FATE THERAPEUTICS INC
Form 10-Q
November 03, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

OR

o 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 of incorporation or organization)	(IRS Employer 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 x No o

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 x No o

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

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

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

As of November 2, 2015, 28,716,570 shares of the registrant s common stock, par value $0.001 per share, were issued and outstanding.

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FATE THERAPEUTICS, INC.

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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)

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 72,857	$ 49,101
Accounts receivable	846	
Prepaid expenses and other current assets	482	760
Total current assets	74,185	49,861
Property and equipment, net	2,072	1,200
Restricted cash	122	122
Other assets	24	
Total assets	$ 76,403	$ 51,183
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,280	$ 645
Accrued expenses	2,317	2,260
Current portion of deferred rent	45	85
Current portion of deferred revenue	2,451	
Repurchase liability for unvested equity awards	9	45
Long-term debt, current portion	6,494	1,535
Total current liabilities	12,596	4,570
Deferred rent	75	51
Deferred revenue	5,460	
Accrued expenses	642	149
Long-term debt, net of current portion	12,635	18,073
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, $0.001 par value; authorized shares 5,000,000 at September 30, 2015 and December 31, 2014; no shares issued or outstanding		
Common stock, $0.001 par value; authorized shares 150,000,000 at September 30, 2015 and December 31, 2014; issued and outstanding shares 28,715,730 at September 30, 2015 and 20,569,399 at December 31, 2014	29	21

Additional paid-in capital		179,904		140,711
Accumulated deficit		(134,938)		(112,392)
Total stockholders equity		44,995		28,340
Total liabilities and stockholders equity	$	76,403	$	51,183

See accompanying notes.

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Fate Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(unaudited)			
Collaboration revenue	$ 1,026	$	$ 1,355	$
Operating expenses:				
Research and development	5,003	4,080	14,428	12,570
General and administrative	2,351	1,904	7,797	6,391
Total operating expenses	7,354	5,984	22,225	18,961
Loss from operations	(6,328)	(5,984)	(20,870)	(18,961)
Other income (expense):				
Interest income	4		7	1
Interest expense	(562)	(187)	(1,683)	(258)
Loss on extinguishment of debt		(432)		(432)
Total other expense, net	(558)	(619)	(1,676)	(689)
Net loss and comprehensive loss	$ (6,886)	$ (6,603)	$ (22,546)	$ (19,650)
Net loss per common share, basic and diluted	$ (0.24)	$ (0.32)	$ (0.92)	$ (0.96)
Weighted-average common shares used to compute basic and diluted net loss per share	28,650,356	20,489,181	24,404,740	20,435,073

See accompanying notes.

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Fate Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30, (unaudited)	
	2015	**2014**
Operating activities		
Net loss	$ (22,546)	$ (19,650)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	477	371
Stock-based compensation	1,920	1,822
Amortization of discounts and debt issuance costs	132	17
Noncash interest expense	494	76
Deferred rent	(16)	(35)
Deferred revenue	7,911	
Stock-based milestone charges		375
Loss on extinguishment of debt		3
Changes in operating assets and liabilities:		
Accounts receivable	(846)	
Prepaid expenses and other current assets	288	520
Accounts payable and accrued expenses	759	236
Net cash used in operating activities	(11,427)	(16,265)
Investing activities		
Purchase of property and equipment	(1,320)	(611)
Net cash used in investing activities	(1,320)	(611)
Financing activities		
Issuance of common stock from equity incentive plans, net of repurchases and issuance costs	385	146
Proceeds from public offering of common stock, net of issuance costs	32,149	
Proceeds from sale of common stock to collaboration partner	4,580	
Proceeds from long-term debt		10,000
Payments on long-term debt	(611)	(1,750)
Payments for the issuance of debt		(26)
Net cash provided by financing activities	36,503	8,370
Net change in cash and cash equivalents	23,756	(8,506)
Cash and cash equivalents at beginning of the period	49,101	54,036
Cash and cash equivalents at end of the period	$ 72,857	$ 45,530

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 biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for the treatment of cancer and immune disorders. Its cell-based product pipeline is comprised of off-the-shelf immuno-oncology therapeutics, including NK- and T-cell-based candidates derived from induced pluripotent cells, and immuno-regulatory therapeutics, including hematopoietic cell-based candidates for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing auto-reactive T cells of patients with auto-immune disorders. The Company s adoptive cell therapy candidates are based on its novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of September 30, 2015, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company s revenues have been derived from collaboration agreements and government grants.

Follow-on Public Equity Offering

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

Use of Estimates

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

accrued expenses. Although these estimates are based on the Company s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Principles of Consolidation

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

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.

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 United States Securities and Exchange Commission (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,

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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, 2014, contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2014 filed by the Company with the SEC on March 12, 2015. The results for the three and nine months ended September 30, 2015 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.

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

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

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

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Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option 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 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.

