FATE THERAPEUTICS INC
Form 10-Q
May 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2017

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT OF 1934
From the transition period from to .

Commission File Number 001-36076

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	65-1311552
(State or other jurisdiction	(IRS Employer
of incorporation or organization)	Identification No.)
3535 General Atomics Court, Suite 200, San Diego, CA	92121
(Address of principal executive offices)	(Zip Code)

(858) 875-1800

(Registrant’s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

As of May 12, 2017, 41,401,422 shares of the registrant’s common stock, par value $0.001 per share, were issued and outstanding.

FATE THERAPEUTICS, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Fate Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 40,608	$ 88,609
Short-term investments	41,692	3,503
Prepaid expenses and other current assets	1,137	1,211
Total current assets	83,437	93,323
Property and equipment, net	1,746	1,579
Restricted cash	122	122
Other assets	24	24
Total assets	$ 85,329	$ 95,048
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,470	$ 934
Accrued expenses	4,699	3,957
Current portion of deferred rent	3	4
Current portion of deferred revenue	2,105	2,105
Long-term debt, current portion	7,620	8,187
Total current liabilities	16,897	15,187
Deferred rent	543	101
Deferred revenue	2,303	2,829
Accrued expenses	647	1,276
Long-term debt, net of current portion	1,081	2,501
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares—5,000,000 at March 31, 2017 and December 31, 2016; 2,819,549 Class A Convertible Preferred shares issued and outstanding at March 31, 2017 and December 31, 2016	3	3
Common stock, $0.001 par value; authorized shares—150,000,000 at March 31, 2017 and December 31, 2016; issued and	41	41

outstanding—41,401,422 at March 31, 2017 and 41,386,506 at December 31, 2016		
Additional paid-in capital	249,820	248,957
Accumulated other comprehensive loss	(34)	(1)
Accumulated deficit	(185,972)	(175,846)
Total stockholders' equity	63,858	73,154
Total liabilities and stockholders' equity	$ 85,329	$ 95,048

See accompanying notes.

Fate Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2017 (unaudited)	2016
Collaboration revenue	$1,027	$1,322
Operating expenses:		
Research and development	7,966	6,636
General and administrative	3,032	2,602
Total operating expenses	10,998	9,238
Loss from operations	(9,971)	(7,916)
Other income (expense):		
Interest income	111	27
Interest expense	(266)	(488)
Total other expense, net	(155)	(461)
Net loss	$(10,126)	$(8,377)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities, net	(33)	14
Comprehensive loss	$(10,159)	$(8,363)
Net loss per common share, basic and diluted	$(0.24)	$(0.29)
Weighted-average common shares used to compute basic and diluted net loss per share	41,388,329	28,777,790

See accompanying notes.

Fate Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,	
	2017	2016
	(unaudited)	
Operating activities		
Net loss	$(10,126)	$(8,377)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	206	227
Stock-based compensation	867	797
Amortization of debt discounts and debt issuance costs	24	40
Amortization of premiums and discounts on investments, net	(1)	55
Noncash interest expense	77	157
Deferred rent	272	(7)
Deferred revenue	(526)	(822)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	75	(112)
Accounts payable and accrued expenses	1,677	790
Net cash used in operating activities	(7,455)	(7,252)
Investing activities		
Purchase of property and equipment	(155)	(178)
Purchases of short-term investments	(39,971)	(16,166)
Maturities of short-term investments	1,750	—
Net cash used in investing activities	(38,376)	(16,344)
Financing activities		
Issuance of common stock from equity incentive plans, net of issuance costs	34	147
Issuance costs from private placement of common stock	(65)	—
Issuance costs from private placement of preferred stock	(128)	—
Payments on long-term debt	(2,011)	(1,873)
Net cash used in financing activities	(2,170)	(1,726)
Net change in cash and cash equivalents	(48,001)	(25,322)
Cash and cash equivalents at beginning of the period	88,609	64,809
Cash and cash equivalents at end of the period	$40,608	$39,487

See accompanying notes.

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Fate Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization

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

As of March 31, 2017, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

Private Placements of Common Stock and Convertible Preferred Stock

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

In November 2016, the Company completed a private placement of common and preferred stock in which investors, including investors affiliated with the Company's directors and officers, purchased convertible preferred stock and common stock of the Company. The Company issued 2,819,549 shares of non-voting Class A Preferred Stock at $13.30 per share, each of which is convertible into five shares of common stock upon certain conditions. The Company also issued 7,236,837 shares of common stock at $2.66 per share. Gross proceeds from the private placement were $56.7 million. After giving effect to costs related to the private placement, net proceeds were $54.9 million. The Company also entered into a registration rights agreement (the "Registration Rights Agreement") with certain of the purchasers in the November 2016 private placement, excluding those purchasers affiliated with the Company's directors and officers, requiring the Company to register for the resale of the relevant shares. The Company registered all of the relevant shares issued in this placement for resale on a Form S-3 filed with the SEC, as required under the Registration Rights Agreement, and the registration statement was declared effective in January 2017. See Note 6 to the Consolidated Financial Statements for additional information related to this offering.

