The FDA, FACT and NMDP allow the use of unlicensed mPB units for transplantation. In our planned Phase 1/2 clinical trial of ProTmune, we intend to use unlicensed mPB units in the manufacture of ProTmune. It may be possible that in the future, regulatory policy could change, and the FDA may later require ProTmune to be manufactured using only licensed mPB units. Additionally, although mPB units from foreign cord blood banks, which are generally unlicensed, are currently available in the United States for use in transplantation, we intend to use only mPB units that are procured in the United States for the Phase 1/2 clinical study of ProTmune. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

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

We have relied upon and expect to continue to rely upon third parties, including clinical research organizations, or CROs, for the conduct of certain research and preclinical development activities, and for the conduct, management, and supervision of our clinical trials. We control only certain aspects of the activities of these third parties through contractual agreements, and will have limited influence over their actual performance. Our reliance on 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, regulatory and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with good clinical practices, or 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 GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development activities or clinical data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our research, preclinical development 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.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, 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 processes used to manufacture them and the methods for using them, in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates. We own and have exclusive licenses to patent portfolios for our product candidates, 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, 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. 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.

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

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

Certain rights to our key technologies and product candidates, including intellectual property relating to ProTmune and our induced pluripotent stem cell 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, 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 incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

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. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. There is a risk that the court will decide that such patents are not valid 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 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. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of ProTmune or any other product candidates that we develop will not infringe third-party patents.

A third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. Patent litigation is costly and time consuming. We may not have sufficient resources to address these actions, and such actions could affect our results of operations and divert the attention of managerial and scientific personnel.

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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, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

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

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

Risks Related to the Commercialization of Our Product Candidates

We have limited marketing experience 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 limited experience in marketing and selling therapeutic products. If any of our product candidates are approved for marketing, we intend to establish marketing and sales capabilities internally or we may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our product revenues will suffer.

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

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

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

- the effectiveness of our marketing strategy; and
- sufficient third-party insurance coverage or governmental reimbursement.

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

We expect to face uncertainty regarding the pricing of ProTmune 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 targeted indication of HSCT procedures in general and our hematopoietic cell 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 therapeutic product candidates that we develop will be relatively high due to their anticipated use in a one-

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time, potentially life-saving procedure with curative intent, the biopharmaceutical industry has recently experienced significant pricing pressures, including in the area of orphan drug products. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

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

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 therapeutics, 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 and 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.

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

Risks Related to Our Business and Industry

The success of our product candidates, including ProTmune, 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, are designed and are being developed as therapeutic entities for use as cellular immunotherapies. Any adverse developments in the field of cellular therapeutics 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. In particular, there are several companies and institutions developing products that may obviate the need for HSCT, or may be competitive to products in our research and development pipeline, or may

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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, or the Sarbanes-Oxley Act, and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

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

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

In July 2014, we entered into an amended and restated loan and security agreement with Silicon Valley Bank, pursuant to which we have been extended term loans in the aggregate principal amount of $20.0 million. Borrowings under this loan and security agreement 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 Silicon Valley Bank and to comply with various operating covenants that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants 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.

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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.

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., or Juno, for the identification and application of small molecule modulators for programming the therapeutic properties of genetically-engineered chimeric antigen receptor (CAR) and T-cell receptor (TCR) based cellular immunotherapies directed against certain targets designated by Juno. Under the agreement, Juno has agreed to fund our collaboration research activities for an initial research term ending in May 2019, subject to a two-year extension under certain circumstances, and we are eligible to receive target selection fees and clinical, regulatory, and commercial milestones, as well as royalties on sales, should any therapies using our modulators be developed and commercialized. Our collaboration with Juno may be terminated, or may not be successful, due to a number of factors. For example, we may be unable to identify small molecule modulators that are effective in modulating genetically-engineered T-cell therapies, or Juno may elect not to develop any genetically-engineered T-cell therapies incorporating any modulators that are identified through the collaboration. 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 that have been genetically-engineered to express chimeric antigen receptors or T-cell receptors against certain targets designated by Juno. Furthermore, during the term of the agreement, we will be unable to conduct, or enable third parties to conduct, research, development and commercialization activities using small molecule modulators to program T-cell therapies that have been genetically-engineered to express chimeric antigen receptors or T-cell receptors directed against certain targets selected by Juno. 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.

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 continue to 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 a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;

- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

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

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

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling 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

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

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

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

We are a clinical-stage biopharmaceutical discovery and development company, formed in 2007, with a limited operating history. We have not yet obtained regulatory approval for any 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, 2015 we had an accumulated deficit of $142.4 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of ProTmune and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our development of, and seek regulatory approval for, our product candidates, in-license or acquire new product development opportunities, implement additional infrastructure and internal systems and hire additional scientific, clinical, and marketing 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 and biological 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 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 others beyond our control, including:

- the timing of the initiation of, and progress in, our planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others;
- developments related to the FDA or to regulations applicable to cellular therapeutics 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 cellular therapeutics or immunotherapeutics;
- announcements or expectations of additional equity or debt financing efforts;
- sales of our common stock by us, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., or by our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- fluctuations in our operating results; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and The NASDAQ Global Market and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management.

Our principal stockholders exercise significant control over our company.

As of February 29, 2016, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 61% of our outstanding voting stock. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

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This concentration of ownership may have the effect of delaying or preventing a change in control of our company or affecting the liquidity and volatility of our common stock, and might affect the market price of our common stock.

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

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding and other collaborations, strategic alliances and licensing arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations, and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. We have an effective shelf registration statement on file with the SEC that provides for the sale of up to $65.5 million in the aggregate of shares of our common stock, preferred stock, debt securities, warrants and/or units by us. Any such sale or issuance of securities may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, in July 2014, we entered into an amended and restated loan and security agreement with Silicon Valley Bank, which imposes restrictive covenants on our operations. Any future debt financings may impose additional restrictive covenants or otherwise adversely affect the holdings or the rights of our stockholders, and any additional equity financings will be dilutive to our stockholders. Furthermore, additional equity or debt financing might not be available to us on reasonable terms, if at all.

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

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

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

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

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

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

acquisition proposal or tender offer is at a premium over the then-current market price for our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, and may result in increased future tax liability to us.

Generally, a change of more than 50% in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) attributable to the period prior to such change. We triggered an ownership change limitation in November 2009 and again in May 2015. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to

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use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Facilities

As of December 31, 2015, we occupy approximately 29,300 square feet of office and laboratory space in San Diego, California under a lease and sublease that each expire in 2017. Both leased properties are in the same building. We believe that our facilities are adequate for our current needs.

ITEM 3. Legal Proceedings

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

ITEM 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market on October 1, 2013 and trades under the symbol "FATE". Prior to October 1, 2013, there was no public market for our common stock. The table below provides the high and low intra day sales prices of our common stock for the periods indicated, as reported by The NASDAQ Global Market.

| | High | Low |
|---|---|---|
| Year ended December 31, 2015 | | |
| Fourth quarter | $6.71 | $3.12 |
| Third quarter | 8.37 | 4.61 |
| Second quarter | 8.78 | 4.46 |
| First quarter | 5.50 | 4.54 |
| Year ended December 31, 2014 | | |
| Fourth quarter | $5.90 | $3.50 |
| Third quarter | 6.94 | 5.01 |
| Second quarter | 9.95 | 5.88 |
| First quarter | 13.55 | 5.85 |

Holders of Common Stock

As of March 1, 2016, there were approximately 52 stockholders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

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Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a $100 investment in the Company's common stock, the NASDAQ Composite® (US) Index and the NASDAQ Biotechnology Index commencing on October 1, 2013 (the date our common stock began trading on the NASDAQ Global Market) and continuing through December 31, 2015. The past performance of our common stock is no indication of future performance.

Assumes $100 invested on Oct. 1, 2013; Assumes dividend reinvested; Fiscal year ending Dec 31, 2015

Dividends

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

Securities Authorized for Issuance under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

During the year ended December 31, 2015, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10 Q or in a Current Report on Form 8 K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the quarter ended December 31, 2015.

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ITEM 6. Selected Financial Data

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

| | Years Ended and as of December 31, | | | | |
|---|---|---|---|---|---|
| | 2015 | 2014 | 2013 | 2012 | 2011 |
| Consolidated Statements of Operations Data (in thousands, except share and per share data): | | | | | |
| Revenue: | | | | | |
| Collaboration revenue | $2,431 | $— | $626 | $1,268 | $833 |
| Grant revenue | — | — | 345 | 1,402 | 337 |
| Total revenue | 2,431 | — | 971 | 2,670 | 1,170 |
| Operating expenses: | | | | | |
| Research and development | 19,861 | 16,435 | 12,007 | 11,999 | 9,858 |
| General and administrative | 10,352 | 8,469 | 6,639 | 4,228 | 4,605 |
| Total operating expenses | 30,213 | 24,904 | 18,646 | 16,227 | 14,463 |
| Loss from operations | (27,782) | (24,904) | (17,675) | (13,557) | (13,293) |
| Total other expense, net | (2,210) | (979) | (3,219) | (682) | (134) |
| Net loss and comprehensive loss | $(29,992) | $(25,883) | $(20,894) | $(14,239) | $(13,427) |
| Net loss per common share, basic and diluted | $(1.18) | $(1.27) | $(3.54) | $(13.06) | $(16.16) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 25,484,262 | 20,451,840 | 5,896,171 | 1,090,317 | 830,959 |
| Consolidated Balance Sheet Data (in thousands): | | | | | |
| Cash and cash equivalents | $64,809 | $49,101 | $54,036 | $9,087 | $6,387 |
| Working capital | 52,211 | 45,291 | 50,051 | 4,943 | 3,013 |
| Total assets | 67,958 | 51,183 | 55,583 | 11,076 | 7,852 |
| Convertible notes, net of discount | — | — | — | — | 1,000 |
| Warrant liability | — | — | — | 184 | 221 |
| Long-term debt, current portion | 7,550 | 1,535 | 1,732 | 1,941 | 248 |
| Long-term debt, net of current portion | 10,688 | 18,073 | — | 1,732 | 3,591 |
| Exchangeable share liability | — | — | — | 551 | 563 |
| Convertible preferred stock | — | — | — | 56,526 | 50,309 |
| Accumulated deficit | (142,384) | (112,392) | (86,509) | (65,615) | (51,376) |
| Total stockholders’ equity (deficit) | $38,038 | $28,340 | $50,848 | $(52,825) | $(50,683) |

ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included under Item 8 of this Annual Report on Form 10 K. The following discussion contains forward looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward looking statements as a result of various factors, including those set forth under the caption “Item 1A. Risk Factors.”

Overview

We are a clinical stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. We are developing our product candidates based on a simple notion: we believe that better cell therapies start with better cells. Our therapeutic approach, which we refer to as cell programming, utilizes pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of cells ex vivo, or outside the body. These programmed cells are then adoptively transferred to patients as therapies. We believe that this highly-differentiated therapeutic paradigm – systematically and precisely programming the biological properties and therapeutic function of cells ex vivo prior to adoptive transfer – is an elegant, cost-effective and scalable approach for maximizing the safety and efficacy of cell therapies. Utilizing our cell programming approach, we program immune cells, such as CD34+ cells, Natural Killer (NK) cells and T cells.