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 have been issued upon the early exercise of stock options and are subject to future vesting and unvested restricted stock totaling 39,279 shares and 73,248 shares for the three months ended September 30, 2015 and 2014, respectively and 49,596 shares and 80,645 shares for the nine months ended September 30, 2015 and 2014, respectively. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents for the periods presented include warrants for the purchase of common stock, and common stock options 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 and nine months ended September 30, 2015, the Company realized a net loss of $6.9 million and $22.5 million, respectively. Shares of potentially dilutive securities totaled 3.1 million for the three and nine months ended September 30, 2015, including options to purchase 3.0 million shares of common stock.

For the three and nine months ended September 30, 2014, the Company realized a net loss of $6.6 million and $19.7 million, respectively. Shares of potentially dilutive securities totaled 2.5 million for each of the three and nine months ended September 30, 2014, including options to purchase 2.4 million shares of common stock.

Recent Accounting Pronouncements

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

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

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

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2. Juno Collaboration and License Agreement

On May 4, 2015, the Company entered into a research collaboration and license agreement (the Agreement) with Juno Therapeutics, Inc. (Juno) to identify small molecules to program the therapeutic properties of Juno s genetically-engineered T-cell product candidates. 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 activities under the collaboration for an exclusive 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 product candidates. 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 and nine months ended September 30, 2015 was $1.0 million and $1.4 million, respectivley. As of September 30, 2015, aggregate deferred revenue related to the Agreement was $7.9 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.

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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 product 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 product upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno product and the fifth Juno product 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 product 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 product that uses or incorporates the Company s small molecule modulators, and continuing until the later of: i) the expiration of 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 product, Juno has agreed to pay the Company royalties in the low single-digits on net sales of each Juno product 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. Asset Acquisition of Verio Therapeutics Inc.

On April 7, 2010, the Company acquired Verio Therapeutics Inc. (Verio), a development stage company headquartered in Ottawa, Ontario to gain access to its exclusively licensed intellectual property. In connection with the asset acquisition of Verio, the stockholders of Verio received 900,000 non-voting shares of Fate Canada (the Exchangeable Shares) that were initially exchangeable into 138,462 shares of the Company s common stock and, subject to the validation of certain scientific data and the achievement of certain preclinical, clinical, commercial and financial milestones, were exchangeable for up to 884,605 shares of the Company s common stock.

As a result of the Company s IPO on October 4, 2013, 480,763 shares of the Company s common stock were issued during the fourth quarter of 2013 pursuant to the redemption of the Exchangeable Shares. The total number of shares of the Company s common stock issued upon the exchange of the Exchangeable Shares as a result of the IPO had increased from 138,462 shares of the Company s common stock to a total of 480,763 shares of the Company s common stock based upon the achievement of certain contractual milestones. Additionally, during the nine months ended September 30, 2014, based on the achievement of certain preclinical milestones, an additional 38,463 shares of the Company s common stock were earned and issued, resulting in a $0.4 million charge to research and development expense.

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

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.

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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. As of September 30, 2015 and December 31, 2014, the carrying amount of cash equivalents was $35.3 million, which approximates fair value and was determined based upon Level 1 inputs. Cash equivalents primarily consisted of money market funds. As of September 30, 2015 and December 31, 2014, the Company did not hold any Level 2 or Level 3 financial assets that are recorded at fair value on a recurring basis.

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 September 30, 2015 and December 31, 2014, 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):

	September 30, 2015	December 31, 2014
Accrued payroll and other employee benefits	$ 1,079	$ 1,234

Accrued clinical trial costs		460		415
Accrued other		778		611
Accrued expenses	$	2,317	$	2,260

During the nine months ended September 30, 2015, the Company issued 19,956 shares of its common stock to certain senior executives of the Company as consideration for a portion of their 2014 annual bonuses. All related amounts were accrued for as liabilities as of December 31, 2014. Future senior executive bonus amounts, timing, and method of payment are at the sole discretion of the Board of Directors of the Company. As such, all relevant bonus estimates are accrued for as liabilities as of September 30, 2015.

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):

		September 30, 2015		**December 31, 2014**
Long-term debt	$	19,389	$	20,000
Less debt issuance costs and discount, net of current portion		(105)		(381)
Long-term debt, net of long-term portion of debt issuance costs and discount		19,284		19,619
Less current portion of long-term debt		(6,649)		(1,546)
Long-term debt, net	$	12,635	$	18,073
Current portion of long-term debt	$	6,649	$	1,546
Less current portion of debt issuance costs and discount		(155)		(11)
Current portion of long-term debt, net	$	6,494	$	1,535

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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 relating to the Company s Phase 2 clinical trial of ProHema, additional term loans totaling up to $10.0 million in the aggregate, which were available until December 31, 2014 (each, a Term B Loan). On December 24, 2014, the Company elected to draw on the full $10.0 million under a Term B Loan.

The Term A Loan and the Term B Loan mature on January 1, 2018 and June 1, 2018, respectively and bear interest at a fixed annual rate of 6.94% and 7.07%, respectively. Interest became payable in cash on a monthly basis beginning the first day of each month following the month in which the funding date of each loan occurred. The Company is required to make a monthly payment of interest only during the first twelve months following the funding date of each loan, and thereafter is required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty-month amortization schedule. During the three and nine months ended September 30, 2015, the Company made principal payments totaling $0.6 million on the Term A Loan.