Use of Estimates

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Therapeutics (Canada), Inc. or "Fate Canada", incorporated in Canada and which was dissolved in November 2016, Fate Therapeutics Ltd., incorporated in the United Kingdom, and Tfinity Therapeutics, Inc., incorporated in the United States. To date, the aggregate operations of these subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Cash and Cash Equivalents

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

Short-Term Investments

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with GAAP and following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2016, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed by the Company with the SEC on March 16, 2017. The results for the three months ended March 31, 2017 are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Revenue Recognition

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

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

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

Revenue arrangements with multiple elements may include license fees, research and development payments, milestone payments, other contingent payments, and royalties on any product sales derived from collaborations. The Company recognizes nonrefundable license fees with stand-alone value as revenue at the time that the Company has satisfied all performance obligations, and recognizes license fees without stand-alone value as revenue in combination with any undelivered performance obligations. The Company recognizes a research and development payment as revenue over the term of the collaboration agreement as contracted amounts are earned, or reimbursable costs are incurred, under the agreement, where contracted amounts are considered to be earned in relative proportion to the performance required under the applicable agreement. The Company recognizes a milestone payment, which is contingent upon the achievement of a milestone in its entirety, as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. These criteria include the following: (i) the consideration being earned

should be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) the consideration being earned should relate solely to past performance; (iii) the consideration being earned should be reasonable relative to all deliverables and payment terms in the arrangement; and (iv) the milestone should be considered in its entirety and cannot be bifurcated into substantive and nonsubstantive components. Any amounts received pursuant to revenue arrangements with multiple elements prior to satisfying the Company's revenue recognition criteria are recorded as deferred revenue on the Company's consolidated balance sheets.

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

Stock-Based Compensation

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

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

Convertible Preferred Stock

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

The Company applies the relevant accounting standards for derivatives and hedging (in addition to distinguishing liabilities from equity) when accounting for hybrid contracts that contain conversion options. Conversion options must be bifurcated from the host instruments and accounted for as free standing financial instruments according to certain criteria. These criteria include circumstances when (i) the economic characteristics and risks of the embedded derivative instruments are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable accounting principles with changes in fair value reported in earnings as they occurred, and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The derivative is subsequently measured at fair value at each reporting date, with the changes in fair value reported in earnings.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non owner sources. Other comprehensive income includes unrealized gains and losses on available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Excluded from the weighted-average number of shares outstanding are shares which were issued upon the early exercise of stock options and were subject to future vesting totaling 13,135 shares for the three months ended March 31, 2016. No such shares were outstanding during the three months ended March 31, 2017. Dilutive common stock equivalents for the periods presented include convertible preferred stock, warrants for the purchase of common stock, and common stock options and restricted stock units outstanding under the Company’s stock option and incentive

plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

For the three months ended March 31, 2017, the Company realized a net loss of $10.1 million. Shares of potentially dilutive securities totaled 20.2 million for the three months ended March 31, 2017, including 14.1 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 6.0 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement of outstanding restricted stock units.

For the three months ended March 31, 2016, the Company realized a net loss of $8.4 million. Shares of potentially dilutive securities totaled 4.5 million for the three months ended March 31, 2016, including an aggregate of 4.4 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement of outstanding restricted stock units.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-09 "ASU 2016-09". ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 became effective for the Company on January 1, 2017. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

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

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

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

In August 2014, the FASB issued ASU 2014-15, which defined management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related disclosure. ASU 2014-15 defined the term substantial doubt and requires an assessment for a period of one year after the date of the issuance of the financial statements. It requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The guidance became effective for reporting periods ending after December 15, 2016. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

In May 2014, the FASB issued ASU 2014-09, which created a single, principle-based revenue recognition model that will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance. Entities will recognize revenue in a manner that depicts the transfer of goods or services to customers at an amount that reflects the

consideration to which the entity expects to be entitled to receive in exchange for those goods or services. The model provides that entities follow five steps: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue. For public business entities, ASU 2014-09 is effective beginning in the first quarter of 2018 using one of two prescribed transition methods: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). The Company expects to adopt ASU 2014-09 in the first quarter of 2018 using the full retrospective method to restate each prior reporting period presented. The Company is currently evaluating the effect that the updated standard and transition method will have on its internal processes, financial statements and related disclosures.

Going Concern Assessment

Pursuant to ASU 2014-15, the Company has assessed its ability to continue as a going concern for a period of one year from the date of the issuance of these financial statements. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern as of the date of the issuance of these financial statements.

2. Juno Collaboration and License Agreement

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

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

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

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

Total revenue recognized under the Agreement for the three months ended March 31, 2017 was $1.0. Total revenue recognized under the Agreement for the three months ended March 31, 2016 was $1.3 million. As of March 31, 2017, aggregate deferred revenue related to the Agreement was $4.4 million.

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

The Company is eligible under the Agreement to receive selection fees for each tumor-associated antigen target selected by Juno and bonus selection fees based on the aggregate number of tumor-associated antigen targets selected by Juno. In accordance with ASC 605-28, Revenue Recognition — Milestone Method, the Company determined that such contingent payments do not constitute

milestone payments and will not be accounted for under the milestone method of revenue recognition. The events leading to these payments do not meet the definition of a milestone under ASU 2010-17 because the achievement of these events depends on Juno's performance and selections. Any revenue from these contingent selection payments would be subject to an allocation of arrangement consideration and would be recognized over any remaining period of performance obligation, if any, relating to the collaboration.

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

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

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

3. Short-term Investments

During the three months ended March 31, 2017 and the year ended December 31, 2016, the Company invested excess cash in United States treasuries with maturities ranging from six to twelve months from the purchase date. These debt securities are classified as short-term investments in the accompanying consolidated balance sheets and are accounted for as available-for-sale securities.