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We are advancing a pipeline of programmed cellular immunotherapies, including both donor-sourced and off-the-shelf, pluripotent cell-derived immune cell therapies, in the fields of immuno-oncology and immuno-regulation. Our clinical program is ProTmune™, a programmed immuno-regulatory cell therapy consisting of donor-sourced mobilized peripheral blood cells which have been modulated using two small molecules, for the prevention of acute graft-versus-host disease (GvHD) and cytomegalovirus (CMV) infection in immunocompromised patients undergoing allogeneic hematopoietic cell transplantation (HCT). Our preclinical programs include NK- and T-cell cancer immunotherapies, including off-the-shelf therapies derived from engineered induced pluripotent cells (denoted as an iNK Cell Therapy and an iT Cell Therapy, respectively), and a CD34+ cell immuno-regulatory therapy to suppress aberrant auto-reactive effector cells for autoimmune diseases.

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

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

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

- initiate and conduct clinical trials of our product candidates;
- continue our research and development activities, including under our collaboration agreements;
- manufacture preclinical study and clinical trial materials;
- maintain, prosecute, protect, expand and enforce our intellectual property portfolio;
- engage with regulatory authorities for the development of, and seek regulatory approvals for, our product candidates;
- hire additional clinical, regulatory, quality control and technical personnel to advance our product candidates;
- hire additional scientific personnel to advance our research and development efforts; and
- hire general and administrative personnel to continue operating as a public company and support our operations.

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

Financial Operations Overview

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Fate Therapeutics (Canada) Inc., or Fate Canada, that were outstanding at December 31, 2015 and directs all of its operational activities, which are insignificant. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc. and Fate Canada. All intercompany transactions and balances are eliminated in consolidation.

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Revenue

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

On May 4, 2015, we entered into a strategic research collaboration and license agreement (the "Agreement") with Juno Therapeutics, Inc. ("Juno") to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. In connection with the Agreement, we received an upfront, non-refundable payment of $5.0 million and $8.0 million for the purchase of 1,000,000 shares of our common stock at $8.00 per share. Based on the upfront payment and the premium paid on the share purchase, we recorded $8.4 million of deferred revenue to be recognized ratably as revenue over the initial four-year research term. Additionally, we will receive a minimum of $2.0 million in research funding annually during the initial four-year term. We account for the research funding as revenue using the gross method and record such amounts received from Juno as revenue when earned.

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

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

In connection with the Agreement, we have recognized $2.4 million during the year ended December 31, 2015 as collaboration revenue in the consolidated statements of operations. As of December 31, 2015, aggregate deferred revenue related to the Agreement was $7.3 million.

Collaboration revenues were also generated from our collaboration agreement with Becton, Dickinson and Company, or BD. In September 2010, we entered into a worldwide exclusive license and collaboration agreement with BD for the joint development and worldwide commercialization of certain induced pluripotent stem cell, or iPSC, tools and technologies for use in drug discovery and development. The license and collaboration agreement was assigned by BD to Corning Incorporated in October 2012. In connection with the agreement, we received an upfront, non-refundable license payment, and received research funding for the conduct of joint development activities during the three-year period ended September 30, 2013. In connection with the arrangement with BD, we recognized $0.6 million for the year ended December 31, 2013 as collaboration revenue in our consolidated statements of operations. We are eligible to receive certain commercialization milestones and royalties on the sale of iPSC reagent products. We do not anticipate generating any significant revenues under the agreement with BD in the future.

Grant revenue has been generated primarily through research and development grant programs offered by the U.S. government and its agencies. In April 2011, we were awarded a $2.1 million grant from the U.S. Army Telemedicine & Advanced Technology Research Center, or TATRC, to identify and develop regenerative medicines for acute sound-induced hearing loss. All funding under the TATRC grant was expended in full as of May 2013.

Research and Development Expenses

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

- salaries and employee-related costs, including stock-based compensation;
- costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs incurred under clinical trial agreements with investigative sites;
- costs incurred under our collaboration agreements;
- costs for laboratory supplies;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials;

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- charges associated with the achievement of milestones pursuant to our asset acquisition of Verio Therapeutics Inc., or Verio, that was completed in April 2010; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

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

- initiating and conducting our clinical trials of ProTmune to examine its safety and efficacy in adult patients with hematologic malignancies undergoing allogeneic HCT;
- conducting preclinical activities to investigate the therapeutic potential of our immuno-oncology programs, including our donor-sourced, adaptive NK-cell cancer immunotherapy and our off-the-shelf NK- and T-cell cancer immunotherapies derived from engineered induced pluripotent cells;
- conducting preclinical activities to investigate the therapeutic potential of our immuno-regulatory programs, including a hematopoietic cell therapy for suppressing auto-reactive T cells of patients with autoimmune disorders; and
- performing research activities under the agreement with Juno.

Due to the inherently unpredictable nature of preclinical and clinical development, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development of our product candidates, including ProTmune. Clinical and preclinical development timelines and costs, and the potential of development success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The following table summarizes our research and development expenses by major programs for the years ended December 31:

| (in thousands) | 2015 | 2014 | 2013 |
|---|---|---|---|
| Hematopoietic cell product candidates | $13,214 | $9,282 | $4,980 |
| Other preclinical programs and technologies | 2,790 | 4,234 | 3,527 |
| Total direct research and development expenses | 16,004 | 13,516 | 8,507 |
| Unallocated expenses | 3,857 | 2,919 | 3,500 |
| Total research and development expenses | $19,861 | $16,435 | $12,007 |

Unallocated expenses consist primarily of facility costs; general equipment and supply costs; depreciation; and other miscellaneous costs, all of which we do not allocate to specific programs as these expenses are deployed across all of our research and development operations.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting and maintaining our intellectual property; and

other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will increase in the future as we increase our research and development activities, maintain compliance with exchange listing and SEC requirements and continue to operate as a public company.

Other Income (Expense)

Other income (expense) consists primarily of interest income earned on cash and cash equivalents, interest expense on convertible notes and on amounts outstanding under our credit facilities, debt extinguishments, changes in the fair value of the exchangeable share liability, while outstanding, and changes in fair value of the warrant liability relating to our warrants that were exercisable for shares of our preferred stock prior to our initial public offering.

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Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

Our revenues have principally consisted of license fees, research and development funding, and milestone payments under our May 2015 license and collaboration agreement with Juno and our September 2010 license and collaboration agreement with BD, as well as funding received under government grants. Our license and collaboration agreements with Juno and BD each contains multiple elements, all of which are accounted for as collaboration revenue. We recognize revenues when all four of the following criteria are met: (i) persuasive evidence that an agreement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured.

Collaboration Revenues

Agreements entered into prior to 2011. For multiple element agreements entered into prior to January 1, 2011 and not materially modified thereafter, such as our agreement with BD, we analyzed the agreement to determine whether the elements within the agreement could be separated or whether they must be accounted for as a single unit of accounting. If the delivered element, which for us is commonly a license, has stand alone value and the fair value of the undelivered elements, which for us are generally collaboration research activities, can be determined, we recognized revenue separately under the residual method as the elements under the agreement are delivered. If the delivered element does not have stand alone value or if the fair value of the undelivered element cannot be determined, the agreement is then accounted for as a single unit of accounting, with consideration received under the agreement recognized as revenue on the straight line basis over the estimated period of performance, which for us is generally the expected term of the research and development activities.

Agreements entered into or materially modified after December 31, 2010. In October 2009, the Financial Accounting Standards Board, or FASB, issued a new accounting standard which amended the guidance on accounting for arrangements involving the delivery of more than one element. This standard addresses the determination of the unit(s) of accounting for multiple element arrangements and how the arrangement's consideration should be allocated to each unit of accounting. In January 2011, we adopted new authoritative guidance on revenue recognition for milestone payments related to agreements under which we have continuing performance obligations. As required under the new literature, we evaluate all milestones at the beginning of the agreement to determine if they meet the definition of a substantive milestone.

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

Collaboration arrangements providing for payments to us upon the achievement of research and development milestones generally involve substantial uncertainty as to whether any such milestone would be achieved. In the event a milestone is considered to be substantive, we expect to recognize future payments as revenue in connection with the milestone as it is achieved. Collaboration arrangements providing for payments to us upon the achievement of milestones that are solely contingent upon the performance of a collaborator also involve substantial uncertainty as to whether any such milestone would be achieved. For such contingent milestones,

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even if they do not meet the definition of a substantive milestone, since they are based solely upon a collaborator's effort, we expect to recognize future payments as revenue when earned under the applicable arrangement, provided that collection is reasonably assured.

Government Grant Revenue

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

Deferred Revenue

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

Accrued Research and Development Expenses

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

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

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

Stock Based Compensation

Stock based compensation expense represents the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight line

basis, net of estimated forfeitures. For stock option grants with performance based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants with both performance based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance based milestone is probable or the performance condition has been achieved. We estimate the fair value of stock option grants using the Black Scholes option pricing model, with the exception of option grants with both performance based milestones and market conditions, which are valued using a lattice based model. The fair value of restricted stock units is based on the closing price of our common stock as reported on The NASDAQ Global Market on the date of grant.

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

We generally estimate the fair value of our stock option awards to employees and non employees using the Black Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. Due to the lack of an adequate

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history of a public market for the trading of our common stock and a lack of adequate company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The risk free interest rates for periods within the expected life of the option are based on the yields of zero coupon U.S. Treasury securities. See Note 6 of the Notes to the Consolidated Financial Statements for additional information.

Total stock based compensation expense for the years ended December 31, 2015, 2014, and 2013, was $2.4 million, $2.4 million, and $1.6 million, respectively. Expense related to unvested employee stock option grants not yet recognized (excluding those with performance based conditions which are unachieved or determined not to be probable of achievement) as of December 31, 2015 was approximately $3.8 million and the weighted average period over which these grants are expected to vest is 2.8 years. As of December 31, 2015, the unrecognized compensation cost related to outstanding restricted stock units was $2.4 million, which is expected to be recognized as expense over approximately 3.8 years.

Determination of the Fair Value of Common Stock

Prior to our IPO, we were required to estimate the fair value of the common stock underlying our stock based awards when performing fair value calculations. The fair value of the common stock underlying our stock based awards was determined on each grant date by our board of directors, taking into account input from management and independent third party valuation analysis. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock prior to our IPO, on each grant date we developed an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock for grants made prior to our IPO were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation, or the Practice Aid.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- contemporaneous valuations prepared by an independent third party valuation specialist effective as of August 31, 2011, July 3, 2012, March 31, 2013, June 30, 2013 and August 12, 2013;
- the prices of our convertible preferred stock sold to investors in arm's length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preferences of our convertible preferred stock;
- our results of operations, financial position and the status of research and development efforts and achievement of enterprise milestones;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;

- our stage of development and business strategy and the material risks related to our business and industry;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an IPO, or a sale of our company, given prevailing market conditions; and
- the state of the IPO market for similarly situated privately held biotechnology companies prior to our IPO.

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There were significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates included assumptions made regarding our future operating performance, the time to completing an IPO or other liquidity events and the determination of the appropriate valuation methods. If we had made different assumptions, our stock based compensation expense, net loss and net loss per common share could have been significantly different.

Common Stock Valuation Methodologies

Our valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics.

February 2012 and March 2012 grants. On each of February 9, 2012, March 13, 2012 and March 23, 2012, our board of directors determined that the fair value of our common stock was $1.63 per share in connection with the grant of stock options. As part of each determination, our board of directors concluded that no significant internal or external value generating events had taken place between the August 2011 valuation analysis and the dates of these stock option grants.