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

A portion of the proceeds from the Term A Loan were used to repay loans outstanding under the Loan Agreement and to pay for transaction fees related to the Restated LSA, including a commitment fee of $0.4 million paid by the Company to the Bank. Net proceeds from the Term A Loan, after repayment of loans outstanding under the Loan Agreement and transaction fees, were $8.8 million. The Company determined 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. During the three and nine months ended September 30, 2014, the Company recorded a loss on debt extinguishment of $0.4 million, primarily related to the commitment fee paid to the Bank.

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

The Company determined the effective interest rates of the Term A Loan and Term B Loan to be 10.3% and 12.0%, respectively. For the three and nine months ended September 30, 2015, the Company recorded $0.6 million and $1.7 million, respectively, in aggregate interest expense related to the Term A and Term B Loans. For the three and nine months ended September 30, 2014, the Company recorded $0.2 million in aggregate interest expense related to the Term A Loan.

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 September 30, 2015, with 5,305 and 30,769 of such warrants having expiration dates in January 2019 and August 2021, respectively.

Facility Leases

The Company leases certain office and laboratory space from a stockholder of the Company under a non-cancelable operating lease. In March 2015, the Company extended the term of the lease on this facility an additional 15 months through September 2017. The lease is subject to additional charges for common area maintenance and other costs. In connection with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit in the amount of $0.1 million. As of September 30, 2015, future minimum payments under the operating lease are $2.0 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 September 30, 2015 are $0.6 million.

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6. Stockholders Equity

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

	Number of Options	Weighted-Average Price
Balance at December 31, 2014	2,425,969	$ 3.83
Granted	1,125,848	5.29
Canceled	(342,100)	5.49
Exercised	(226,375)	1.85
Balance at September 30, 2015	2,983,342	$ 4.34

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 268	$ 280	$ 988	$ 1,074
General and administrative	306	247	932	748
	$ 574	$ 527	$ 1,920	$ 1,822

As of September 30, 2015, the outstanding options included 120,953 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 September 30, 2015 was $0.4 million.

As of September 30, 2015, the unrecognized compensation cost related to outstanding options (excluding those with performance-based conditions) was $4.7 million and is expected to be recognized as expense over approximately 2.7 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:

	Nine Months Ended September 30,	
	2015	2014
Risk-free interest rate	1.6%	1.9%
Expected volatility	81.9%	94.5%
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:

	Nine Months Ended September 30,	
	2015	**2014**
Risk-free interest rate	0.8%	2.2%
Expected volatility	69.5%	92.2%
Remaining contractual term (in years)	2.8	6.7
Expected dividend yield	0.0%	0.0%

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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, 2014 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 12, 2015.

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 and similar 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 biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for the treatment of cancer and immune disorders. Our cell-based product pipeline is comprised of off-the-shelf immuno-oncology therapeutics, including NK- and T-cell-based candidates derived from induced pluripotent cells, and immuno-regulatory therapeutics, including hematopoietic cell-based candidates for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing auto-reactive T cells of patients with auto-immune disorders. Our adoptive cell therapy candidates are based on our novel *ex vivo* cell programming approach, which we apply to modulate the therapeutic function and direct the fate of immune cells.

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

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

- conduct clinical trials of our product candidates;

- continue our research and development efforts, including under our collaboration agreement;

- manufacture preclinical study and clinical trial materials;

- maintain, expand and protect 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 operate as a public company and support our operations.

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

Financial Operations Overview

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Fate Therapeutics (Canada) Inc., or Fate Canada, that were outstanding at September 30, 2015 and directs all of its operational activities, which are insignificant. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc. and Fate Canada. All intercompany transactions and balances are eliminated in consolidation.

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 research collaboration and license agreement (the Agreement) with Juno Therapeutics, Inc. (Juno) to identify small molecules to program the therapeutic properties of Juno s genetically-engineered T-cell product candidates. In connection with the Agreement, we received an upfront, non-refundable payment of $5.0 million and $8.0 million for the purchase of 1,000,000 shares of our common stock at $8.00 per share. Based on the upfront payment and the premium paid on the share purchase, we recorded $8.4 million of deferred revenue to be recognized ratably as revenue over the initial four-year research term. Additionally, we will receive a minimum of $2.0 million in research funding annually during the initial four-year term. We account for the research funding as revenue using the gross method and record such amounts received from Juno as revenue when earned.

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

Additionally, we are eligible to receive certain contingent payments related to the selection of certain modulated targets by Juno, and to the achievement of certain preclinical, regulatory, and commercial milestones and royalties on commercial sales of each Juno product that

uses or incorporates our small molecule modulators, under the Agreement. To date, no such payments have been received by us.

In connection with the Agreement, we have recognized $1.0 million and $1.4 million during the three and nine months ended September 30, 2015, respectively, as collaboration revenue in the consolidated statements of operations. As of September 30, 2015, aggregate deferred revenue related to the Agreement was $7.9 million.