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

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
March 31, 2017					
U.S. Treasury debt securities	1 or less	41,726	(34)	—	41,692
Total		$ 41,726	$ (34)	$ —	$ 41,692
December 31, 2016					

U.S. Treasury debt securities	1 or less	3,504	(1)	—	3,503
Total		$ 3,504	$ (1)	$ —	$ 3,503

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

4. Fair Value Measurements

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

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an

exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

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

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

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and short-term investments. Cash equivalents consisted of money market funds and short-term investments consisted of U.S. treasuries. The following table presents the Company's assets which were measured at fair value on a recurring basis as of March 31, 2017 and December 31, 2016 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of March 31, 2017:				
Cash equivalents	$40,365	$40,365	$ —	$ —
U.S. Treasury debt securities	41,692	41,692	—	—
Total assets	$82,057	$82,057	$ —	$ —
As of December 31, 2016:				
Cash equivalents	$88,609	$88,609	$ —	$ —
U.S. Treasury debt securities	3,503	3,503	—	—
Total assets	$92,112	$92,112	$ —	$ —

The Company obtains pricing information from quoted market prices from our investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades,

broker/dealer quotes, and bids and/or offers.

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

As of March 31, 2017, and December 31, 2016, the Company had no material liabilities measured at fair value on a recurring basis.

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

Accrued Expenses

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

	March 31, 2017	December 31, 2016
Accrued payroll and other employee benefits	$1,041	$ 1,505
Accrued clinical trial related costs	1,205	1,043
Accrued final payment fee on debt	705	—
Accrued other	1,748	1,409
Current accrued expenses	$4,699	$ 3,957

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

Long-Term Debt

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

	March 31, 2017	December 31, 2016
Long-term debt	$8,753	$ 10,765
Less debt issuance costs and discount, net of current portion	(1)	(7)
Long-term debt, net of long-term portion of debt issuance costs and discount	8,752	10,758
Less current portion of long-term debt	(7,671)	(8,257)
Long-term debt, net	$1,081	$ 2,501
Current portion of long-term debt	$7,671	$ 8,257
Less current portion of debt issuance costs and discount	(51)	(70)
Current portion of long-term debt, net	$7,620	$ 8,187

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

The Term A Loan and the Term B Loan mature on January 1, 2018 and June 1, 2018, respectively and bear interest at a fixed annual rate of 6.94% and 7.07%, respectively. Interest became payable in cash on a monthly basis beginning the first day of each month following the month in which the funding date of each loan occurred. The Company was required to make a monthly payment of interest only during the first twelve months following the funding date of each loan, and thereafter is required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty-month amortization schedule. During the three months ended March 31, 2017 and 2016 the Company made aggregate principal payments totaling $2.0 million and $1.9 million, respectively, on the Term A and Term B Loans.

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

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

Agreement was a debt extinguishment, and accounted for the Term A Loan at fair value as of the issuance date accordingly.

Proceeds from the Term B Loan were $10.0 million. In connection with the funding of the Term B Loan, the Company issued the Bank and one of its affiliates fully-exercisable warrants to purchase an aggregate of 98,039 shares of the Company's common stock (the "Warrants") at an exercise price of $4.08 per share. The Warrants expire in December 2021. The aggregate fair value of the Warrants was determined to be $0.4 million using the Black-Scholes option pricing model and was recorded as a debt discount on the Term B Loan and is amortized to interest expense over the term of the Term B Loan using the effective interest method.

For the three months ended March 31, 2017 and 2016, the Company recorded $0.3 million and $0.5 million, respectively, in aggregate interest expense related to the Term A and Term B Loans.

Warrants to purchase 36,074 shares of the Company's common stock at a weighted average exercise price of $7.21 per share issued in connection with the Loan Agreement remain outstanding as of March 31, 2017 with 5,305 and 30,769 of such warrants having expiration dates in January 2019 and August 2021, respectively.

In addition, the Company is required under the Loan Agreement to maintain its deposit and securities accounts with the Bank and to comply with various operating covenants and default clauses. A breach of any of these covenants or clauses could result in a

default under the Loan Agreement, which would cause all of the outstanding indebtedness under the facility to become immediately due and payable. The Company is in compliance with all such covenants and clauses.

Facility Leases

The Company leases certain office and laboratory space from a stockholder of the Company under a non-cancelable operating lease. In June 2016, the Company amended the operating lease, 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. The lease is subject to additional charges for common area maintenance and other costs. In connection with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit in the amount of $0.1 million. As of March 31, 2017, future minimum payments under the operating lease are $13.7 million.

In January 2015, the Company entered into a sublease for additional laboratory space. The sublease is accounted for as an operating lease and expires in September 2017. Under the sublease, total future minimum payments as of March 31, 2017 are $0.2 million.

6. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

In November 2016, the Company completed a private placement of stock in which investors, certain of which are affiliated with the directors and officers of the Company, purchased convertible preferred stock and common stock of the Company (the "November 2016 Placement"). The Company issued 2,819,549 shares of non-voting Class A Convertible Preferred Stock (the "Class A Preferred") at $13.30 per share, each of which is convertible into five shares of common stock upon certain conditions defined in the Certificate of Designation of Preferences, Rights and Limitations of the Class A Preferred filed with the Delaware Secretary of State on November 22, 2016 (the "CoD"). The Class A Preferred were purchased exclusively by entities affiliated with Redmile Group, LLC (collectively, "Redmile"). The terms of the CoD prohibited Redmile from converting the Class A Preferred into shares of the Company's common stock if, as a result of conversion, Redmile, together with its affiliates, would own more than 9.99% of the Company's common stock then issued and outstanding (the "Redmile Percentage Limitation"), which percentage could change at Redmile's election upon 61 days' notice to the Company to i) any other number less than or equal to 19.99% or (ii) subject to approval of the Company's stockholders to the extent required in accordance with the NASDAQ Global Market rules, any number in excess of 19.99%. On May 2, 2017, the Company's stockholders approved the issuance of up to an aggregate of 14,097,745 shares of common stock upon the conversion of the outstanding shares of Class A Preferred. As a result, Redmile has the right to increase the Redmile Percentage Limitation to any percentage in excess of 19.99% at its election. The Company also issued 7,236,837 shares of common stock at $2.66 per share as part of the November 2016 Placement. Gross proceeds from the November 2016 Placement were $56.7 million, and after giving effect to costs related to placement, net proceeds were $54.9 million.

