

K12 INC
Form 8-K
December 10, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

December 5, 2013

K12 Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-33883

95-4774688

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

2300 Corporate Park Drive, Herndon, Virginia

20171

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(703) 483-7000

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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The annual meeting of the stockholders of K12 Inc. (the Company) was held on December 5, 2013. The Company previously filed with the Securities and Exchange Commission the proxy statement and related materials pertaining to this meeting, which describe in detail each of the three proposals submitted to stockholders at the meeting. The final results for the votes regarding each proposal are set forth below.

Proposal 1: Election of Directors

The ten nominees for the Board of Directors were elected to hold office until the next annual meeting of stockholders and/or until their successors are duly elected or appointed. The tabulation of votes is set forth below:

	For	Withheld	Broker Non-Vote
Craig R. Barrett	32,161,976	116,616	3,745,887
Guillermo Bron	32,163,168	115,424	3,745,887
Adam L. Cohn	32,162,402	116,190	3,745,887
Nathaniel A. Davis	31,854,698	418,894	3,745,887
John M. Engler	32,162,653	115,939	3,745,887
Steven B. Fink	32,117,845	116,229	3,745,887
Mary H. Futrell	30,561,954	1,711,638	3,745,887
Ronald J. Packard	32,163,105	115,487	3,745,887
Jon Q. Reynolds, Jr.	31,630,777	647,815	3,745,887
Andrew H. Tisch	31,002,157	1,276,435	3,745,887

Proposal 2: Advisory Vote on Executive Compensation

Approved, on an advisory basis (non-binding), the compensation of the Company's named executive officers as described in the Compensation Discussion and Analysis and the accompanying tables in the proxy statement. There were 17,238,622 votes for the proposal, 15,011,056 votes against the proposal, 28,914 abstentions and 3,745,887 broker non-votes.

Proposal 3: Ratification of Appointment of Independent Auditor

The appointment of BDO USA, LLP as the Company's independent registered public accounting firm for the fiscal year ending June 30, 2014 was ratified with 36,014,528 votes for, 2,901 votes against, and 7,050 abstentions.

Top of the Form**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

December 10, 2013

K12 Inc.

By: /s/ Howard D. Polsky

Name: Howard D. Polsky

Title: General Counsel and Secretary

critical accounting policies and estimates during the nine months ended September 30, 2016.

See Note 1 to the Condensed Consolidated Financial Statements for information related to recent accounting pronouncements.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the three months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended		Increase/ (Decrease)
	September 30, 2016	September 30, 2015	
Collaboration revenue	\$1,026	\$1,026	\$ —
Research and development expense	6,804	5,003	1,801
General and administrative expense	2,611	2,351	260
Total other expense, net	348	558	(210)

Revenue. During the three months ended September 30, 2016 and 2015, we recognized revenue of \$1.0 million under the Agreement with Juno, which we entered into in May 2015.

Research and development expenses. Research and development expenses were \$6.8 million for the three months ended September 30, 2016, compared to \$5.0 million for the three months ended September 30, 2015. The increase in research and development expenses primarily includes the following changes:

- \$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
- \$0.7 million increase in compensation and benefits expense, including employee stock-based compensation expense, relating to an increase in employee headcount to support our research activities, including our activities under our collaboration with Juno.

General and administrative expenses. General and administrative expenses were \$2.6 million for the three months ended September 30, 2016, compared to \$2.4 million for the three months ended September 30, 2015. The increase in general and administrative expenses primarily relates to a \$0.3 million increase in intellectual property-related expenses.

Other expense, net. Other expense, net was \$0.3 million for the three months ended September 30, 2016 and \$0.6 million for the three months ended September 30, 2015. Other expense, net for each period consisted primarily of interest expense relating to our term loans with Silicon Valley Bank.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the nine months ended September 30, 2016 and 2015 (in thousands):

	Nine Months Ended		Increase/ (Decrease)
	September 30, 2016	2015	
Collaboration revenue	\$3,375	\$1,355	\$ 2,020
Research and development expense	20,222	14,428	5,794
General and administrative expense	7,462	7,797	(335)
Total other expense, net	1,213	1,676	(463)

Revenue. During the nine months ended September 30, 2016 and 2015, we recognized revenue of \$3.4 million and \$1.4 million respectively, under the Agreement with Juno, which we entered into in May 2015. The increase was driven by an increase in our research activities.

Research and development expenses. Research and development expenses were \$20.2 million for the nine months ended September 30, 2016, compared to \$14.4 million for the nine months ended September 30, 2015. The increase in research and development expenses primarily includes the following changes:

- \$2.2 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;
- \$1.9 million increase in compensation and benefits expense, including employee stock-based compensation expense, relating to an increase in employee headcount to support the conduct of our research activities, including our activities under our collaboration with Juno; and
- \$1.3 million increase in expenditures for laboratory equipment and supplies relating to the conduct of our research activities, including our activities under our collaboration with Juno.