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

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

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Research and Development Expenses

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

- salaries and employee-related costs, including stock-based compensation;
- costs associated with conducting our preclinical, clinical and regulatory activities, including fees paid to third-party professional consultants and service providers;
- costs incurred under clinical trial agreements with investigative sites;
- costs incurred under our collaboration agreements;
- costs for laboratory supplies;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials;
- charges associated with the achievement of milestones pursuant to our asset acquisition of Verio Therapeutics Inc., or Verio, that was completed in April 2010; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

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

- conducting our clinical trials of ProHema to examine its safety and its curative potential in adult patients (the PUMA study) and in pediatric patients (the PROMPT study) with hematologic malignancies, and in pediatric patients (the PROVIDE study) with inherited metabolic disorders, undergoing allogeneic hematopoietic stem cell transplants, or HSCT;

- conducting preclinical research and submitting an IND for, and initiating clinical development of, ProTmune to examine its safety and curative potential in adult patients with hematologic malignancies undergoing allogeneic HSCT;

- conducting preclinical research to investigate the therapeutic potential of our off-the-shelf immuno-oncology therapeutics, including NK- and T-cell-based candidates derived from induced pluripotent cells;

- conducting preclinical research to investigate the therapeutic potential of our immuno-regulatory therapeutics, including hematopoietic cell-based candidates for suppressing auto-reactive T cells of patients with auto-immune disorders; and

- performing research activities under the Agreement with Juno.

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

The following table summarizes our research and development expenses by major programs for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Hematopoietic cell-based programs	$ 3,436	$ 2,573	$ 9,692	$ 6,874
Other preclinical programs and technologies	651	784	1,982	3,473
Total direct research and development expenses	4,087	3,357	11,674	10,347
Unallocated expenses	916	723	2,754	2,223
Total research and development expenses	$ 5,003	$ 4,080	$ 14,428	$ 12,570

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting and maintaining our intellectual property; and other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will increase in the future as we increase our research and development activities, maintain compliance with exchange listing and SEC requirements and continue to operate as a public company.

Other Income (Expense), Net

Other income (expense) consists primarily of interest income earned on cash and cash equivalents, interest expense on convertible notes and on amounts outstanding under our credit facilities, and debt extinguishments.

Critical Accounting Policies and Significant Judgments and Estimates

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

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, 2014 continue to be our critical accounting policies. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2015.

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

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2014

The following table summarizes the results of our operations for the three months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Increase/ (Decrease)
	2015	2014	
Collaboration revenue	$ 1,026	$	$ 1,026
Research and development expense	5,003	4,080	923
General and administrative expense	2,351	1,904	447
Total other expense, net	558	619	(61)

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

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Research and development expenses. Research and development expenses were $5.0 million for the three months ended September 30, 2015, compared to $4.1 million for the three months ended September 30, 2014. The increase in research and development expenses primarily includes the following changes:

- $0.3 million increase in third-party professional consultant and service provider expenses relating to the clinical development of ProHema and the conduct of our research activities;

- $0.2 million increase in compensation and benefits expense, including employee stock-based compensation expense, relating to an increase in employee headcount to support the conduct of our research activities; and

- $0.2 million increase in expenditures for laboratory equipment and supplies relating to the conduct of our research activities.

General and administrative expenses. General and administrative expenses were $2.4 million for the three months ended September 30, 2015, compared to $1.9 million for the three months ended September 30, 2014. The increase in general and administrative expenses primarily reflects a $0.2 million increase in compensation and benefits expense, including employee stock-based compensation expense.

Other expense, net. Other expense, net was $0.6 million for the three months ended September 30, 2015, compared to $0.6 for the three months ended September 30, 2014. The change in other expense was primarily due to a $0.4 million increase in interest expense relating to our term loans with Silicon Valley Bank, offset by a $0.4 million loss on debt extinguishment during the three months ended September 30, 2014.

Comparison of the Nine Months Ended September 30, 2015 and 2014

The following table summarizes the results of our operations for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,		
	2015	**2014**	**Increase**
Collaboration revenue	$ 1,355	$	$ 1,355
Research and development expense	14,428	12,570	1,858

General and administrative expense	7,797	6,391	1,406
Total other expense, net	1,676	689	987

Revenue. During the nine months ended September 30, 2015, we recognized revenue of $1.4 million under the Agreement with Juno, which we entered into in May 2015.

Research and development expenses. Research and development expenses were $14.4 million for the nine months ended September 30, 2015, compared to $12.6 million for the nine months ended September 30, 2014. The increase in research and development expenses primarily reflects the following:

- $0.7 million increase in compensation and benefits expense, including stock-based compensation expense, relating to an increase in employee headcount to support the clinical development of ProHema and the evaluation of our other product candidates;

- $0.6 million increase in third-party professional consultant and service provider expenses relating to the clinical development of ProHema and the conduct of our research activities; and

- $0.5 million increase in expenditures for laboratory equipment and supplies relating to the conduct of our clinical trials and our research activities; which were partially offset by

- $0.4 million non-cash charge during the nine months ended September 30, 2014 relating to the achievement of a pre-clinical milestone under our agreement with the former Verio stockholders.