The rights of the Class A Preferred issued in November 2016 are set forth in the CoD. The Class A Preferred are non-voting shares and have a stated par value of $0.001 per share and are convertible into five shares of the Company's common stock at a conversion price of $2.66 per share, which was the fair value of the Company's common stock on the date of issuance. Holders of the Class A Preferred have the same dividend rights as holders of the Company's common stock. Additionally, the liquidation preferences of the Class A Preferred are pari passu among holders of the Company's common stock and holders of the Class A Preferred, pro rata based on the number of shares held by each such holder (treated for this purpose as if the Class A Preferred had been converted to common stock).

The Company evaluated the Class A Preferred for liability or equity classification under ASC 480, Distinguishing Liabilities from Equity, and determined that equity treatment was appropriate because the Class A Preferred did not meet the definition of the liability instruments defined thereunder for convertible instruments. Specifically, the Class A Preferred are not mandatorily redeemable and do not embody an obligation to buy back the shares outside of the Company's control in a manner that could require the transfer of assets. Additionally, the Company determined that the Class A Preferred would be recorded as permanent equity, not temporary equity, based on the guidance of ASC 480 given that they are not redeemable for cash or other assets (i) on a fixed or determinable date, (ii) at the option of the holder, and (iii) upon the occurrence of an event that is not solely within control of the Company.

The Company has also evaluated the Class A Preferred in accordance with the provisions of ASC 815, Derivatives and Hedging, including the consideration of embedded derivatives requiring bifurcation from the equity host. Based on this assessment, the Company determined that the conversion option is clearly and closely related to the equity host, and thus, bifurcation is not required.

The issuance of convertible preferred stock could generate a beneficial conversion feature ("BCF"), which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor (or in-the-money) at inception because the conversion option has an effective strike price that is less than the market price of the underlying stock on the commitment date. The Class A Preferred have an effective conversion price of $2.66 per common share, which was equal to the market price of the Company's stock on the commitment date. Therefore, no BCF is present.

The Company also entered into a registration rights agreement (the "Registration Rights Agreement") with certain of the purchasers in the November 2016 Placement, excluding those purchasers affiliated with the Company's directors and officers, requiring the Company to register for the resale of the relevant shares. The Company registered all of the relevant shares issued in the November 2016 Placement for resale on a Form S-3 filed with the SEC, as required under the Registration Rights Agreement, and the registration statement was declared effective in January 2017.

Stock Options and Restricted Stock Units

Stock option activity under all equity and stock option plans is summarized as follows:

	Number of Options	Weighted-Average Price
Balance at December 31, 2016	3,910,350	$ 3.77
Granted	1,851,980	2.74
Canceled	(235,950)	3.55
Exercised	(14,916)	2.87
Balance at March 31, 2017	5,511,464	$ 3.44

Restricted stock unit activity under all equity and stock option plans is summarized as follows:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value per Share
Balance at December 31, 2016	525,250	$ 4.89
Granted	—	—
Canceled	(35,000)	4.89
Vested	—	—
Balance at March 31, 2017	490,250	$ 4.89

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

	Three Months Ended March 31,	
	2017	2016
Research and development	$569	$442
General and administrative	298	355
	$867	$797

As of March 31, 2017, the outstanding options included 333,600 performance-based options for which the achievement of the performance-based vesting provisions was determined not to be probable. The aggregate grant date fair value of these unvested options at March 31, 2017 was $0.7 million.

As of March 31, 2017, the unrecognized compensation cost related to outstanding options (excluding those with performance-based conditions determined not to be probable) was $6.8 million and is expected to be recognized as expense over a weighted average period of approximately 3.0 years.

As of March 31, 2017, the unrecognized compensation cost related to restricted stock units was $1.5 million which is expected to be recognized as expense over approximately 2.5 years.

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

	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	2.1 %	1.7 %
Expected volatility	90.2%	79.2%
Expected term (in years)	6.0	6.0
Expected dividend yield	0.0 %	0.0 %

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the non-employee stock option grants were as follows:

	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	2.1 %	1.4 %
Expected volatility	90.8%	80.9%
Remaining contractual term (in years)	8.7	6.5
Expected dividend yield	0.0 %	0.0 %

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2016 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2017.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terms such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" expressions. Factors that could cause or contribute to differences in results include, but are not limited to, those set forth under "Risk Factors" under Item 1A of Part II below. Except as required by law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. We are developing first-in-class cell therapy product candidates based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we use a therapeutic approach that we generally refer to as cell programming. For certain of our cell therapy product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells "iPSCs", generate a master iPSC line having preferred biological properties and direct the fate of the iPSC line to create a clonal population of our cell therapy product candidate. We believe the use of master pluripotent cell lines may enable the creation of cell therapy product candidates that are well-defined and uniform in composition; that can be reproducibly manufactured at significant scale; and that can be effectively used to treat a large number of patients in an off-the-shelf manner. Utilizing these therapeutic approaches, we program cells of the immune system, including Natural Killer "NK" cells, T cells and CD34 cells, and are advancing a pipeline of programmed cellular immunotherapies in the therapeutic areas of immuno-oncology and immuno-regulation.

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

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

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Since our inception in 2007, we have devoted substantially all of our resources to our cell programming approach and the research and development of our product candidates, the creation, licensing and protection of related intellectual property, and the provision of

general and administrative support for these activities. To date, we have funded our operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants.