General and administrative expenses. General and administrative expenses were \$7.5 million for the nine months ended September 30, 2016, compared to \$7.8 million for the nine months ended September 30, 2015. The decrease in general and administrative expenses primarily relates to a \$0.1 million decrease in corporate stock fees, a \$0.1 million decrease in corporate legal fees, and a \$0.1 million decrease in intellectual property-related expenses.

Other expense, net. Other expense, net was \$1.2 million and \$1.7 million for the nine months ended September 30, 2016 and 2015, respectively. Other expense, net for each period consisted primarily of interest expense relating to our term loans with Silicon Valley Bank.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of September 30, 2016, we had an accumulated deficit of \$167.9 million and anticipate that we will continue to incur net losses for the foreseeable future.

Operating Activities

Cash used in operating activities increased from \$11.4 million for the nine months ended September 30, 2015 to \$22.3 million for the nine months ended September 30, 2016. The primary driver of this change in cash used in operating activities was a \$9.8 million change in deferred revenue resulting from the Agreement with Juno in May 2015 and our increase in net loss in the periods presented.

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 September 30, 2016, we have received a total of \$2.8 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 September 30, 2016, 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 September 30, 2016, no royalties have been received by us.

Investing Activities

During the nine months ended September 30, 2016 and 2015, investing activities used cash of \$10.1 million and \$1.3 million, respectively. During the nine months ended September 30, 2016, we purchased \$19.7 million in U.S. Treasuries as short-term investments, offset by \$10.0 million in maturities of these short-term investments. All other investing activities for the periods presented were attributable to the purchase of property and equipment.

Financing Activities

For the nine months ended September 30, 2016, financing activities provided cash of \$4.6 million, which consisted of \$10.2 million of net proceeds from our private placement of common stock completed in August 2016 in which we sold 5,250,000 shares of our common stock at a price of \$1.96 per share, offset by \$5.7 million of principal payments on our term loans outstanding with Silicon Valley Bank. Gross proceeds from the private placement were \$10.3 million.

For the nine months ended September 30, 2015, financing activities provided cash of \$36.5 million, which consisted primarily of \$4.6 million from our Agreement with Juno, which amount represents the fair value of common stock purchased by Juno under the Agreement, and \$32.1 million of net proceeds from a follow-on public offering of our common stock completed in May 2015 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.

From our inception through September 30, 2016, we have funded our consolidated operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of September 30, 2016, we had aggregate cash and cash equivalents and short-term investments of \$46.6 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 us 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, we 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. We are required to make a monthly payment of interest only during the first twelve months following the funding date of each loan, and thereafter are required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty month amortization schedule. During the nine months ended September 30, 2016, we made aggregate principal

payments totaling \$5.7 million on the Term A Loan and Term B Loan. We are required to make a final payment fee of 7.5%, equaling \$0.8 million of the funded amount for each of the Term A 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 us 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, we issued the Bank and one of its affiliates fully-exercisable warrants to purchase an aggregate of 98,039 shares of our 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.

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 statement 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 November 7, 2016, after taking into 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.

Operating Capital Requirements

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

We believe our existing cash and cash equivalents and short-term investments as of September 30, 2016 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research and development of our product candidates, and we may be forced to seek additional funds sooner than expected to pursue our research and development activities. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity or debt securities. However, additional capital may not be available to us on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or

discontinue the research or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects.

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

- the initiation, timing, progress, size, duration, costs and results of our preclinical studies and clinical trials for our product candidates;
- the number and the nature of product candidates that we pursue;
- the cost of 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 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

In July 2014, we entered into the Restated LSA with the Bank. Pursuant to the Restated LSA, the Bank agreed to make loans to us in an aggregate principal amount of up to \$20.0 million, which we have fully drawn upon. See Note 5 of the Condensed Consolidated Financial Statements for further details.

The Company leases office and laboratory space under non-cancelable operating leases. Effective as of June 1, 2016, the Company entered into an amendment to its existing facilities lease agreement extending the term of the lease through June 2023 and agreeing to lease additional space comprising approximately 24,000 square feet in the same building as its existing space. As of September 30, 2016, aggregate future minimum payments under these operating leases are \$14.5 million. See Note 5 of the Condensed Consolidated Financial Statements for further details.

We have no material contractual obligations not fully recorded on our Condensed Consolidated Balance Sheets or fully disclosed in the notes to the financial statements.

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 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of September 30, 2016 our cash and cash equivalents consisted of cash and money market mutual funds, and our short-term investments consisted of United States treasuries with maturities ranging from six to twelve months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates.

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However, because of the short-term nature and low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations.