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General and administrative expenses. General and administrative expenses were $7.8 million for the nine months ended September 30, 2015, compared to $6.4 million for the nine months ended September 30, 2014. The increase in general and administrative expenses primarily reflects the following:

- $0.5 million increase in compensation and benefits expense, including stock-based compensation expense;
- $0.2 million increase in intellectual property-related expenses; and
- $0.2 million increase in facility- and infrastructure- related expenses.

Other expense, net. Other expense, net was $1.7 million for the nine months ended September 30, 2015, compared to $0.7 million for the nine months ended September 30, 2014. The change in other expense was primarily due to a $1.4 million increase in interest expense relating to our term loans with Silicon Valley Bank, partially offset by a $0.4 million loss on debt extinguishment during the three months ended September 30, 2014.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of September 30, 2015, we had an accumulated deficit of $134.9 million and anticipate that we will continue to incur net losses for the foreseeable future.

Operating Activities

Cash used in operating activities decreased from $16.3 million for the nine months ended September 30, 2014 to $11.4 million for the nine months ended September 30, 2015. The primary driver of this change in cash used in operating activities was $7.9 million in deferred revenue resulting from the Agreement with Juno in May 2015, offset by our increase in net loss from 2014 to 2015.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a research collaboration and license agreement with Juno to identify small molecules to program the therapeutic properties of Juno s genetically-engineered T-cell product candidates. 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 activities under the collaboration for an exclusive four-year research term beginning on the effective date of the Agreement, with minimum annual research payments of $2.0 million to us. Juno has the option to extend the exclusive research term for an additional two years beyond the initial four-year term, subject to the payment of an extension fee of $3.0 million and the continued funding of our activities under the collaboration during the extended term, with minimum annual research payments of $4.0 million to us during the two-year extension period. As of September 30, 2015, no research payments have been received by us, although $0.8 million are included in accounts receivable.

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 product 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 product upon the achievement of various clinical, regulatory and commercial milestones. Additionally, in connection with the third Juno product and the fifth Juno product 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 product upon the achievement of various clinical, regulatory, and commercial milestones. As of September 30, 2015, no selection fees or milestone payments have been received by us.

Beginning on the date of the first commercial sale (in each country) for each Juno product that uses or incorporates our small molecule modulators, and continuing until the later of i) the expiration of 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 product, Juno has agreed to pay us royalties on net sales of each Juno product that uses or incorporates our small molecule modulators in the low single-digits. As of September 30, 2015, no royalties have been received us.

Investing Activities

During the nine months ended September 30, 2015 and 2014, investing activities used cash of $1.3 million and $0.6 million, respectively, for the purchase of property and equipment.

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Financing Activities

For the nine months ended September 30, 2015, financing activities provided cash of $36.5 million. Financing activities primarily consisted of $32.1 million of net proceeds from our May 2015 follow-on public offering of our common stock and $4.6 million from our May 2015 collaboration agreement with Juno, which amount represents the fair value of the equity component from Juno s common stock purchase under the agreement. For the nine months ended September 30, 2014, financing activities provided cash of $8.4 million, which primarily related to $10.0 million of proceeds from long-term debt, partially offset by payments on long-term debt of $1.8 million.

From our inception through September 30, 2015, we have funded our consolidated operations primarily through the public sale of common stock, the private placement of preferred stock and convertible notes, collaboration agreements, and through commercial bank debt that included the issuance of warrants. As of September 30, 2015, we had cash and cash equivalents of $72.9 million.

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

Our IPO on October 4, 2013 resulted in net proceeds of $40.5 million.

Silicon Valley Bank Debt Facility

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

The Term A Loan and the Term B Loan mature on January 1, 2018 and June 1, 2018, respectively and bear interest at a fixed annual rate of 6.94% and 7.07%, respectively. Interest became payable in cash on a monthly basis beginning the first day of each month following the month in which the funding date of each loan occurred. We are required to make a monthly payment of interest only during the first twelve months following the funding date of each loan, and thereafter are required to repay the principal and interest under each loan in thirty equal monthly installments based on a thirty-month amortization schedule. 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 Loan and Term B Loan on their respective maturity dates. We made principal payments of $0.6 million during the three and nine months ended September 30, 2015 related to the Term A Loan.

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

Proceeds from the Term B Loan were $10.0 million. In connection with the funding of the Term B Loan, we issued the Bank and one of its affiliates fully-exercisable warrants to purchase an aggregate of 98,039 shares of our common stock (the Warrants) at an exercise price of $4.08 per share. The Warrants expire in December 2021. The aggregate fair value of the Warrants was determined to be $0.4 million using the Black-Scholes option pricing model. The net proceeds from the Term A and Term B Loans have been used for, and we expect to continue to use net proceeds for, working capital purposes, including the research and development of our product candidates and cellular programming technology.

Shelf Registration Statement

In October 2014, the SEC declared effective a shelf registration 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 for an aggregate offering price of up to $100 million. The specific terms of any offering, if any, under the shelf registration statement would be established at the time of such offering. As of November 3, 2015, after taking into account the May 2015 public offering of common stock, there is $65.5 million remaining under the shelf registration statement.

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Agreement with Juno Therapeutics, Inc.