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

- conduct our Phase 1/2 clinical trial of ProTmune, and initiate and conduct any additional clinical trials of ProTmune;
- support our first-in-human clinical trial of FATE-NK100 under an investigator-initiated clinical trial agreement with the University of Minnesota, and initiate and conduct additional clinical trials of FATE-NK100 including under our own Investigational New Drug application;

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

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

Financial Operations Overview

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

Revenue

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

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

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

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

In connection with the Agreement, we have recognized $1.0 million and $1.3 million during the three months ended March 31, 2017 and 2016, respectively, as collaboration revenue in the consolidated statements of operations. As of March 31, 2017, aggregate deferred revenue related to the Agreement was $4.4 million.

Research and Development Expenses

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

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

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

- initiating and conducting our clinical trials of ProTmune to examine its safety and efficacy in adult patients with hematologic malignancies undergoing allogeneic HCT;
- supporting the first-in-human clinical trial of FATE-NK100 under an investigator-initiated clinical trial agreement with the University of Minnesota, and initiating and conducting our clinical trials of FATE-NK100, to examine its safety and efficacy in cancer;
- conducting preclinical and clinical translation activities to investigate the therapeutic potential of our immuno-oncology programs, including our off-the-shelf NK- and T-cell cancer immunotherapies derived from engineered induced pluripotent stem cell lines;
- conducting preclinical activities to investigate the therapeutic potential of our immuno-regulatory programs, including a hematopoietic cell therapy for regulating auto-reactive T cells of patients with autoimmune disorders; and
- performing research, preclinical development, process development and clinical translation activities under our sponsored research and collaboration agreements, including our agreements with the University of Minnesota, Memorial Sloan Kettering and Juno.

Due to the inherently unpredictable nature of preclinical and clinical development, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development of our product candidates, including ProTmune and FATE-NK100. Clinical and preclinical development timelines and costs, and the potential of development success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative Expenses

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

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

Other Income (Expense)

Other income (expense) consists primarily of interest income earned on cash and cash equivalents, interest income from short-term investments (including the amortization of discounts and premiums), and interest expense on amounts outstanding under our credit facilities.

Critical Accounting Policies and Significant Judgments and Estimates

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

The estimates and judgments involved in the accounting policies as described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2016 continue to be our critical accounting policies. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2017.

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 March 31, 2017 and 2016

The following table summarizes the results of our operations for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,		Increase/ (Decrease)
	2017	2016	
Collaboration revenue	$1,027	$1,322	$ (295)
Research and development expense	7,966	6,636	1,330
General and administrative expense	3,032	2,602	430
Total other expense, net	155	461	(306)

Revenue. During the three months ended March 31, 2017 and 2016, we recognized revenue of $1.0 million and $1.3 million, respectively, under the Agreement with Juno, which we entered into in May 2015.

Research and development expenses. Research and development expenses were $8.0 million for the three months ended March 31, 2017, compared to $6.6 million for the three months ended March 31, 2016. The increase in research and development expenses primarily includes the following changes:

- $0.8 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
- $0.6 million increase in compensation and benefits expense, including employee stock-based compensation expense, relating to employee headcount costs to support our clinical development and research activities, including our activities under our collaboration with Juno.

General and administrative expenses. General and administrative expenses were $3.0 million for the three months ended March 31, 2017, compared to $2.6 million for the three months ended March 31, 2016. The increase in general and administrative expenses primarily relates to a $0.2 million increase in intellectual property-related expenses.

Other expense, net. Other expense, net was $0.2 million for the three months ended March 31, 2017 and $0.5 million for the three months ended March 31, 2016. Other expense, net for each period consisted primarily of interest expense relating to our term loans with Silicon Valley Bank, interest income earned on cash and cash equivalents, and interest income from short-term investments (including the amortization of discounts and premiums).

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of March 31, 2017, we had an accumulated deficit of $186.0 million and anticipate that we will continue to incur net losses for the foreseeable future.

Operating Activities

Cash used in operating activities increased from $7.3 million for the three months ended March 31, 2016 to $7.5 million for the three months ended March 31, 2017. The primary driver of this change in cash used in operating activities was our increase in net loss for the periods presented, partially offset by an increase in accounts payable and accrued expenses.

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 March 31, 2017, we have received a total of $3.8 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 March 31, 2017, 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 March 31, 2017, no royalties have been received by us.

Investing Activities

During the three months ended March 31, 2017 and 2016, investing activities used cash of $38.4 million and $16.3 million, respectively. During the three months ended March 31, 2017, we purchased $40.4 million in U.S. Treasuries as short-term investments, offset by $1.8 million in maturities of these short-term investments. During the three months ended March 31, 2016, we purchased $16.2 million in U.S. Treasuries as short-term investments. All other investing activities for the periods presented were attributable to the purchase of property and equipment.

Financing Activities

For the three months ended March 31, 2017, financing activities used cash of $2.2 million, which primarily consisted of $2.0 million of principal payments on our term loans outstanding with Silicon Valley Bank.

For the three months ended March 31, 2016, financing activities used cash of $1.7 million, which consisted of $1.8 million of principal payments on our term loans outstanding with Silicon Valley Bank, offset by $0.1 million received from the issuance of common stock.

From our inception through March 31, 2017, we have funded our consolidated operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of March 31, 2017, we had aggregate cash and cash equivalents and short-term investments of $82.3 million.

Private Placements of Common and Convertible Preferred Stock

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

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

Silicon Valley Bank Debt Facility

On July 30, 2014, we entered into an Amended and Restated Loan and Security Agreement (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, 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 three months ended March 31, 2017, we made aggregate principal payments totaling $2.0 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.

We are required under the Loan Agreement to maintain our deposit and securities accounts with the Bank and to comply with various default clauses and operating covenants that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness

under the facility to become immediately due and payable.