July 2012 valuation and grants. The common stock fair value was estimated by our board of directors to be $1.37 per share in July 2012, with input from both management and an independent third party valuation specialist, in connection with the grant of stock options. The fair value per share of $1.37 represented a decrease of $0.26 per share from the $1.63 per share utilized for the March 2012 option grants. The decrease in fair value was primarily related to our issuance in May 2012 of Series C preferred stock at a price per share reflecting an enterprise value below that of our most recent preferred stock financing.

October 2012, December 2012, January 2013 and February 2013 grants. On each of October 10, 2012, December 12, 2012, January 14, 2013 and February 6, 2013, our board of directors determined that the fair value of our common stock was $1.37 per share in connection with the grant of stock options. As part of each determination, our board of directors concluded that no significant internal or external value generating events had taken place between the July 2012 valuation analysis and the dates of these stock option grants.

March 2013 valuation. The common stock fair value was estimated by our board of directors to be $1.63 per share in March 2013, with input from both management and an independent third party valuation specialist. The fair value per share of $1.63 represented an increase of $0.26 per share from the $1.37 per share utilized for the February 2013 option grants.

May 2013 grants. On May 13, 2013, our board of directors determined that the fair value of our common stock was $1.63 per share in connection with the grant of stock options. As part of this determination, our board of directors concluded that no significant internal or external value generating events had taken place between the March 2013 valuation analysis and the date of these stock option grants.

June 2013 valuation. The common stock fair value was estimated by our board of directors to be $4.49 per share in June 2013, with input from both management and an independent third party valuation specialist. The fair value per share of $4.49 represented an increase of $2.86 per share from the $1.63 per share utilized for the May 2013 option grants.

August 2013 valuation and grants. The common stock fair value was estimated by our board of directors to be $7.87 per share on August 12, 2013, with input from both management and an independent third party valuation specialist, in connection with the grant of stock options. The fair value per share of $7.87 represented an increase of $3.38 per share from the $4.49 per share utilized for the June 2013 valuation.

Initial public offering price

Our initial public offering price was $6.00 per share. In comparison, our estimate of the fair value of our common stock was determined to be $7.87 per share as of August 12, 2013 using a contemporaneous valuation prepared by management and an independent third party valuation specialist.

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Warrant Liability

Freestanding warrants for the purchase of convertible preferred stock were classified as liabilities on the consolidated balance sheets at their estimated fair value since the underlying convertible preferred stock was classified as temporary equity. At the end of each reporting period or at the time of conversion to warrants to purchase shares of the Company's common stock, changes in the estimated fair value during the period were recorded as a component of other income (expense). The freestanding warrants for the purchase of convertible preferred stock were converted into warrants to purchase shares of the Company's common stock in connection with the completion of our IPO on October 4, 2013. After such date, we no longer adjust the fair value of the warrants. Prior to the completion of our IPO, we estimated the fair value of the convertible preferred stock warrants using the Black Scholes option pricing model based on inputs as of the valuation measurement dates for: the estimated fair value of the underlying convertible preferred stock; the remaining contractual terms of the warrants; the risk free interest rates; the expected dividend yield; and the estimated volatility of the price of the convertible preferred stock.

Exchangeable Share Liability and Exchangeable Shares

In April 2010, we acquired Verio, a development stage company headquartered in Ottawa, Ontario. In connection with the acquisition, the stockholders of Verio received 900,000 non voting shares of Fate Canada (the "Exchangeable Shares") that were initially exchangeable into 138,462 shares of our common stock and, subject to the validation of certain scientific data and the achievement of certain preclinical, clinical, commercial and financial milestones, were exchangeable for up to 884,605 shares of our common stock.

Based on our evaluation of the set of activities and assets of Verio, at the acquisition date, we determined that Verio did not meet the definition of a business. In addition, we determined that Verio was a development stage enterprise without any material inputs; without any processes that create, or have the ability to create, outputs; and without any outputs. As such, the Verio acquisition was accounted for as an asset acquisition and we charged the $0.4 million purchase price to research and development expense. The initial purchase price of the Verio assets consisted of $0.2 million of assumed net liabilities and an initial exchangeable share liability of $0.2 million. This amount represents the estimated fair value of purchased in process technology for projects that, as of the acquisition date, had not yet reached technological feasibility and had no alternative future use.

Prior to our IPO, on the date of achievement of a milestone, the fair value of the related increase in the number of shares of our common stock into which the Exchangeable Shares were exchangeable was charged to research and development expense. Additionally, the fair value of the Exchangeable Shares was re measured at each reporting date, with any changes in fair value being recognized in the change in fair value of the exchangeable share liability, a component of other income (expense), in the accompanying consolidated statements of operations for the year ended December 31, 2013. The fair value of the exchangeable share liability was equal to the fair value of the number of shares of our common stock into which the Exchangeable Shares were exchangeable.

During the year ended December 31, 2014, based on the achievement of certain preclinical milestones, 38,463 shares of our common stock of the Company were earned and issued, resulting in a $0.4 million charge to research and development expense. During the year ended December 31, 2013, we recorded a charge of $0.3 million to research and development expense related to an increase in the number of shares of common stock issuable upon the exchange of the Exchangeable Shares of 76,922 shares. In April 2015, the contractual earn-out period during which milestones were eligible to be earned and achieved expired under the Verio agreement, and, as such, there are no additional contractual milestones that remain eligible for achievement. Accordingly, no additional shares of the Company's common stock remain issuable under the Verio agreement.

For the year ended December 31, 2013, we recorded other expense related to the change in fair value of the Exchangeable Shares of $2.4 million. During the fourth quarter of 2013, we adjusted the exchangeable share liability to its then current fair value upon the closing of our IPO, and reclassified the liability to additional paid in capital.

Other Company Information

JOBS Act

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

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

Recent Accounting Pronouncements

For a discussion of recently issued accounting pronouncements, please see Note 1 of the Notes to the Consolidated Financial Statements.

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

The following table summarizes the results of our operations for the years ended December 31, 2015 and 2014:

| | Years Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| | (in thousands) | |
| Collaboration revenue | $2,431 | $— |
| Research and development expenses | 19,861 | 16,435 |
| General and administrative expenses | 10,352 | 8,469 |
| Total other income (expense), net | (2,210) | (979) |

Revenue. During the year ended December 31, 2015, we recognized revenue of $2.4 million under the Agreement with Juno, which we entered into in May 2015.

Research and development expenses. Research and development expenses were $19.9 million for the year ended December 31, 2015, compared to $16.4 million for the year ended December 31, 2014. The $3.5 million increase in research and development expenses primarily reflects the following:

- $1.3 million increase in employee compensation and benefits expense, including employee stock based compensation expense, primarily relating to an increase in employee headcount to support the conduct of our research activities;
- $0.9 million increase in third-party professional consultant and service provider expenses relating to the clinical development of our product candidates and the conduct of our research activities; and
- $0.9 million increase in expenditures for laboratory equipment and supplies relating to the conduct of our clinical trials and our research activities.

General and administrative expenses. General and administrative expenses were $10.4 million for the year ended December 31, 2015, compared to $8.5 million for the year ended December 31, 2014. The $1.9 million increase in general and administrative expenses primarily reflects the following:

- $0.6 million increase in employee compensation and benefits expense, including stock-based compensation expense;
- $0.5 million increase in intellectual property related expenses;
- $0.3 million increase in facility and infrastructure related expenses; and
- $0.2 million increase in third party service fees, including accounting and legal professional services fees, to support our operations as a public company.

Other expense, net. Other expense, net, was $2.2 million for the year ended December 31, 2015, compared to $1.0 million for the year ended December 31, 2014. The $1.2 million change in other expenses, net, was primarily due to a $1.7 million increase in interest expense relating to our term loans with Silicon Valley Bank, partially offset by a $0.4 million loss on debt extinguishment during the year ended December 31, 2014.

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Comparison of Years Ended December 31, 2014 and 2013

The following table summarizes the results of our operations for the years ended December 31, 2014 and 2013:

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (in thousands) | |
| Collaboration revenue | $— | $626 |
| Grant revenue | — | 345 |
| Research and development expenses | 16,435 | 12,007 |
| General and administrative expenses | 8,469 | 6,639 |
| Total other income (expense), net | (979) | (3,219) |

Revenue. We did not generate any revenue for the year ended December 31, 2014, compared to $1.0 million for the year ended December 31, 2013. The decrease was due to the completion of a government grant in May 2013, and the conclusion of the three year joint development period under our license and collaboration agreement with BD in September 2013. We do not expect to generate any significant revenue under these agreements in the future.

Research and development expenses. Research and development expenses were $16.4 million for the year ended December 31, 2014, compared to $12.0 million for the year ended December 31, 2013. The $4.4 million increase in research and development expenses primarily reflects the following:

- $2.3 million increase in employee compensation and benefits expense, including employee stock based compensation expense, relating to an increase in employee headcount to support the clinical development of ProHema and the preclinical development of our other product candidates;
- $1.5 million increase in third party professional consultant and service provider expenses relating to the preparation for and conduct of our PUMA study and the preparation for the commencement of our PROMPT and PROVIDE studies of ProHema; and a
- $1.0 million increase in expenditures for laboratory equipment and supplies relating to the preparation and conduct of our clinical trials, and to the conduct of our preclinical research activities; which were partially offset by a
- $0.5 million decrease in non employee stock based compensation expense.

General and administrative expenses. General and administrative expenses were $8.5 million for the year ended December 31, 2014, compared to $6.6 million for the year ended December 31, 2013. The $1.9 million increase in general and administrative expenses primarily reflects the following:

- $1.4 million increase in compensation and benefits expense, including employee stock based compensation expense, relating to an increase in employee headcount to support the expansion of our financial and administrative operations;
- $0.4 million increase in corporate insurance fees, including director and officer insurance premiums; and a
- $0.4 million increase in third party service fees, including accounting and legal professional services fees and exchange listing fees, to support our operations as a public company; which were partially offset by a
- $0.3 million decrease in non employee stock based compensation expense; and a

- $0.2 million decrease in intellectual property related expenses.

Other expense, net. Other expense, net, was $1.0 million for the year ended December 31, 2014, compared to $3.2 million for the year ended December 31, 2013. The $2.2 million decrease in other expenses, net, was primarily due to a non recurring $0.4 million loss on the extinguishment of debt during the year ended December 31, 2014, which was offset by a non recurring $2.4 million fair value charge on the exchangeable share liability during the year ended December 31, 2013.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of December 31, 2015, we had an accumulated deficit of $142.4 million and anticipate that we will continue to incur net losses for the foreseeable future.

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

| | 2015 | 2014 | 2013 |
|---|---|---|---|
| | (in thousands) | | |
| Net cash used in operating activities | $(18,397) | $(22,419) | $(15,373) |
| Net cash used in investing activities | (1,498) | (882) | (238) |
| Net cash provided by financing activities | 35,603 | 18,366 | 60,560 |
| Net increase (decrease) in cash and cash equivalents | $15,708 | $(4,935) | $44,949 |

Operating Activities

Cash used in operating activities decreased from $22.4 million for the year ended December 31, 2014 to $18.4 million for the year ended December 31, 2015. The primary driver of this change in cash used in operating activities was $7.3 million in deferred revenue resulting from the Agreement with Juno in May 2015, offset by our increase in net loss from 2014 to 2015.

Cash used in operating activities increased from $15.4 million for the year ended December 31, 2013 to $22.4 million for the year ended December 31, 2014. The primary driver of operating cash requirements was our net loss in each period.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement with Juno to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. Pursuant to the terms of the Agreement, Juno paid us an upfront payment of $5.0 million, and purchased one million shares of our common stock, at $8.00 per share, for an aggregate purchase price of $8.0 million. Additionally, Juno agreed to fund all of our collaboration research activities for an initial four-year research term beginning on the effective date of the Agreement, with minimum annual research payments of $2.0 million to us. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of an extension fee of $3.0 million and the continued funding of our activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to us during the two-year extension period. As of December 31, 2015, we have received a total of $1.3 million of such research payments.