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

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

Operating Capital Requirements

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

We believe our existing cash and cash equivalents as of September 30, 2015 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

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

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

- the initiation, progress, size, timing, duration, costs and results of preclinical studies and clinical trials for our product candidates;

- the time, cost and outcome of seeking and obtaining regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;

- the number and characteristics of product candidates that we pursue;

- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;

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- the extent to which milestones are achieved under our collaboration agreement with Juno, and the time to achievement of such milestones;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- our need to expand our research and development activities, including our need and ability to hire additional employees;

- our need to implement additional infrastructure and internal systems and hire additional employees to operate as a public company;

- the establishment and continuation of collaborations and strategic alliances;

- the effect of competing technological and market developments; and

- the cost of establishing sales, distribution, marketing and manufacturing capabilities, and the pricing and reimbursement, for 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.

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.

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Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2015 consisted of cash and money market mutual funds. 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 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 and chief 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, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2015.

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.

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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

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

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

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

- determining that a product candidate is ineffective or causes harmful side effects during preclinical studies or clinical trials;

- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;

- difficulties in manufacturing a product candidate, including the inability to manufacture a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under processes acceptable to the FDA for marketing approval;

- the proprietary rights of third parties, which may preclude us from developing or commercializing a product candidate;

- determining that a product candidate may be uneconomical to develop or commercialize, or may fail to achieve market acceptance or adequate reimbursement;

- our inability to secure strategic partners which may be necessary for advancement of a product candidate into clinical development or commercialization; or

- our prioritization of other product candidates for advancement.

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

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

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

- the progress, results, timing and costs of our preclinical studies and clinical trials;

- continued progress in our research and development programs, including the preclinical studies and clinical trials of our product candidates;

- our ability to initiate, and the progress, results, size, timing and costs of, additional future clinical trials of our product candidates that will be necessary to support any application for regulatory approval;

- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- the cost of commercialization activities and arrangements, including the commercial manufacturing of our product candidates; and

- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators to advance the research, development and commercialization of therapeutic products.

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

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

Interim results from ongoing clinical trials and results from preclinical studies and earlier clinical trials are not predictive of the results of our ongoing 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. For example, although an independent data monitoring committee, or iDMC, supported the continuation of our Phase 2 PUMA study of ProHema based upon two scheduled interim data reviews, the PUMA study has not been completed and the interim data reviews, which were based upon data from a limited number of subjects who are still under evaluation and subject to ongoing safety surveillance, may not be predictive of safety or efficacy of ProHema in the final analysis of the PUMA study. In addition, although the results of our completed Phase 1b ProHema-01 study in adults with hematologic malignancies undergoing double umbilical cord blood transplant demonstrated human proof-of-concept, we may not achieve efficacy or duplicate these results in the PUMA study or in planned additional clinical trials of ProHema, including the PROMPT or PROVIDE studies in pediatric patients.

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

- we may not demonstrate the potency and efficacy benefits observed in preclinical studies or earlier clinical trials;

- our efforts to standardize and automate the manufacture of ProHema may adversely affect its safety, purity, potency or efficacy;

- the expansion in the number of participating clinical centers, which are independent institutions and are more geographically dispersed, may introduce additional variability and complexity in conducting clinical trials and in evaluating clinical results;

- deviations in the manufacture of ProHema by cell processing facilities at clinical centers participating in clinical trials that we conduct;

- use of our product candidates in pediatric patients may result in side effects or other adverse events not observed in adult patients;

- 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 current or future clinical trials;

- safety or adverse events in patients enrolled in current or future clinical trials; and

- later-stage trials that enroll a larger number of patients may not produce the same or similar results as earlier trials with fewer patients.

Results from preclinical testing and early clinical trials are not necessarily predictive of the results of later clinical trials, and interim results from any clinical trial do not necessarily predict final results of that trial. Even if our ongoing clinical trials are successful, we will likely need to conduct additional clinical trials, including registrational trials and trials in additional patient populations or under different treatment conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and prospects.

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

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

- difficulties in identifying eligible patients for participation in our clinical trials due to our focus on the development of product candidates for the treatment of rare diseases;

- difficulties enrolling a sufficient number of suitable patients to conduct our clinical trials, including difficulties relating to patients enrolling in studies with agents sponsored by our competitors;

- difficulties in achieving study endpoints, demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;

- the occurrence of unexpected safety issues or adverse events in any current or subsequent clinical trial of any product candidate;

- securing and maintaining the support of clinical investigators and investigational sites, and obtaining institutional review board, or IRB, approval at each site for the conduct of our clinical trials;

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

- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and clinical trial sites;

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

- our failure, or the failure of third-party service providers or clinical trial sites, to ensure the proper and timely conduct and analysis of our clinical trials;

- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators and IRBs;

- obtaining sufficient quantities of critical reagents and other materials and equipment necessary for the manufacture and processing of any product candidate;

- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;

- the serious, life-threatening diseases of the patients in our clinical trials, who may die or suffer adverse medical events for reasons that may not be related to our product candidates;

- failure of patients to complete clinical trials due to safety issues, side effects, or other reasons; and

- approval of competitive agents that may materially alter the standard of care or otherwise render our product candidates or clinical trial designs obsolete.