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 May 15, 2017, after taking into account our 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 March 31, 2017 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

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

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

- the initiation, timing, progress, size, duration, costs and results of our preclinical studies and clinical trials for our product candidates;
- the number and the nature of product candidates that we pursue;
- the cost of process development and manufacturing of our product candidates, including the cost of supplies and materials to support these activities;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;
- 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 leasing additional space comprising approximately 24,000 square feet in the same building as its existing space. As of March 31, 2017, aggregate future minimum payments under these operating leases are $13.9 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

We are exposed to market risk related to changes in interest rates. As of March 31, 2017, our cash and cash equivalents consisted of cash and money market mutual funds, and our short-term investments consisted of United States treasuries with maturities ranging from six to twelve months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature and low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations.

Our outstanding debt 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 March 31, 2017.

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

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

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

- difficulties in identifying eligible patients for participation in clinical trials of our product candidates due to our focus on the development of product candidates for the treatment of rare diseases;
- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties relating to patients enrolling in studies of therapeutics sponsored by our competitors;
- difficulties in obtaining agreement from regulatory authorities on study endpoints, achieving study endpoints, demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- difficulties in obtaining agreement from regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for approval of an investigational new drug application, or IND, to initiate and conduct clinical trials for any of our product candidates;
- the occurrence of unexpected safety issues or adverse events in any current or subsequent clinical trial of our product candidates;
- securing and maintaining the support of clinical investigators and investigational sites, including investigators and sites who may conduct clinical trials under an investigator-initiated IND with our financial support, and obtaining institutional review board, or IRB, approval at each site for the conduct of our clinical trials;
-

governmental or regulatory delays, failure to obtain regulatory approval, or uncertainty or changes in regulatory requirements, policy or guidelines;

- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and clinical trial sites;
- failure, by us, cell processing facilities at our clinical trial sites, or third parties that we contract with, to manufacture certain of our product candidates consistently in accordance with our protocol-specified processes and applicable regulatory requirements for use in our clinical trials;
- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators and IRBs;

- obtaining sufficient quantities of critical reagents and other materials and equipment necessary for the manufacture 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 there are delays in initiating or conducting 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 initiating, conducting or completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the initiation, conduct or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner. For example, with respect to the development of ProTmune, there are currently only a limited number of specialized transplant centers that perform hematopoietic stem cell transplants, 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 ability to develop ProTmune. Our ability to enroll patients in our clinical trials, including in our current Phase 1/2 PROTECT 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, prospects, financial condition, results of operations, and market price of shares of our common stock.

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

Developing therapeutic products, including conducting preclinical studies, process development and manufacturing activities, and clinical trials of cellular immunotherapies, is expensive. Based upon our currently expected level of

operating expenditures, we believe that we will be able to fund our operations for at least the next twelve months. However, our resources will likely be

insufficient to conduct research and development programs, process development and manufacturing activities, and clinical development to the full extent currently planned. We will require substantial additional capital to conduct the research and development, process development, manufacturing, and clinical and regulatory activities necessary to bring any of our product candidates to market. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our current Phase 1/2 PROTECT clinical trial of ProTmune, the planned Phase 1 clinical trial of FATE-NK100 under an investigator-initiated clinical trial agreement with the University of Minnesota, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate clinical trials for our product candidates;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing, and clinical trials, of any additional product candidates we may identify for development;
- our ability and the ability of our investigators to initiate, and the progress, results, size, timing and costs of, clinical trials of our product candidates, including ProTmune and FATE-NK100, that will be necessary to support any application for regulatory approval;
- our ability to manufacture, or enter into arrangements with third parties for the manufacture of, our product candidates, including ProTmune and FATE-NK100, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing and commercialization activities and arrangements, including the manufacturing of our product candidates and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Juno, the University of Minnesota and Memorial Sloan Kettering Cancer Center, to advance the research, development and commercialization of therapeutic products.

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

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

Our clinical development of ProTmune, and the initiation of clinical development of our other product candidates, could be substantially delayed if the FDA requires us to conduct unanticipated studies, including preclinical studies, or clinical trials or imposes other requirements or restrictions, including on the manufacture of our product candidates.

The FDA may require us to generate additional preclinical, product, manufacturing, or clinical data as a condition to continuing our current clinical trial of ProTmune, or initiating and conducting any future clinical trials of ProTmune, FATE-NK100 or our other product candidates, including our iPSC-derived cell product candidates. Additionally, the FDA may in the future have comments, or impose requirements, on our protocols or processes for conducting clinical trials of ProTmune, FATE-NK100, or our iPSC-derived cell product candidates, including the protocols, materials, and processes we use to manufacture our product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, materials, or processes, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical

trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with ProTmune, FATE-NK100, our iPSC-derived cell product candidates, or any other product candidates we may identify, we may:

- be delayed in obtaining, or unable to obtain, regulatory approval for such product candidates;
- be required to amend the protocols for our clinical trials, perform additional nonclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or
- in the event a product candidate is approved, have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

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

All of our product candidates are currently in research or early clinical development, including ProTmune, FATE-NK100, and our iPSC-derived cell product candidates. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety and efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

We may delay or cancel our ongoing research and development activities and our current or planned clinical development for any of our product candidates, including ProTmune,FATE-NK100, and our iPSC-derived cell product candidates, for a variety of reasons, including:

- determining that a product candidate is ineffective 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 and with materials acceptable to the FDA for conduct of clinical trials or 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 or through clinical development, regulatory approval and 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 such product candidate is manufactured in accordance with applicable regulatory requirements, is safe and effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies, process development and manufacturing activities, and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety profiles that do not potentially outweigh the therapeutic benefit, and whether regulatory agencies agree that the data from our clinical trials and our manufacturing processes are sufficient to support approval. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. The final results of our current and future clinical trials may not meet the FDA’s or other regulatory agencies’ requirements

to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing 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.