We are eligible under the Agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. Additionally, in connection with each Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million, in the aggregate, per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates our small molecule modulators, Juno has agreed to pay us additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones. As of December 31, 2015, no selection fees or milestone payments have been received by us.

Beginning on the date of the first commercial sale (in each country) for each Juno therapy that uses or incorporates our small molecule modulators, and continuing until the later of i) the expiration of the last valid patent claim, ii) ten years after such first commercial sale, or iii) the expiration of all data and other regulatory exclusivity periods afforded each therapy, Juno has agreed to pay us royalties in the low single-digits on net sales of each Juno therapy that uses or incorporates our small molecule modulators. As of December 31, 2015, no royalties have been received by us.

Investing Activities

During the years ended December 31, 2015, 2014 and 2013, investing activities used cash of $1.5 million, $0.9 million and $0.2 million, respectively, for the purchase of property and equipment.

Financing Activities

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

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Financing activities provided cash of $18.4 million for the year ended December 31, 2014, primarily from $20.0 million of proceeds from long term borrowings, offset by $1.8 million of principal payments on our long-term debt.

Financing activities provided cash of $60.6 million for the year ended December 31, 2013, primarily from net proceeds from our IPO of $40.5 million and $23.7 million of proceeds from the issuance of convertible promissory notes, offset by $2.0 million of principal payments on our long-term debt under our loan and security agreement and $1.7 million of payments of outstanding principal and accrued interest on the convertible promissory notes.

From our inception through December 31, 2015 we have funded our consolidated operations primarily through the public sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of December 31, 2015, we had cash and cash equivalents of $64.8 million.

In May 2015, we completed a public offering of common stock in which we sold 6,900,000 shares of our common stock at an offering price of $5.00 per share. Gross proceeds from the offering were $34.5 million. Total underwriting discounts, commissions, and other cash costs related to the offering were $2.4 million. After giving effect to all such costs, total net proceeds from the offering were $32.1 million.

Silicon Valley Bank Debt Facility

On July 30, 2014, we entered into an Amended and Restated Loan and Security Agreement (the “Restated LSA”) with Silicon Valley Bank (the “Bank”), collateralized by substantially all of our assets, excluding certain intellectual property. The Restated LSA amends and restates the Loan and Security Agreement, dated as of January 5, 2009, as amended, by and between the Company and the Bank (the “Loan Agreement”). Pursuant to the Restated LSA, the Bank agreed to make loans to us in an aggregate principal amount of up to $20.0 million, comprised of (i) a $10.0 million term loan, funded at the closing date (the “Term A Loan”) and (ii) subject to the achievement of a specified clinical milestone relating to our Phase 2 clinical trial of ProHema, additional term loans totaling up to $10.0 million in the aggregate, which were available until December 31, 2014 (each, a “Term B Loan”). On December 24, 2014, the Company elected to draw $10.0 million under the Term B Loan.

The Term A Loan and the Term B Loan mature on January 1, 2018 and June 1, 2018, respectively and bear interest at a fixed annual rate of 6.94% and 7.07%, respectively. Interest became payable in cash on a monthly basis beginning the first day of each month following the month in which the funding date of each loan occurred. The Company is required to make a monthly payment of interest only during the first twelve months following the funding date of each loan, and thereafter is required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty month amortization schedule. During the year ended December 31, 2015, the Company made principal payments totaling $1.5 million on the Term A Loan.

The Company is required to make a final payment fee of 7.5%, equaling $0.8 million, of the funded amount for each of the Term A Loan and Term B Loan on their respective maturity dates.

A portion of the proceeds from the Term A Loan were used to repay loans outstanding under the Loan Agreement and to pay for transaction fees related to the Restated LSA, including a commitment fee of $0.4 million paid by the Company to the Bank. Net proceeds from the Term A Loan, after repayment of loans outstanding under the Loan Agreement and transaction fees, were $8.8 million.

Proceeds from the Term B Loan were $10.0 million. In connection with the funding of the Term B Loan, the Company issued the Bank and one of its affiliates fully exercisable warrants to purchase an aggregate of 98,039 shares of the Company's common stock (the "Warrants") at an exercise price of $4.08 per share. The Warrants expire in December 2021. The aggregate fair value of the Warrants was determined to be $0.4 million using the Black Scholes option pricing model (see Notes 5 and 6 of the Notes to the Consolidated Financial Statements for additional information).

The net proceeds from the Term A and Term B Loans have been used for, and we expect to continue to use net proceeds for, working capital purposes, including the research and development of our product candidates and cellular programming technology.

Shelf Registration Statement

In October 2014, the SEC declared effective a shelf registration filed by us in October 2014. The shelf registration statement allows us to issue certain securities, including shares of our common stock, from time to time. The specific terms of any offering, if any, under the shelf registration statement would be established at the time of such offering. As of March 3, 2016, after taking into

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account the May 2015 public offering of common stock, we are eligible to issue an aggregate of $65.5 million in securities under the shelf registration statement.

Agreement with Juno Therapeutics, Inc.

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

See the Operating Activities in the “Liquidity and Capital Resources” section above for further discussion on the Agreement.

Initial Public Offering and 2013 Convertible Note Financings

On October 4, 2013, we completed our IPO, whereby we sold 7,666,667 shares of common stock at a public offering price of $6.00 per share. Gross proceeds from the offering were $46.0 million. After giving effect to underwriting discounts, commissions, and other cash costs related to the offering, net proceeds were $40.5 million.

In June and July 2013, we issued convertible promissory notes in an aggregate principal amount of $3.7 million to certain existing stockholders. In connection with the completion of our IPO on October 4, 2013, the outstanding principal and all accrued and unpaid interest due on the notes converted to 625,828 shares of our common stock. The notes accrued interest at 2% per year.

In August 2013, we issued convertible promissory notes in an aggregate principal amount of $20.0 million to certain new investors. In connection with the completion of our IPO on October 4, 2013, we repaid $1.7 million of then outstanding principal and unpaid accrued interest on the notes in cash, with the remaining outstanding principal converting to 3,053,573 shares of our common stock. The notes accrued interest at 2% per year.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the research and development of, and seek regulatory approvals for, our product candidates. Our product candidates have not yet achieved regulatory approval, and we may not be successful in achieving commercialization of our product candidates.

We believe our existing cash and cash equivalents as of December 31, 2015 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the

probability of success, the duration and the cost of our research and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research and development of our product candidates, and we may be forced to seek additional funds sooner than expected to pursue our research and development activities. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity or debt securities. However, additional capital may not be available to us on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the research or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects.

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

- the initiation, timing, progress, size, duration, costs and results of our preclinical studies and clinical trials for our product candidates;
- the number and the nature of product candidates that we pursue;
- the cost of procuring clinical supplies of our product candidates;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;
- the extent to which milestones are achieved under our collaboration agreement with Juno, and the time to achievement of such milestones;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the expansion of our research and development activities, including our need and ability to hire additional employees and procure additional equipment, materials and supplies;
- the implementation of additional infrastructure and internal systems, and the hiring of additional employees, to operate as a public company;
- the establishment and continuation of collaborations and strategic alliances;
- the timing and terms of future in-licensing and out-licensing transactions; and
- the cost of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval.

If we cannot continue or expand our research and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2015 that are expected to affect our liquidity and cash flows in future periods:

| (in thousands) | Total | Less than 1 Year | Years 1 - 3 | Years 3 - 5 | More than 5 Years |
|---|---|---|---|---|---|
| Long-term debt (including interest and fees) | $21,569 | $8,757 | $12,812 | $ — | $ — |
| Operating lease obligations | 2,358 | 1,270 | 1,088 | — | — |
| Total | $23,927 | $10,027 | $13,900 | $ — | $ — |

We also have obligations under various license agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing for product approval with the FDA or other regulatory agencies, product approval by the FDA or other regulatory agencies, product launch or product sales) or on the sublicense of our rights to another party. We have not included these commitments on our balance sheet or in the table above because the achievement and timing of these events is not fixed and determinable. Certain milestones are in advance of receipt of revenue from the sale of products and, therefore, we may require additional debt or equity capital to make such payments. These commitments include:

- Under an exclusive license agreement with Children's Medical Center Corporation pursuant to which we license certain patents relating to our ex vivo cell programming approach and our programmed hematopoietic cell therapies, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $5.0 million. We will also be required to pay a royalty on net sales of

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products covered by the in licensed intellectual property in the low to mid single digits. The royalty is subject to reduction for any third party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.

- Under an exclusive license agreement with the Whitehead Institute for Biomedical Research, pursuant to which we license certain patents relating to the reprogramming of somatic cells, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $2.3 million. We will also be required to pay a royalty on net sales of products covered by the in licensed intellectual property in the low single digits. The royalty is subject to reduction for any third party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- We are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by various exclusive license agreements with The Scripps Research Institute, or TSRI, pursuant to which we license certain patents relating to the use of small molecules in the reprogramming of somatic cells. We will also be required to pay a royalty on net sales of products covered by the in licensed intellectual property in the low to mid single digits. The royalty is subject to reduction for any third party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, but will be required to pay a percentage of any sublicense income.

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

Off Balance Sheet Arrangements

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

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2015, we had cash and cash equivalents of $64.8 million, including $35.3 million of money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in short term securities. Due to the short term duration of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not be expected to have a material effect on the fair market value of our portfolio.

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ITEM 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Fate Therapeutics, Inc.

We have audited the consolidated balance sheets of Fate Therapeutics, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Fate Therapeutics, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 3, 2016

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Fate Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except par value and share data)

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $64,809 | $49,101 |
| Prepaid expenses and other current assets | 843 | 760 |
| Total current assets | 65,652 | 49,861 |
| Property and equipment, net | 2,160 | 1,200 |
| Restricted cash | 122 | 122 |
| Other assets | 24 | — |
| Total assets | $67,958 | $51,183 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | $996 | $645 |
| Accrued expenses | 2,439 | 2,260 |
| Current portion of deferred rent | 54 | 85 |
| Current portion of deferred revenue | 2,401 | — |
| Repurchase liability for unvested equity awards | 1 | 45 |
| Long–term debt, current portion | 7,550 | 1,535 |
| Total current liabilities | 13,441 | 4,570 |
| Deferred rent | 58 | 51 |
| Deferred revenue | 4,934 | — |
| Accrued expenses | 799 | 149 |
| Long–term debt, net of current portion | 10,688 | 18,073 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' Equity: | | |
| Preferred stock, $0.001 par value; authorized shares—5,000,000 at December 31, 2015 and December 31, 2014; no shares issued or outstanding | — | — |
| Common stock, $0.001 par value; authorized shares—150,000,000 at December 31, 2015 and December 31, 2014; issued and outstanding—28,716,570 at December 31, 2015 and 20,569,399 at December 31, 2014 | 29 | 21 |
| Additional paid–in capital | 180,393 | 140,711 |

| | | |
|---|---|---|
| Accumulated deficit | (142,384) | (112,392) |
| Total stockholders' equity | 38,038 | 28,340 |
| Total liabilities and stockholders' equity | $67,958 | $51,183 |