If we experience delays in the completion of any clinical trial of our product candidates or any of these clinical trials are terminated before completion, the commercial prospects of our product candidates will be harmed. In addition, any delays in commencing or completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition and results of operations.

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

The FDA may require us to generate additional preclinical, product or clinical data, including data supporting the use of our nutrient rich media, or NRM, formulation, or our reduced volume formulation for pediatric use, as a condition to continuing and completing the PUMA and PROMPT studies, or to initiating and completing the PROVIDE study or any other subsequent clinical trials, of ProHema. Additionally, the FDA may in the future have comments, or impose requirements, on our protocols for conducting the PUMA, PROMPT, or PROVIDE studies, or any other subsequent clinical trials, of ProHema. Any requirements to generate additional data or redesign or modify our protocols, or other additional comments, requirements or impositions by the FDA, may cause delays in the conduct of the PUMA study, the PROMPT study or the PROVIDE study, or other subsequent clinical development activities for ProHema, and could require us to incur additional development costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our clinical development activities for ProHema, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for ProHema.

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

- be delayed in obtaining, or unable to obtain, regulatory approval for our product candidates;

- be required to amend the protocols for our clinical trials, perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;

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- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or

- have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Our plans for clinical development and commercialization of our product candidates could be substantially delayed or restricted if the FDA or other regulatory authorities impose additional requirements on our manufacturing processes or if we are required to change our manufacturing processes to comply with regulatory requirements.

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

While ProHema is currently manufactured 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 ProHema in compliance with applicable regulatory requirements, and in the future we may manufacture ProHema at facilities operated by us, by transplant centers, or by third parties. Any requirements to modify our manufacturing processes, and any delays in, or inability to, establish manufacturing processes acceptable to the FDA could require us to incur additional development costs or result in delays to our clinical development plans, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for ProHema. Any such events could delay or prevent our ability to obtain regulatory approval or commercialize ProHema, which would adversely affect our business, financial condition and results of operations.

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

Patients undergoing treatment with certain of our product candidates, including ProHema, 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 be using. Any of these events could prevent us from advancing ProHema 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 ProHema 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.

Our planned clinical development activities for ProHema in pediatric patients, including our PROMPT and PROVIDE studies, present additional operational, technical and timeline risks.

Many clinical centers that could potentially participate in our pediatric clinical trials of ProHema are distinct and separate from the centers participating in the PUMA study, and finding a sufficient number of qualified centers that would be interested in participating in our pediatric trials may take additional time. There are fewer eligible patients with hematologic malignancies and rare genetic disorders for our PROMPT and PROVIDE studies because the total number of pediatric patients who undergo allogeneic HSCT for the treatment of such diseases and disorders is lower than it is in adults. This may increase the time to commencement of our planned and future pediatric studies, or may delay or limit our ability to enroll patients in these studies, and any of these events may impair our ability to complete our planned and future pediatric studies, including our PROMPT and PROVIDE studies.

Further, to evaluate ProHema in pediatric patients, we have developed a reduced volume formulation of ProHema for children, due to their smaller size and requirement for smaller infusion volume. Although we have received permission from the FDA to use a formulation of ProHema having a reduced volume for the treatment of pediatric patients in our planned PROMPT and PROVIDE studies, the FDA may require us to generate additional preclinical, product, or clinical data to support the use of any reduced volume formulation of ProHema in these studies prior to or following their commencement, or in any subsequent trials of ProHema, or may impose other restrictions on the use of any reduced volume formulation of ProHema. Any such requirement or imposition may present technical challenges and may cause further delays in the commencement or conduct of our planned pediatric clinical trials. Any delays in, or any inability to conduct, our planned clinical development activities for pediatric patients would have an adverse effect on our business operations.

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

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

Cellular therapeutics, and stem cell therapies in particular, represent a relatively new therapeutic area, and the FDA has cautioned consumers about potential safety risks associated with these therapies. To date, there are relatively few approved cellular therapeutics. In addition, there are currently no approved products in any major territory throughout the world with a label designation that supports the use of a product to improve multi-lineage engraftment or survival in patients undergoing HSCT, which makes it difficult to determine the time and cost required to obtain regulatory approvals in the United States or other jurisdictions for ProHema or any other product candidates that we may develop.

Regulatory requirements governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements for or identify different regulatory pathways for approval for any of our product candidates. For example, the FDA established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review, and it is possible that new or different bodies may be established or be granted the responsibility for regulating pharmacologically modulated cellular therapeutics such as ours. In particular, there is uncertainty as to whether the FDA will regulate pharmacologically modulated cellular therapeutics, such as ProHema and other product candidates that we may develop, as biological products (and therefore subject to approval under a biologics license application, or BLA) or as drug products (and therefore subject to approval under a new drug application, or NDA) and to date our discussions with the FDA have not been determinate. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the clinical development of, and obtain regulatory approval for our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products will likely be reviewed by the FDA s advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing

requirements, requirements relating to current good manufacturing practices, or cGMP, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse conditions, including significant delays in bringing our product candidates to market and or being precluded from manufacturing or selling our product candidates, any of which could significantly harm our business.