Manufacture of our product candidates, particularly our proposed iPSC-derived cell product candidates, is complex. 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 protocols and processes or if we are required to change our manufacturing protocols and processes to comply with regulatory requirements.

The manufacture of ProTmune in close proximity to transplant centers within a short period of time before transplantation, and of FATE-NK100 within a short period of time before administration to a patient, may present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. We will need to standardize the process for manufacturing ProTmune and FATE-NK100, and any product that is 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, protocols, and materials used for the manufacture of ProTmune, FATE-NK100, 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 for ProTmune, FATE-NK100, or any of our iPSC-derived cell product candidates could require us to incur additional development costs or result in delays to our clinical development plans, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for such product candidates.

In addition, the manufacturing processes required for producing our proposed iPSC-derived cell product candidates may be complex, as these processes are novel and have not been validated for clinical and commercial production. Any product candidates that we develop using iPSCs will require processing steps that are more complex than those required for most small molecule drugs and other cellular immunotherapies.

Further, for certain of our product candidates, including our proposed iPSC-derived cell product candidates, we are still developing reproducible and commercial-scale manufacturing processes, and we will need to transfer these manufacturing processes to third parties, including larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, to support commercialization of any approved product candidates. We may run into technical or scientific issues related to manufacturing or development of any of our product candidates, including problems establishing manufacturing processes acceptable to the FDA, that we may be unable to resolve in a timely manner or with available funds. In addition, we may experience technical issues or delays in transferring our internal manufacturing processes to third parties for manufacture of our product candidates for conduct of clinical trials or for commercialization of our product candidates.

In addition, we will make changes as we work to optimize our manufacturing processes, and we cannot be sure that even minor changes in the processes will not result in changes to the efficacy and safety our product candidates. In some circumstances, changes in a manufacturing process, including to our protocols or materials used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates.

Problems with the manufacturing processes, even minor deviations from the normal processes, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient supplies of our product candidates for our planned clinical trials or eventual commercialization. Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA,

EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

Any such events could delay or prevent our ability to obtain regulatory approval or commercialize ProTmune, FATE-NK100 or our other product candidates, which would adversely affect our business, financial condition and results of operations.

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

Patients treated with ProTmune in our ongoing clinical trial, as well as patients who may undergo treatment with other product candidates that we may develop, such as FATE-NK100, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients

may receive. Any of these events could prevent us from advancing ProTmune, FATE-NK100, or other product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance ProTmune, FATE-NK100, or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

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

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

The preclinical and clinical development, manufacture, and regulatory requirements for approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the preclinical and clinical development, manufacture, and regulatory requirements for approval of our product candidates, we may be required to modify or change our preclinical and clinical development plans or our manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent our ability to develop, manufacture, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular immunotherapies, and stem cell therapies and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to prevent acute graft-versus-host disease in patients undergoing allogeneic HSCT, which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for ProTmune.

Regulatory requirements in the United States and in other countries governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the Center for Biologics Evaluation and Research, or CBER, recently announced that the Office of Cellular, Tissue and Gene Therapies would be restructured to create a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products, such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical

development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products will likely be reviewed by the FDA's advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

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

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Results from preclinical testing, process development and manufacturing

activities, and earlier clinical studies, including clinical studies with similar product candidates, are not necessarily predictive of future results, including clinical trial results. While we have demonstrated in preclinical models that a single administration of ProTmune resulted in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, we may not observe similar results in future preclinical or clinical studies of ProTmune, including our Phase 1/2 PROTECT study. Additionally, while subjects treated with one of our prior product candidates, which was undergoing development for use as an allogeneic umbilical cord blood graft in HSCT, experienced a reduction in the number of severe viral infection-related adverse events in an earlier clinical trial, these results should not be relied upon as predictive of any clinical study results with ProTmune. Although ProTmune is of similar composition, ProTmune is a different product candidate resulting from a different manufacturing process. For example, our prior product candidate consisted of umbilical cord blood programmed ex vivo with FT1050, while ProTmune consists of mobilized peripheral blood programmed ex vivo with FT1050 and a second small molecule, FT4145. Further, the earlier clinical trial was 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 improve, standardize and automate the manufacture of our product candidates, including ProTmune and FATE-NK100, and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency or efficacy of such product candidates;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and
- safety issues or adverse events in patients that enroll in our current or future clinical trials.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing processes or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and prospects.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Any product candidate for which we obtain marketing approval, along with the manufacturing 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 PROTECT 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 manufacture, 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 our product candidates 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 our product candidates, including ProTmune and FATE-NK100. 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 our pharmacologic modulators 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 materials required for the manufacture of our product candidates, 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 our product candidates.

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

We face a variety of challenges and uncertainties associated with our dependence on human 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 PROTECT clinical study. The availability of mPB for the manufacture of ProTmune depends on a number of regulatory, political, economic and technical factors outside of our control, including:

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

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

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

later require that mPB units be licensed, and that ProTmune be manufactured using only licensed mPB units. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

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

We rely upon third parties, including medical institutions, clinical investigators, cell processing laboratories, and clinical research organizations, or CROs, for the conduct of certain research and preclinical development activities, process development and manufacturing activities, and for the conduct, management, and supervision of clinical trials of our product candidates. We do not have direct control over the activities of these third parties, and may have limited influence over their actual performance. Our reliance on these third parties and CROs does not relieve us of our responsibilities to ensure that our clinical studies are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with applicable 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, process development, manufacturing, 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, process development and manufacturing activities, and clinical trials, and the development of our product candidates, may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties or CROs are terminated for any reason, the development of our product candidates may be delayed or impaired, and we may be unable to advance our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our collaborators and strategic partners may control aspects of our clinical trials, which could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.