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Revenue: | | | |
| Collaboration revenue | $2,431 | $— | $626 |
| Grant revenue | — | — | 345 |
| Total revenue | 2,431 | — | 971 |
| Operating expenses: | | | |
| Research and development | 19,861 | 16,435 | 12,007 |
| General and administrative | 10,352 | 8,469 | 6,639 |
| Total operating expenses | 30,213 | 24,904 | 18,646 |
| Loss from operations | (27,782) | (24,904) | (17,675) |
| Other income (expense): | | | |
| Interest income | 10 | 2 | 6 |
| Interest expense | (2,220) | (549) | (796) |
| Loss on extinguishment of debt | — | (432) | — |
| Change in fair value of exchangeable shares | — | — | (2,421) |
| Change in fair value of warrant liability | — | — | (8) |
| Total other expense, net | (2,210) | (979) | (3,219) |
| Net loss and comprehensive loss | $(29,992) | $(25,883) | $(20,894) |
| Net loss per common share, basic and diluted | $(1.18) | $(1.27) | $(3.54) |
| Weighted–average common shares used to compute basic and diluted net loss per share | 25,484,262 | 20,451,840 | 5,896,171 |

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| Balance at December 31, 2012 | 44,967,690 | 56,526 | 1,334,115 | 1 | 12,789 | (65,615) | (52,825) |
| Exercise of stock options | — | — | 35,852 | — | 23 | — | 23 |
| Repurchase liability for unvested equity awards | — | — | — | — | 49 | — | 49 |
| Stock–based compensation | — | — | — | — | 1,554 | — | 1,554 |
| Issuance of common stock for technology | — | — | 7,692 | — | 13 | — | 13 |
| Beneficial conversion feature related to convertible notes | — | — | — | — | 336 | — | 336 |
| Impact of initial public offering: | | | | | | | |
| Initial public offering of common stock, net of $5,520 of offering costs | — | — | 7,666,667 | 8 | 40,472 | — | 40,480 |
| Conversion of convertible preferred stock into common stock | (44,967,690) | (56,526) | 7,229,590 | 7 | 56,519 | — | 56,526 |
| Conversion of convertible notes into common stock | — | — | 3,679,401 | 4 | 22,072 | — | 22,076 |
| Exchange of exchangeable shares into common stock | — | — | 480,763 | — | 3,318 | — | 3,318 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Warrant liability reclassification | — | — | — | — | 192 | — | 192 |
| Net loss | — | — | — | — | — | (20,894) | (20,894) |
| Balance at December 31, 2013 | — | — | 20,434,080 | 20 | 137,337 | (86,509) | 50,848 |
| Exercise of stock options, net of issuance costs | — | — | 96,856 | 1 | 141 | — | 142 |
| Repurchase liability for unvested equity awards | — | — | — | — | 49 | — | 49 |
| Stock–based compensation | — | — | — | — | 2,434 | — | 2,434 |
| Issuance of warrants for common stock | — | — | — | — | 375 | — | 375 |
| Issuance of stock on achievement of milestone | — | — | 38,463 | — | 375 | — | 375 |
| Net loss | — | — | — | — | — | (25,883) | (25,883) |
| Balance at December 31, 2014 | — | $— | 20,569,399 | $ 21 | $ 140,711 | $ (112,392) | $ 28,340 |
| Exercise of stock options, net of issuance costs | — | — | 227,215 | — | 420 | — | 420 |
| Repurchase liability for unvested equity awards | — | — | — | — | 44 | — | 44 |
| Stock–based compensation | — | — | — | — | 2,400 | — | 2,400 |
| Senior executive incentive bonuses paid in common stock | — | — | 19,956 | — | 97 | — | 97 |
| Public offering of common stock, net of $2,353 of offering costs | — | — | 6,900,000 | 7 | 32,142 | — | 32,149 |
| Issuance of common stock to collaboration partner | — | — | 1,000,000 | 1 | 4,579 | — | 4,580 |
| Net loss | — | — | — | — | — | (29,992) | (29,992) |
| Balance at December 31, 2015 | — | $— | 28,716,570 | $ 29 | $ 180,393 | $ (142,384) | $ 38,038 |

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Cash flows from operating activities | | | |
| Net loss | $(29,992) | $(25,883) | $(20,894) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Depreciation and amortization | 687 | 496 | 571 |
| Issuances of common stock for technology | — | — | 13 |
| Stock–based compensation | 2,400 | 2,434 | 1,554 |
| Amortization of discounts | 176 | 24 | 394 |
| Noncash interest expense | 651 | 167 | 147 |
| Deferred rent | (24) | (52) | (195) |
| Deferred revenue | 7,335 | — | (63) |
| Stock–based milestone charges and change in fair value of exchangeable shares | — | 375 | 2,767 |
| Change in fair value of preferred stock warrants | — | — | 8 |
| Loss on disposal of assets | — | — | 18 |
| Loss on extinguishment of debt | — | 3 | — |
| Changes in assets and liabilities: | | | |
| Prepaid expenses and other assets | (107) | (146) | (1,271) |
| Accounts payable and accrued expenses | 477 | 163 | 1,578 |
| Net cash used in operating activities | (18,397) | (22,419) | (15,373) |
| Cash flows from investing activities | | | |
| Purchase of property and equipment | (1,498) | (882) | (244) |
| Proceeds from sale of property and equipment | — | — | 6 |
| Net cash used in investing activities | (1,498) | (882) | (238) |
| Cash flows from financing activities | | | |
| Issuance of common stock, net of repurchases and issuance cost | 420 | 142 | 23 |
| Proceeds from public offering of common stock, net of issuance costs | 32,149 | — | 40,480 |
| Issuance of convertible promissory notes | — | — | 23,736 |
| Proceeds from sale of common stock to collaboration partner | 4,580 | — | — |
| Proceeds from long–term debt | — | 20,000 | — |
| Payments on long–term debt | (1,546) | (1,750) | (2,000) |
| Payment on convertible promissory note | — | — | (1,679) |
| Payments for the issuance of debt | — | (26) | — |
| Net cash provided by financing activities | 35,603 | 18,366 | 60,560 |
| Net change in cash and cash equivalents | 15,708 | (4,935) | 44,949 |
| Cash and cash equivalents at beginning of the period | 49,101 | 54,036 | 9,087 |
| Cash and cash equivalents at end of the period | $64,809 | $49,101 | $54,036 |

| | | | |
|---|---|---|---|
| Supplemental disclosure of cash flow information | | | |
| Interest paid | $1,353 | $494 | $250 |
| Supplemental schedule of noncash investing and financing activities | | | |
| Issuance of warrants for common stock in connection with long–term debt | $— | $375 | $— |
| Beneficial conversion feature related to convertible notes | $— | $— | $336 |
| Conversion of convertible preferred stock into common stock | $— | $— | $56,526 |
| Conversion of convertible notes into common stock | $— | $— | $22,076 |
| Exchange of exchangeable shares into common stock | $— | $— | $3,318 |
| Warrant liability reclassification to equity | $— | $— | $192 |

See accompanying notes.

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Fate Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Fate Therapeutics, Inc. (the "Company") was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's cell therapy pipeline is comprised of immuno-oncology programs, including off-the-shelf NK- and T-cell cancer immunotherapies derived from engineered induced pluripotent cells, and immuno-regulatory programs, including hematopoietic cell immunotherapies for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing autoimmunity. Its adoptive cell therapy programs are based on the Company's novel ex vivo cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of December 31, 2015, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

Initial Public Offering

On October 4, 2013, the Company completed its initial public offering (the "IPO") whereby it sold 7,666,667 shares of common stock at a public offering price of $6.00 per share. Gross proceeds from the offering were $46.0 million. After giving effect to underwriting discounts, commissions and other cash costs related to the offering, net proceeds were $40.5 million. In addition, each of the following occurred in connection with the completion of the IPO on October 4, 2013:

- the conversion of all outstanding shares of the Company's convertible preferred stock into 7,229,590 shares of the Company's common stock;
- the conversion of the Company's $22.1 million of outstanding principal and accrued interest on its convertible notes into 3,679,401 shares of common stock, the write off of $0.3 million of unamortized debt discount and the related cash repayment of $1.7 million of outstanding principal and accrued interest on the convertible notes;
- the issuance of 480,763 shares of the Company's common stock pursuant to the redemption of an aggregate of 900,000 exchangeable shares of Fate Therapeutics (Canada) Inc. ("Fate Canada"), a subsidiary of the Company incorporated in Canada, resulting in a final fair value adjustment charge of $0.4 million on the exchangeable shares, and the resultant reclassification of the exchangeable share liability to additional paid in capital;
- the conversion of warrants to purchase 230,000 shares of convertible preferred stock into warrants to purchase 36,074 shares of the Company's common stock, and the resultant reclassification of the warrant liability to additional paid in capital; and
- the filing of an amended and restated certificate of incorporation on October 3, 2013, authorizing 150,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

Follow-on Public Equity Offering

In May 2015, the Company completed a public offering of common stock in which the Company sold 6,900,000 shares of its common stock at an offering price of $5.00 per share. Gross proceeds from the offering were $34.5

million. Total underwriting discounts, commissions, and other cash costs related to the offering were $2.4 million. After giving effect to all such costs, total net proceeds from the offering were $32.1 million.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with United States generally accepted accounting principles ("GAAP"). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to accrued expenses. Although these estimates are based on the Company's

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knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Therapeutics (Canada), Inc. or "Fate Canada", incorporated in Canada, Fate Therapeutics Ltd., incorporated in the United Kingdom, and Destin Therapeutics Inc., incorporated in Canada, which was dissolved in June 2014. To date, the aggregate operations of these subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Segment Reporting

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

Fair Value of Financial Instruments

The carrying amounts of accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long term debt approximates its carrying value.

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

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

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

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

As of each of December 31, 2015 and 2014, the carrying amount of cash equivalents was $35.3 million, which approximates fair value and was determined based upon Level 1 inputs. Cash equivalents primarily consisted of money market funds. As of December 31, 2015 and 2014, the Company did not hold any Level 2 or Level 3 financial assets that are recorded at fair value on a recurring basis.

As of December 31, 2015 and 2014, the Company had no liabilities measured at fair value on a recurring basis. Financial liabilities that were previously measured at fair value on a recurring basis include the preferred stock warrant liability and exchangeable shares for the period the liabilities were outstanding. The preferred stock warrant

liability was recorded at fair value using the Black Scholes option pricing model and the exchangeable share liability was recorded at fair value based on the fair value of the underlying common stock. These liabilities were reclassified from liabilities to stockholders' equity as a result of the completion of the Company's IPO on October 4, 2013, which was the final fair value measurement date for each.

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

Cash and Cash Equivalents

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

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Concentration of Credit Risk

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

Property and Equipment

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

Impairment of Long Lived Assets

Long lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long lived assets and, accordingly, has not recognized any impairment losses since inception.

Deferred Rent

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

Revenue Recognition

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

Revenue arrangements with multiple elements are analyzed to determine whether the elements can be divided into separate units of accounting or whether the elements must be accounted for as a single unit of accounting. The Company divides the elements into separate units of accounting and applies the applicable revenue recognition criteria to each of the elements, if the delivered elements have value to the customer on a stand-alone basis, if the arrangement includes a general right of return relative to the delivered elements, and if the delivery or performance of the undelivered elements is considered probable and substantially within the Company's control.

For transactions entered into prior to 2011, revenue was allocated to each element based on its relative fair value when objective and reliable evidence of fair value existed for all elements in an arrangement. If an element was sold on a stand-alone basis, the fair value of the element was the price charged for the element. When the Company was unable to establish fair value for delivered elements or when fair value of undelivered elements had not been established,

revenue was deferred until all elements were delivered or until fair value could be objectively determined for any undelivered elements.