Our outstanding debt bears interest at a fixed rate and therefore has no exposure to changes in interest rates.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer, who serves as both our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, the individual serving as our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, 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 any of 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, our current Phase 1/2 clinical trial of ProTmune and any other additional clinical trials;
- continued progress in our research and development programs, including the preclinical studies and planned clinical trials of any additional product candidates we may identify for clinical development;
- our ability to initiate, and the progress, results, size, timing and costs of, additional future clinical trials of our product candidates, including ProTmune, 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 encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner. In addition, there are currently only a limited number of specialized transplant centers that perform hematopoietic stem cell transplants, or HSCTs, and among physicians who perform HSCTs, some may not choose to perform these procedures under conditions that fall within our protocols, which would have an adverse effect on our development of ProTmune. Our ability to enroll patients in our clinical trials, including in our current Phase 1/2 clinical trial of ProTmune, is affected by factors including:

- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- design of the trial protocol;
- the relatively small size and nature of the patient population for the trial in question;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

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 completed 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 our current or future clinical trials, and we do not know whether we will be able to initiate, enroll patients in, or complete, our clinical trials on time, if at all. Our current and future 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 current or subsequent 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;

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failure of cell processing facilities at our clinical trial sites to manufacture certain of our product candidates consistently in accordance with our protocol-specified processes for use in our clinical trials;

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- 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
- 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 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 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.

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 we have demonstrated in preclinical models that a single administration of ProTmune resulted in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, we may not observe similar results in future preclinical or clinical studies of ProTmune. Additionally, while subjects treated with ProHema, one of our prior product candidates, 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 any 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 product candidates 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 current clinical trial of ProTmune.

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

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to 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;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and

• safety issues or adverse events in patients that enroll in our current or future clinical trials. Even if our current clinical trial is successful, we will need to conduct additional clinical trials, which may include 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.

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 is currently in Phase 1/2 clinical development. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety and efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

We may delay or cancel our ongoing research and development activities and our current or planned clinical development for any of our product candidates, including ProTmune, 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 current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing 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.

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 current or future clinical trials of ProTmune. Additionally, the FDA may in the future have comments, or impose requirements, on our protocols for conducting 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 current or future 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 ProTmune or any of our other 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 non-clinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;

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- 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.

The manufacture of 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 ProTmune is currently manufactured prior to transplantation at clinical cell processing facilities operated by or affiliated with our clinical sites, 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 treated with ProTmune in our ongoing clinical trial, as well as patients who may undergo treatment with other product candidates that we may develop, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing ProTmune 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 clinical endpoints and data required to support an application or regulatory approval and 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 product candidates, 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.

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

We expect to 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. We have been granted orphan drug designation in the United States for ex vivo programmed mobilized peripheral blood for the prevention of GvHD in patients undergoing allogeneic hematopoietic cell transplantation, and in the European Union for ProTmune for treatment in hematopoietic stem cell transplantation. While we have been granted these orphan designations, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

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 currently 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.

ProTmune is currently manufactured for our Phase 1/2 clinical trial 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 anticipated manufacture of 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 biologics license application, or 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 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 is currently procured directly by the clinical cell processing facilities from the National Marrow Donor Program (NMDP) for our ongoing 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;
- NMDP and individual blood bank policies and practices relating to mPB acquisition and banking;
- the pricing of mPB;
- the methods used in searching for and matching mPB to patients, which involve emerging technology related to current and future mPB parameters that guide the selection of an appropriate unit of mPB for transplantation; and
- methods for the procurement and shipment of mPB and its handling and storage at clinical sites.

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

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

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 applicable 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 applicable GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development 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, and our cell programming approach, in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell therapy technology. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. 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.

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, or the use of our cell programming technology, 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.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property rights, unless that third party grants us rights to use its intellectual property. 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-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. 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, may be competitive to product candidates in our research and development pipeline, or may render our product candidates obsolete or noncompetitive. Should one or more of these products be successful, the market for our products may be reduced or eliminated, and we may not achieve commercial success.

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

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

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

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended, 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.

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 (other than T cells derived from induced pluripotent stem 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, unless such T cells are derived from induced pluripotent stem cells. 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 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 September 30, 2016 we had an accumulated deficit of \$167.9 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.

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 current and planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours;
- developments related to the FDA or to regulations applicable to cellular 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;

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- 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 November 4, 2016, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 67% 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. 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. For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. As a result, all of these shares are currently available for resale to the public, which may result in dilution to our stockholders. In addition, 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 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

- a) All information with respect to this item has been previously reported in our Current Report on Form 8-K.
- b) None.
- c) None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

See Exhibit Index.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Fate Therapeutics, Inc.

Date: November 7, 2016 By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer and Director

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Index to Exhibits

Exhibit

Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	S-1/A	333-1906083.2		August 29, 2013
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-1906083.4		August 29, 2013
4.1	Specimen Common Stock Certificate	S-1/A	333-1906084.1		August 29, 2013
10.1	Securities Purchase Agreement, dated August 6, 2016, by and among the Company and the Purchasers	8-K	001-36076	10.1	August 8, 2016
10.2	Registration Rights Agreement, dated August 6, 2016, by and among the Company and the Purchasers	8-K	001-36076	10.2	August 8, 2016
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	XBRL Instance Document	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith