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

We expect to rely on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of manufacturing for each of our product candidates, and currently rely, and expect to continue to rely, on third parties, including cell processing facilities associated with clinical trial sites, to manufacture our product candidates for use in conducting clinical trials of our product candidates and for commercial sale upon approval of any of our product candidates. In some cases these third parties are academic, research or similar institutions that may not apply the same quality control protocols utilized in certain commercial settings.

In addition, we do not own any facility that may be used as a clinical-scale manufacturing and processing facility. The facilities used to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. Because we will not control all aspects of the manufacturing process for each of our product candidates, we will be dependent on third parties, including cell processing facilities at sites conducting clinical trials of our product candidates, for manufacture of our product candidates in compliance with regulatory requirements, known as cGMP requirements. If such third parties cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If third parties fail to meet the regulatory requirements of the FDA and other foreign regulatory agencies in manufacturing our product candidates, such failure could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs, and prevent us from commercializing our products successfully.

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

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

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

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, 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 also for our cell programming technology in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell programming approach. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Even if we obtain patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products.

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

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

Certain rights to our key technologies and product candidates, including intellectual property relating to ProTmune, FATE-NK100, and our 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 and FATE-NK100, through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We may incur substantial costs as a result of litigation or other proceedings relating to the enforcement of 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. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the U.S. Patent and Trademark Office and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

We cannot guarantee that the manufacture, use or marketing of ProTmune, FATE-NK100, our iPSC-derived cell product candidates, or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering products and

technologies similar to ours. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of the manufacturing process of any of our product candidates, any compositions formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property rights, unless that third party grants us rights to use its intellectual property. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an

infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

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

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

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 novel nature of our product candidates, and the targeted indication of HSCT procedures in general and our cellular immunotherapy product candidates in particular, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular immunotherapy product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures, including in the area of orphan drug products. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

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

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

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If the market opportunities for our product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.

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

Risks Related to Our Business and Industry

The success of our product candidates, including ProTmune, 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 immunotherapy generally, and in the practice of HSCT in particular, will negatively affect our ability to develop and commercialize our product candidates. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the need for patients to undergo HSCT procedures is obviated due to the development and commercialization of therapeutics targeting the underlying cause of diseases addressed by HSCT, our business prospects will be significantly harmed.

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

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

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

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

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

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended, 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 and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

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

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. Additionally, beginning on the second anniversary of the agreement in May 2017, Juno may terminate the agreement upon six (6) months' written notice to us. If the collaboration is unsuccessful for these or other reasons, or is otherwise terminated for any reason, we may not receive all or any of the research program funding, target selection fees, milestone payments or royalties under the agreement. Any of the foregoing could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

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

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into business combinations with other companies. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

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

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

The use of our product candidates in clinical trials, and the sale of any products for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, hospitals, medical centers, healthcare providers, pharmaceutical companies, and consumers, or by others selling, manufacturing or otherwise coming into contact with our product candidates. We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs. In addition, if and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain insurance coverage for any approved products on commercially reasonable terms or in sufficient amounts to protect us against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim, or a series of claims, brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for a variety of reasons. Such events, whether or not resulting from our product candidates, could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively affect or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of March 31, 2017, we had an

accumulated deficit of $186.0 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 FATE-NK100 and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to

raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Our stock price is subject to fluctuation based on a variety of factors.

The market price of shares of our common stock could be subject to wide fluctuations as a result of many risks listed in this section, and other risks beyond our control, including:

- the timing of the initiation of, and progress in, our current and planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours;
- developments related to the FDA or to regulations applicable to cellular immunotherapies generally or our product candidates in particular including, but not limited to, regulatory pathways and clinical trial requirements for approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments related to proprietary rights including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;
- developments of technological innovations or new therapeutic products by us or others in the field of immunotherapy;
- announcements or expectations of additional equity or debt financing efforts;
- sales of our common stock by us, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., or by our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- fluctuations in our operating results; and
- general economic and market conditions.

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

Our principal stockholders exercise significant control over our company.

As of May 9, 2017, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 73.77% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 6 of the Notes to the Consolidated Financial Statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 6 of the Notes to the Consolidated Financial Statements herewith) elects to remove certain limitations on the percentage of the Company's outstanding common stock that it may own such that the 2,819,549 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 14,097,745 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 78.89%.Although we are not aware of any voting arrangements in place among these

stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company or affecting the liquidity and volatility of our common stock, and might affect the market price of our common stock.

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

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, state or government grants, strategic alliances, licensing and collaboration arrangements, or other third-party business arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations, and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. We also registered all of the 6,766,915 shares of common stock issued by us and all 14,097,745 shares of common stock issuable upon the conversion of an aggregate of 2,819,549 shares of Class A Convertible Preferred Stock issued by us in our November 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in January 2017. As a result, all of these shares are currently available for resale to the public, which may result in dilution to our stockholders. In addition, 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, and beginning in May 2017, Juno is entitled to registration rights with respect to shares of our common stock held by it. Any sale or issuance of securities pursuant to a registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, 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, cash equivalents and any additional funds that we may raise to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates. We may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

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

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

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

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

Our ability to use our net operating loss carryforwards and certain other tax benefits may be limited and, as a result, our future tax liability may increase.

Generally, a change of more than 50% in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards and other pre-change tax benefits (such as research tax credits) attributable to the period prior to such change. We triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that there were

no ownership changes from May 2015 through March 2017. In the future, we may experience ownership changes as a result of 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) None.
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.

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: May 15, 2017 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	333-190608	3.2	August 29, 2013
3.2	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-190608	3.4	August 29, 2013
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
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

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