Beginning in 2011, revenue has been allocated to each element at the inception of the arrangement using the relative selling price method that is based on a three-tier hierarchy. The relative selling price method requires that the estimated selling price for each element be based on vendor-specific objective evidence ("VSOE") of fair value, which represents the price charged for each element when it is sold separately or, for an element not yet being sold separately, the price established by management. When VSOE of fair value is not available, third-party evidence ("TPE") of fair value is acceptable, or a best estimate of selling price is used if neither VSOE nor TPE is available. A best estimate of selling price should be consistent with the objective of determining the price at which the Company would transact if the element were sold regularly on a stand-alone basis and should also take into account market conditions and company-specific factors.

Revenue arrangements with multiple elements may include license fees, research and development payments, milestone payments, other contingent payments, and royalties on any product sales derived from collaborations. The Company recognizes nonrefundable license fees with stand-alone value as revenue at the time that the Company has satisfied all performance obligations,

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

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

Research and Development Costs

All research and development costs are expensed as incurred.

Patent Costs

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

Stock Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. For stock option grants for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants for which vesting is subject to both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants for which vesting is subject to both performance-based milestones and market conditions, which are valued using a lattice-based model. The fair value of restricted stock units is based on the closing price of the Company's common stock as reported on The NASDAQ Global Market on the date of grant.

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

Income Taxes

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

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

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

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Excluded from the weighted average number of shares outstanding are shares which have been issued upon the early exercise of stock options and are subject to future vesting and unvested restricted stock totaling 44,381 shares, 76,947 shares, and 107,570 shares for the years ended December 31, 2015, 2014, and 2013, respectively. Diluted net loss per common share is calculated by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury stock method. Dilutive common stock equivalents are comprised of convertible preferred stock, warrants for the purchase of convertible preferred stock and common stock, exchangeable shares and common stock options outstanding under the Company's stock option plans. For all periods presented, there is no difference in the number of common shares used to calculate basic and diluted common shares outstanding due to the Company's net loss position.

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

| | As of December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Warrants for common stock | 134,113 | 134,113 | 36,074 |
| Common stock options | 2,587,474 | 2,425,969 | 1,726,991 |
| | 2,721,587 | 2,560,082 | 1,763,065 |

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2016-02 (ASU 2016-02). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its Consolidated Financial Statements.

In November 2015, the FASB issued ASU 2015-17, which requires that all deferred tax assets and liabilities be classified as noncurrent on the balance sheet, instead of separating deferred taxes into current and noncurrent amounts. The update is effective for financial statements issued for fiscal years beginning after December 15, 2016. As early adoption of this amendment is permitted, the Company has adopted the update prospectively during the year ended December 31, 2015. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

In April 2015, the FASB issued ASU 2015-03, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The update is effective for financial statements issued for fiscal years beginning after December 15, 2015. As early adoption of this amendment is permitted, the Company has implemented the update accordingly by reclassifying prior period and current period amounts from assets to liabilities. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

In August 2014, the FASB issued ASU 2014-15, which defined management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosure. ASU 2014-15 defined the term substantial doubt and requires an assessment for a period of one year after the date of the issuance of the financial statements. It

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requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The guidance becomes effective for reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not believe that the adoption of this guidance will have a material impact on its Consolidated Financial Statements.

In May 2014, the FASB issued ASU 2014-09, which created a single, principle-based revenue recognition model that will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. The model provides that entities follow five steps: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue. For public business entities, the guidance becomes effective for annual reporting periods beginning after December 15, 2017, and interim periods therein. The Company is currently evaluating the impact the adoption of this guidance will have on its Consolidated Financial Statements.

2. Collaboration and License Agreements

Juno Collaboration Agreement

On May 4, 2015, the Company entered into a strategic research collaboration and license agreement (the "Agreement") with Juno Therapeutics, Inc. ("Juno") to screen for and identify small molecules that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. Pursuant to the terms of the Agreement, Juno paid the Company a non-refundable upfront payment of $5.0 million and purchased 1,000,000 shares of the Company's common stock at a price of $8.00 per share.

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

The Company applied Accounting Standards Codification ("ASC") 605-25, Revenue Recognition — Multiple Element Arrangements, to evaluate the appropriate accounting for the Agreement. In accordance with this guidance, the Company assessed the potential deliverables, including an exclusive license granted by the Company to Juno for certain intellectual property and research services to be performed by the Company, and determined that the deliverables did not have stand-alone value. The Company determined that the license deliverable granted under the Agreement does not have standalone value given the highly specific nature of the small molecules to be identified for use with Juno's genetically-engineered T-cell immunotherapies. The Company concluded that there is one single unit of accounting, and the arrangement consideration will be recognized in the same manner as the final deliverable, which is the research services. As such, the upfront payment of $5.0 million was recorded as deferred revenue and is

being recognized over the initial four-year research term under the Agreement. With respect to the $8.0 million payment for the Company's common stock, the Company determined that the common stock purchase price of $8.00 per share represented a premium of $3.40 per share. This premium represents arrangement consideration and therefore the aggregate premium of $3.4 million was recorded as deferred revenue and is being recorded as revenue ratably over the initial four-year research term. The remaining $4.6 million consideration that represents the purchase of common stock was recorded as the issuance of common stock in shareholders' equity.

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

Total revenue recognized under the Agreement for year ended December 31, 2015 was $2.4 million. As of December 31, 2015, aggregate deferred revenue related to the Agreement was $7.3 million.

Under the Agreement, the Company has granted Juno an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the collaboration, to make, use, sell and otherwise exploit genetically-engineered T-

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cell immunotherapies using or incorporating small molecule modulators directed against certain designated tumor-associated antigen targets, subject to the selection of a target by Juno. The Company has retained exclusive rights to such intellectual property, including its intellectual property arising under the collaboration, for all other purposes, including its use outside of those targets selected by Juno.

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

In connection with each Juno therapy that uses or incorporates the Company's small molecule modulators, Juno has agreed to pay the Company non-refundable, non-creditable milestone payments totaling up to approximately $51.0 million in the aggregate per therapy upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno therapy and the fifth Juno therapy that uses or incorporates the Company's small molecule modulators, Juno has agreed to pay the Company additional non-refundable, non-creditable bonus milestone payments totaling up to approximately $116.0 million and $137.5 million, respectively, in the aggregate, per therapy upon the achievement of various clinical, regulatory, and commercial milestones. In accordance with ASU 2010-17, the Company determined that these contingent payments meet the definition of a milestone under ASU 2010-17, and that the milestones are substantive given that the milestones are commensurate with the Company's performance, relate solely to the Company's past performance, and are reasonable relative to other deliverables and payments under the Agreement. Accordingly, the milestones under the Agreement will be accounted for as revenue on the achievement date, if any.

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

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

Becton, Dickinson and Company Collaboration Agreement

On September 30, 2010, the Company entered into a worldwide exclusive collaboration and license agreement with Becton, Dickinson and Company ("BD") for the joint development and worldwide commercialization of certain induced pluripotent stem cell ("iPSC") tools and technologies for use in drug discovery and development. In connection with the agreement, the Company received a $0.3 million upfront, nonrefundable license payment and received research funding of $0.8 million per year, during a three year joint development period, for the conduct of its development activities. In addition, the Company is eligible to receive: (i) milestone payments in the amount of $0.5 million, $0.7 million and $0.8 million in connection with the first commercial sale of up to three different iPSC products developed under the agreement, (ii) milestone payments of up to an aggregate amount of $4.0 million in connection with the achievement of certain annual net sales of iPSC products and (iii) royalties on the sale of such iPSC products. In 2012, the Company received a milestone payment of $0.5 million in connection with the first commercial sale of an

iPSC product. The Company does not believe it is probable that it will receive any future milestone payments in connection with the first commercial sale of an iPSC product or the achievement of certain annual net sales of iPSC products, or any material royalties, under the agreement.

License payments under the BD agreement were recorded as deferred revenue upon receipt and recognized ratably as revenue over the three year program period as a result of the Company's continuing involvement with the collaboration. Funding received for the Company's research efforts under the program was recognized as revenue as costs were incurred, which approximated the level of effort over the three year period of the program. The Company recognized revenue from milestone payments when earned, provided that (i) the milestone event is substantive in that it can only be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance and its achievability was not reasonably assured at the inception of the agreement, (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone and (iii) it would result in the receipt of additional payments. A milestone payment is considered substantive if all of the following conditions are met: (i) the milestone payment is non refundable; (ii) achievement of the milestone was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved to achieve the milestone; and (iv) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestones in the

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arrangement and the related risk associated with the achievement of the milestone. Royalties received under the agreement will generally be recognized as revenue upon receipt of the related royalty payment. In connection with the BD agreement for the year ended December 31, 2013 the Company recognized $0.6 million as revenue in its consolidated statements of operations.

3. Asset Acquisition of Verio Therapeutics Inc.

Acquisitions are analyzed to determine whether an acquired set of activities and assets represents a business. A business is considered to be an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants. A business commonly has three elements: inputs, processes applied to those inputs, and outputs. A set of activities and assets is required to have only the first two of those three elements, which together are or will be used to create outputs, to be considered a business. If an acquired set of activities and assets does not represent a business, the acquired set of activities and assets represents an asset.

On April 7, 2010, the Company acquired Verio Therapeutics Inc. (“Verio”), a development stage company headquartered in Ottawa, Ontario to gain access to its exclusively licensed intellectual property. Based on its evaluation of the set of activities and assets of Verio, the Company determined that Verio did not meet the definition of a business. Based on its assessment, the Company determined that Verio was a development stage enterprise without any material inputs; without any processes that create, or have the ability to create, outputs; and without any outputs. As such, the Company accounted for the acquisition of Verio as an asset acquisition and charged the associated consideration paid for the assets to research and development expense.

In connection with the asset acquisition of Verio, the stockholders of Verio received 900,000 non voting shares of Fate Canada (the “Exchangeable Shares”) that were initially exchangeable into 138,462 shares of the Company’s common stock and, subject to the validation of certain scientific data and the achievement of certain preclinical, clinical, commercial and financial milestones, were exchangeable for up to 884,605 shares of the Company’s common stock. Additionally, the Company assumed $212,090 of net liabilities of Verio. The purchase price of the Verio asset acquisition is summarized as follows (in thousands):

| | |
|---|---|
| Net liabilities | $212 |
| Initial fair value of Exchangeable Shares | 234 |
| | $446 |

The amounts in the table above represent an estimate of the fair value of purchased in process technology for projects that, as of the acquisition date, had not yet reached technological feasibility and had no alternative future use.

As a result of the Company’s IPO on October 4, 2013, 480,763 shares of the Company’s common stock were issued during the fourth quarter of 2013 pursuant to the redemption of the Exchangeable Shares. The total number of shares of the Company’s common stock issued upon the exchange of the Exchangeable Shares as a result of the IPO had

increased from 138,462 shares of the Company's common stock to a total of 480,763 shares of the Company's common stock based upon the achievement of certain contractual milestones.

During the year ended December 31, 2014, based on the achievement of certain preclinical milestones, an additional 38,463 shares of the Company's common stock were earned and issued, resulting in a $0.4 million charge to research and development expense.

In April 2015, the contractual earn-out period during which milestones were eligible to be earned and achieved expired under the Verio agreement and, as such, there are no additional contractual milestones that remain eligible for achievement. Accordingly, no additional shares of the Company's common stock remain issuable under the Verio agreement.

Prior to the Company's IPO, on the date of achievement of a milestone, the fair value of the related increase in the number of shares of common stock of the Company into which the Exchangeable Shares were exchangeable was charged to research and development expense. Additionally, the fair value of the Exchangeable Shares was re measured at each reporting date, with any changes in fair value being recognized in the change in fair value of the exchangeable share liability, a component of other income (expense), in the accompanying consolidated statements of operations. The fair value of the exchangeable share liability was equal to the fair value of the number of shares of common stock of the Company into which the Exchangeable Shares were exchangeable.

For the year ended December 31, 2013, the Company recorded other expense related to the change in fair value of the Exchangeable Shares of $2.4 million. For the fourth quarter of 2013, the Company recorded other expense of $0.4 million related to

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the final fair value adjustment of the exchangeable share liability as of the IPO date, and reclassified the then corresponding $3.3 million exchangeable share liability into additional paid in capital.

The changes in the number of shares of the Company's common stock issuable, and the initial fair value of the issuable shares, are summarized as follows (in thousands, except share and per share amounts):

| | Shares of Common Stock | Fair Value Per Share of Underlying Common Stock | Initial Fair Value of Common Stock |
|---|---|---|---|
| April 2010 | 138,462 | $ 1.69 | $ 234 |
| March 2011 | 92,308 | 1.69 | 156 |
| May 2011 | 115,380 | 1.69 | 195 |
| April 2012 | 57,691 | 1.37 | 78 |
| July 2013 | 76,922 | 4.49 | 346 |
| March 2014 | 38,463 | 9.74 | 375 |
| | 519,226 | | $ 1,384 |

4. Property and Equipment

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

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Furniture and fixtures | $324 | $265 |
| Computer and office equipment | 300 | 169 |
| Software | 103 | 103 |
| Leasehold improvements—building | 180 | 66 |
| Scientific equipment | 4,725 | 3,384 |
| Property and equipment, gross | 5,632 | 3,987 |
| Less accumulated depreciation and amortization | (3,472) | (2,787) |
| Property and equipment, net | $2,160 | $1,200 |

Depreciation expense related to property and equipment was $0.7 million, $0.5 million, and $0.6 million, for the years ended December 31, 2015, 2014, and 2013, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2015, 2014, and 2013.

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

Accrued Expenses

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

| | December 31, 2015 | December 31, 2014 |
|---|---|---|
| Accrued payroll and other employee benefits | $ 993 | $ 1,234 |
| Accrued clinical trial costs | 446 | 415 |
| Accrued other | 1,000 | 611 |
| Accrued expenses | $ 2,439 | $ 2,260 |

During the year ended December 31, 2015, the Company issued 19,956 shares of its common stock to certain senior executives of the Company as consideration for a portion of their 2014 annual bonuses.

During January 2016, the Company issued 37,641 shares of its common stock to certain senior executives of the Company as consideration for a portion of their 2015 annual bonuses. All related amounts were accrued for as liabilities as of December 31, 2015

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and 2014. Future senior executive bonus amounts, timing, and method of payment are at the sole discretion of the Board of Directors of the Company. As such, all relevant bonus estimates are accrued for as liabilities.

Long-term accrued expenses consist primarily of accruals for the final payment fees associated with our long-term debt.

Long Term Debt

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

| | December 31, 2015 | December 31, 2014 |
|---|---|---|
| Long-term debt | $ 18,454 | $ 20,000 |
| Less debt issuance costs and discount, net of current portion | (77) | (381) |
| Long-term debt, net of long-term portion of debt issuance costs and discount | 18,377 | 19,619 |
| Less current portion of long-term debt | (7,689) | (1,546) |
| Long-term debt, net | $ 10,688 | $ 18,073 |
| Current portion of long-term debt | $ 7,689 | $ 1,546 |
| Less current portion of debt issuance costs and discount | (139) | (11) |
| Current portion of long-term debt, net | $ 7,550 | $ 1,535 |

In July 30, 2014, the Company entered into an Amended and Restated Loan and Security Agreement (the “Restated LSA”) with Silicon Valley Bank (the “Bank”), collateralized by substantially all of the Company’s assets, excluding certain intellectual property. The Restated LSA amends and restates the Loan and Security Agreement, dated as of January 5, 2009, as amended, by and between the Company and the Bank (the “Loan Agreement”). Pursuant to the Restated LSA, the Bank agreed to make loans to the Company in an aggregate principal amount of up to $20.0 million, comprised of (i) a $10.0 million term loan, funded at the closing date (the “Term A Loan”) and (ii) subject to the achievement of a specified clinical milestone relating to the Company’s Phase 2 clinical trial of ProHema, additional term loans totaling up to $10.0 million in the aggregate, which were available until December 31, 2014 (each, a “Term B Loan”). On December 24, 2014, the Company elected to draw on the full $10.0 million under a Term B Loan.

The Term A Loan and the Term B Loan mature on January 1, 2018 and June 1, 2018, respectively and bear interest at a fixed annual rate of 6.94% and 7.07%, respectively. Interest became payable in cash on a monthly basis beginning the first day of each month following the month in which the funding date of each loan occurred. The Company is required to make a monthly payment of interest only during the first twelve months following the funding date of each

loan, and thereafter is required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty month amortization schedule. During the year ended December 31, 2015, the Company made principal payments totaling $1.5 million on the Term A Loan.

The Company is required to make a final payment fee of 7.5%, equaling $0.8 million, of the funded amount for each of the Term A Loan and Term B Loan on the respective maturity dates. The final payment fees are accrued as interest expense over the terms of the loans and recorded in long term accrued expenses.

A portion of the proceeds from the Term A Loan were used to repay loans outstanding under the Loan Agreement and to pay for transaction fees related to the Restated LSA, including a commitment fee of $0.4 million paid by the Company to the Bank. Net proceeds from the Term A Loan, after repayment of loans outstanding under the Loan Agreement and transaction fees, were $8.8 million.

The Company determined the repayment of the Loan Agreement was a debt extinguishment, and accounted for the Term A Loan at fair value as of the issuance date accordingly. During the year ended December 31, 2014, the Company recorded a loss on debt extinguishment of $0.4 million, primarily related to the commitment fee paid to the Bank.

Proceeds from the Term B Loan were $10.0 million. In connection with the funding of the Term B Loan, the Company issued the Bank and one of its affiliates fully exercisable warrants to purchase an aggregate of 98,039 shares of the Company’s common stock (the “Warrants”) at an exercise price of $4.08 per share. The Warrants expire in December 2021. The aggregate fair value of the Warrants was determined to be $0.4 million using the Black Scholes option pricing model (see Note 6 of the Notes to the

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Consolidated Financial Statements for additional information) and was recorded as a debt discount on the Term B Loan and is amortized to interest expense over the term of the Term B Loan using the effective interest method.

The Company determined the effective interest rates of the Term A Loan and Term B Loan to be 10.3% and 12.0%, respectively. For the years ended December 31, 2015 and 2014 the Company recorded $2.2 million and $0.5 million, respectively, in aggregate interest expense related to the Term A and Term B Loans. For the years ended December 31, 2014 and 2013, the Company recorded aggregate interest expense related to the Loan Agreement of $0.1 million and $0.3 million, respectively.

Warrants to purchase 36,074 shares of the Company's common stock at a weighted average exercise price of $7.21 per share issued in connection with the Loan Agreement remain outstanding as of December 31, 2015, with 5,305 and 30,769 of such warrants having expiration dates in January 2019 and August 2021, respectively.

June and July 2013 Convertible Note Financing

In June and July 2013, the Company issued convertible promissory notes in an aggregate principal amount of $3.7 million to certain existing stockholders. The notes accrued interest at 2% per year and were due on June 24, 2014. The outstanding principal and all accrued and unpaid interest due on the notes were converted into 625,828 shares of the Company's common stock as a result of the Company's IPO on October 4, 2013.

In connection with the issuance of the convertible notes, the Company recorded a debt discount of $0.3 million related to a beneficial conversion feature that was recorded as the proceeds allocated to the debt instrument were less than the gross fair value of the shares of Series C convertible preferred stock into which the notes could convert. This debt discount was amortized as interest expense utilizing the effective interest method over the one year term of the notes. For the year ended December 31, 2013, the entire $0.3 million debt discount was charged to interest expense in connection with its amortization during the period for which the notes were outstanding and the conversion of the notes into common stock pursuant to the Company's IPO on October 4, 2013.

August 2013 Convertible Note Financing

In August 2013, the Company issued convertible promissory notes in an aggregate principal amount of $20.0 million to certain new investors. The notes accrued interest at 2% per year and were due on August 8, 2016. In connection with the completion of the Company's IPO on October 4, 2013, the Company repaid $1.7 million of then outstanding principal and unpaid accrued interest on the notes in cash, with the remaining outstanding principal converting to 3,053,573 shares of the Company's common stock. For the year ended December 31, 2013, the Company recorded aggregate interest expense of $0.1 million on the stated interest rate of the notes issued in August 2013.

Facility Lease

The Company leases certain office and laboratory space from a stockholder of the Company under a non-cancelable operating lease. In March 2015, the Company extended the term of the lease on this facility an additional 15 months through September 2017. The lease is subject to additional charges for common area maintenance and other costs. In connection with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit in the amount of $0.1 million. As of December 31, 2015, future minimum payments under the operating lease are $1.8 million.

In January 2015, the Company entered into a sublease for additional laboratory space. The sublease is accounted for as an operating lease and expires in September 2017. Under the sublease, total future minimum payments as of December 31, 2015 are $0.5 million.

Aggregate contractual rent expense for both leases was $1.2 million, $0.9 million, and $0.9 million for the years ended December 31, 2015, 2014, and 2013, respectively.

License Agreements

The Company has entered into exclusive license agreements with certain academic institutions and universities pursuant to which the Company acquired certain intellectual property. Pursuant to each agreement, as consideration for an exclusive license to the intellectual property, the Company paid a license fee, reimbursed the institution for historical patent costs and, in certain instances, issued the institution shares of restricted common stock. Additionally, under each agreement, the institution is generally eligible to receive future consideration including, but not limited to, annual maintenance fees, royalties, milestone payments and sublicensing

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fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. Minimum annual payments to maintain these cancelable licenses total an aggregate of $0.3 million.

Commitments

Future minimum payments under the long term debt and the non cancelable operating leases as of December 31, 2015 are as follows (in thousands):

| | Long–Term Debt | Operating Leases | Total |
|---|---|---|---|
| Years Ending December 31, | | | |
| 2016 | $ 8,757 | 1,270 | 10,027 |
| 2017 | 8,757 | 1,088 | 9,845 |
| 2018 | 4,055 | — | 4,055 |
| Total | $ 21,569 | $ 2,358 | $23,927 |
| Less interest | (1,615) | | |
| Less additional payments due upon maturity | (1,500) | | |
| Less unamortized debt discount and debt issuance costs | (216) | | |
| Less current portion of long–term debt | (7,550) | | |
| Long–term debt, net of current portion | $ 10,688 | | |

6. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

The authorized, issued and outstanding shares of convertible preferred stock by series immediately prior to October 4, 2013 (the date each outstanding share of convertible preferred stock was converted to common stock as a result of the Company's IPO) is as follows:

| | Shares Authorized | Shares Outstanding |
|---|---|---|
| Series A | 14,609,186 | 14,609,186 |
| Series B | 12,080,000 | 12,050,000 |
| Series B–1 | 1,500,000 | 1,500,000 |
| Series C | 29,000,000 | 16,808,504 |
| Series C–1 | 11,171,000 | — |
| | 68,360,186 | 44,967,690 |

In connection with the completion of the Company's IPO on October 4, 2013, all of the outstanding shares of convertible preferred stock converted into 7,229,590 shares of the Company's common stock. Each outstanding share of Series A and Series C convertible preferred stock converted into approximately 0.1538 shares of common stock, or 4,833,490 common shares, and each outstanding share of Series B and Series B 1 convertible preferred stock converted into approximately 0.1768 shares of common stock, or 2,396,100 common shares.

Description of Securities

Dividends

As of December 31, 2015, the Board of Directors of the Company has not declared any dividends.

2007 Equity Incentive Plan and 2013 Stock Option and Incentive Plan

The Company adopted an Equity Incentive Plan in 2007 (the 2007 Plan) under which, as amended in August 2013, 2,423,072 shares of common stock were reserved for issuance to employees, nonemployee directors and consultants of the Company. The 2007 Plan provides for the grant of incentive stock options, non statutory stock options, rights to purchase restricted stock, stock appreciation rights, dividend equivalents, stock payments, and restricted stock units to eligible recipients. In connection with the issuance of restricted common stock, the Company maintains a repurchase right where shares of restricted common stock are released

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from such repurchase right over a period of time of continued service by the recipient. Effective upon the completion of the Company's IPO, the board of directors determined not to grant any further awards under the 2007 Plan.

On August 28, 2013, the Company's board of directors and stockholders approved and adopted the 2013 Stock Option and Incentive Plan (the "2013 Plan" and collectively with the 2007 Plan "the Plans"). The 2013 Plan became effective immediately prior to the Company's IPO. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, directors or consultants of the Company or its subsidiaries. A total of 1,020,000 shares of common stock were initially reserved for issuance under the 2013 Plan. The shares issuable pursuant to awards granted under the 2013 Plan will be authorized, but unissued shares. The shares of common stock underlying any awards from the 2013 Plan and the 2007 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of common stock, expire or are otherwise terminated (other than by exercise) under the 2013 Plan and the 2007 Plan will be added back to the shares of common stock available for issuance under the 2013 Plan.

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

Recipients of incentive stock options under the Plans shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Under the Plans, stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, or vest monthly over four years, unless they contain specific performance and/or market based vesting provisions. The maximum term of stock options granted under the Plans is ten years.

Restricted stock units under the 2013 Plan generally vest 50% on the second anniversary of the grant date, and 50% on the fourth anniversary of the grant date.

Employee Stock Purchase Plan

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

No purchases have been made to date under the ESPP.

Stock Options and Restricted Stock Awards

Stock Options. The following table summarizes stock option activity and related information under the Plans for the year ended December 31, 2015:

| | Options | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value (in 000s) |
|---|---|---|---|---|
| Outstanding at December 31, 2014 | 2,425,969 | $ 3.83 | 8.06 | $ 4,839 |
| Granted | 1,345,744 | 5.23 | | |
| Exercised | (227,215 ) | 1.85 | | |
| Cancelled | (957,024 ) | 4.20 | | |
| Outstanding at December 31, 2015 | 2,587,474 | $ 4.59 | 6.92 | $ 1,486 |
| Options vested and expected to vest at December 31, 2015 | 2,478,573 | $ 4.54 | 8.01 | $ 1,481 |
| Options exercisable at December 31, 2015 | 1,309,010 | $ 3.71 | 4.99 | $ 1,330 |

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As of December 31, 2015 and 2014, the outstanding options included 14,769 and 138,649, respectively, of performance based options for which the achievement of the performance based vesting provisions was determined not to be probable. The aggregate grant date fair value of these options at December 31, 2015 and December 31, 2014 was $0.1 million and $0.6 million, respectively.

For the years ended December 31, 2015, 2014 and 2013, the Company granted its employees 1.2 million, 0.9 million and 0.3 million stock options, respectively, at a weighted average grant date fair value per share equal to $3.54, $5.10 and $4.40, respectively.

As of December 31, 2015 and 2014, the unrecognized compensation cost related to outstanding options (excluding those with unachieved performance based conditions) was $3.8 million and $4.1 million, respectively, which is expected to be recognized as expense over approximately 2.8 years and 2.6 years, respectively.

The total intrinsic value, which is the amount by which the exercise price was exceeded by the price of the Company's common stock on the date of exercise, of stock options exercised during the year ended December 31, 2015 was $1.0 million. Total cash received upon the exercise of stock options was $0.4 million for the year ended December 31, 2015.

Restricted Stock Units. For the year ended December 31, 2015, the Company granted its employees 0.5 million restricted stock units at a weighted average grant date price per share equal to $4.89. As of December 31, 2015, 0.5 million restricted stock units were outstanding.

As of December 31, 2015 the unrecognized compensation cost related to outstanding restricted stock units was $2.4 million which is expected to be recognized as expense over approximately 3.8 years.

Restricted Stock Awards. Unvested outstanding restricted stock awards, issued under the 2007 Plan, as of December 31, 2015 and 2014 were 26,270 and 62,150 shares, respectively. As of December 31, 2015, these awards consist entirely of shares that cliff vest in April 2018 or earlier upon the achievement of specified milestones.

Stock Based Compensation Expense

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Research and development | $1,241 | $1,416 | $912 |
| General and administrative | 1,159 | 1,018 | 642 |
| Total stock-based compensation expense | $2,400 | $2,434 | $1,554 |

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Risk–free interest rate | 1.6% | 1.9 % | 1.6 % |
| Expected volatility | 81 % | 94 % | 90 % |
| Expected term (in years) | 6.0 | 6.0 | 5.9 |
| Expected dividend yield | 0.0% | 0.0 % | 0.0 % |

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

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

Expected volatility. Due to the Company's limited operating history and lack of company specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

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Expected term. The expected term represents the period of time that options are expected to be outstanding. As the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Based on historical employee turnover experience, pre vesting forfeitures for all employee stock option grants was at estimated at 0% for each of the years ended December 31, 2015, 2014, and 2013.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Risk–free interest rate | 0.8% | 2.1 % | 2.1 % |
| Expected volatility | 72 % | 87 % | 91 % |
| Expected term (in years) | 2.7 | 6.5 | 7.3 |
| Expected dividend yield | 0.0% | 0.0 % | 0.0 % |

Warrants to Purchase Common Stock in Connection with Debt Issuance

As a result of the financing of the Term B Loan on December 24, 2014, the Company issued the Bank and one of its affiliates fully exercisable warrants to purchase an aggregate of 98,039 shares of the Company's common stock at an exercise price of $4.08 per share. The warrants expire in December 2021. See Note 5 of the Notes to the Consolidated Financial Statements for additional information on the debt issuance.

The fair value of the warrants was determined to be $0.4 million, which was recorded to additional paid in capital as a debt discount. The weighted average assumptions used in the Black Scholes option pricing model to determine the fair value of the warrants issued were as follows:

| | As of December 24, 2014 | |
|---|---|---|
| Risk–free interest rate | 2.1 | % |
| Expected volatility | 85 | % |
| Expected term (in years) | 7.0 | |
| Expected dividend yield | 0.0 | % |

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

| | December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Common stock warrants | 134,113 | 134,113 |
| Common stock options | 2,587,474 | 2,425,969 |
| Awards available under the 2013 Plan | 908,288 | 999,482 |
| Exchangeable shares | — | 365,379 |
| Employee stock purchase plan | 729,000 | 729,000 |
| | 4,358,875 | 4,653,943 |

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7. Income Taxes

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Tax computed at federal statutory rate | $(10,198) | $(8,800) | $(7,104) |
| State tax, net of federal tax benefit | 2,226 | (1,311) | (1,011) |
| Permanent differences | 43 | 159 | 755 |
| Stock compensation | 213 | 426 | 161 |
| R&D tax credits | (594) | (596) | (373) |
| Reserve for uncertain tax positions | 1,733 | — | — |
| Tax attribute limitation | 2,727 | — | — |
| Other | (37) | (256) | (8) |
| Valuation allowance | 3,887 | 10,378 | 7,580 |
| Income tax expense | $— | $— | $— |

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

| | As of December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Deferred tax assets: | | |
| Section 59e amortization | $13,042 | $13,905 |
| Net operating losses | 28,963 | 25,620 |
| R&D tax credits | 1,274 | 2,221 |
| Depreciation and amortization | 921 | 1,050 |
| Deferred revenue | 2,494 | — |
| Other | 950 | 961 |
| Deferred tax assets | 47,644 | 43,757 |
| Valuation allowance | (47,644) | (43,757) |
| Net deferred tax assets | $— | $— |

A valuation allowance of $47.6 million and $43.8 million at December 31, 2015 and 2014, respectively, has been established to offset the deferred tax assets, as realization of such assets is uncertain.

At December 31, 2015, the Company had federal, California and Canadian net operating loss ("NOL") carryforwards of approximately $79.8 million, $61.9 million and $0.3 million, respectively, which may be available to offset future taxable income. The federal, California and Canadian NOL carryforwards begin to expire in 2027, 2028 and 2030,

respectively, unless previously utilized. At December 31, 2015, the Company had federal and California research and development ("R&D") credit carryforwards of approximately $0.4 million and $2.7 million, respectively. The federal R&D tax credit carryforwards will begin to expire in 2035 unless previously utilized. The California R&D credit carryforwards will carry forward indefinitely.

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

The Company files income tax returns in the United States, California and Canada. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal, state and Canadian tax

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authorities for years beginning in 2012, 2011, and 2011, respectively. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where NOLs and tax credits were generated and carried forward, and make adjustments up to the amount of the carryforwards.

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

| | |
|---|---|
| Balance at December 31, 2012 | $1,034 |
| Increase related to current year tax positions | 295 |
| Balance at December 31, 2013 | $1,329 |
| Increase related to current year tax positions | 491 |
| Balance at December 31, 2014 | $1,820 |
| Increase related to current year tax positions | 374 |
| Increase related to prior year tax positions | 2,624 |
| Decrease related to prior year tax positions | (949 ) |
| Balance at December 31, 2015 | $3,869 |

The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2015 will significantly change within the next twelve months. Due to the valuation allowance recorded against the Company's deferred tax assets, none of the total unrecognized tax benefits as of December 31, 2015 would reduce the effective tax rate if recognized. The Company has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

During the year ended December 31, 2015, the Company adopted ASU 2015-17 and applied the standard prospectively (prior period amounts were not retrospectively adjusted). With this adoption our deferred tax assets and liabilities are no longer classified between current and non-current. All deferred tax assets and liabilities are now classified as non-current regardless of their classification on the balance sheet and the timing of their anticipated reversal. The Company's deferred tax assets are fully offset by a valuation allowance, and therefore, the non-current deferred tax asset balance as of December 31, 2015 is zero.

8. Employee Benefits

Effective January 1, 2009, the Company adopted a defined contribution 401(k) plan for employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. No matching contributions have been made by the Company since the adoption of the 401(k) plan.

9. Selected Quarterly Financial Data

| (in thousands, except per share data) (unaudited) | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| 2015 | | | | |
| Revenues | $— | $329 | $1,026 | $1,076 |
| Total operating expenses | 7,324 | 7,547 | 7,354 | 7,988 |
| Net loss | (7,881) | (7,779) | (6,886) | (7,446) |
| Basic and diluted net loss per common share | $(0.38) | $(0.33) | $(0.24) | $(0.26) |
| 2014 | | | | |