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We expect to 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 ProHema 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. The FDA has granted orphan designation for ProHema for the enhancement of stem cell engraftment to treat neutropenia, thrombocytopenia, lymphopenia and anemia, and the European Commission has granted orphan designation for ProHema for the treatment of acute myeloid leukemia. 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 have been 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 depend on facilities operated by transplant centers for the manufacture of ProHema under specific conditions. Any failure by these facilities to manufacture ProHema 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, ProHema.

ProHema is currently manufactured at clinical cell processing facilities operated by or affiliated with our clinical sites and is required to be manufactured in close proximity to the treatment site on the same day as product administration. The FDA has stated that we will be required to standardize the manufacture of ProHema, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProHema for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the use of our current manufacturing processes to manufacture ProHema for commercialization may require each of the clinical cell processing facilities at which ProHema is manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a BLA or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with the FDA s requirements and to properly execute the protocol for the manufacture of ProHema. 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 ProHema in a manner that conforms to our specifications and

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the FDA s strict regulatory requirements, we may be required to identify alternative processes or facilities for the manufacture of ProHema, which may require us to spend significant additional time and resources, and would impair our ability to complete the clinical development of, and to commercialize, ProHema. To comply with applicable regulatory requirements and our protocols for the manufacture of ProHema, 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 ProHema, it will be restricted or prohibited from manufacturing ProHema and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProHema may adversely affect the safety and efficacy profile of ProHema or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProHema 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 ProHema 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 ProHema. We have not entered into, and may not be able to enter into, agreements for the supply of certain components. Even if we are able to enter into such agreements, we may be limited to a sole third-party for the supply of certain required components, including FT1050 and components for our NRM formulation. 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 ProHema from third parties. We rely on the general commercial availability of these materials, and we do not have any current contractual relationships for the supply of these materials. Accordingly, we may incur delays or increased costs due to any interruption in supply, and we cannot guarantee that we will have an adequate supply of components, equipment, materials and disposables to complete our planned clinical development and commercialization of ProHema.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of ProHema, we may be required to change our manufacturing processes or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could delay, or increase the costs required to complete, our clinical development and commercialization of ProHema. Additionally, any such change or modification may adversely affect the safety, efficacy or potency of ProHema, and could adversely affect our clinical development of ProHema and harm our business.

We face a variety of challenges and uncertainties associated with our dependence on the availability of human umbilical cord blood units, or CBUs, at cord blood banks for the manufacture of ProHema.

CBUs are one of the raw materials for the manufacture of ProHema. The CBUs currently used in the manufacture of ProHema are procured directly by the clinical cell processing facilities from cord blood banks. The availability of CBUs for the manufacture of ProHema depends on a number of regulatory, political, economic and technical factors outside of our control, including:

- government policies relating to the regulation of CBUs for clinical use;

- the availability of government funding for cord blood banks;

- individual cord blood bank policies and practices relating to CBU acquisition and banking;

- the pricing of CBUs;

- the methods used in searching for and matching CBUs to patients, which involve emerging technology related to current and future CBU parameters that guide the selection of an appropriate CBU for transplantation; and

- methods for the procurement and shipment of CBUs and their handling and storage at clinical sites.

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

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In the United States, cord blood banks are required to file a biologics license application, or BLA, and to meet certain continued regulatory requirements, in order to bank and provide CBUs for transplantation. CBUs from a cord blood bank that maintains a BLA are considered to be licensed and have a product label describing their intended use. While the FDA currently allows unlicensed CBUs to be used for transplantation, and we have used both unlicensed and licensed CBUs in the manufacture of ProHema for our clinical trials, the FDA may later prohibit the use of unlicensed CBUs for transplantation or require ProHema to be manufactured using only licensed CBUs. Additionally, although CBUs from foreign cord blood banks, which are generally unlicensed, are currently available in the United States for use in transplantation and we have used CBUs from foreign cord blood banks in our clinical trials, changes in U.S. and foreign regulations may prohibit or limit the future use of foreign CBUs in the United States. Any inability to procure adequate supplies of CBUs will adversely affect our ability to develop and commercialize ProHema.

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

We have relied upon and expect to continue to rely upon third parties for the conduct of certain research and preclinical development activities and for the execution of our clinical trials. We control only certain aspects of the activities of these third parties. We are responsible for complying, and we are responsible for ensuring that our third-party service providers comply, with good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA, as well as comparable foreign regulations and guidelines, for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development activities or clinical data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our research, preclinical development activities and clinical trials, and the development of our product candidates, may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties 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.

We rely on third parties for the manufacture of our product candidates.

We do not independently conduct all aspects of our product manufacturing, and currently rely and expect to continue to rely on third-party manufacturers for the manufacture of any product candidates that we may develop. These third-party manufacturers will be required to comply with applicable FDA regulatory requirements and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our product candidates or any products that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. In addition, we anticipate that the manufacture of our product candidates will be difficult, and it is possible that any third-party manufacturers that we engage may experience delays or technical challenges in such manufacture. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or

commercialize our product candidates, and would adversely affect our business.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.

Our commercial success will depend in part on our ability to obtain and maintain intellectual property protection for our product candidates, the processes used to manufacture them and the methods for using them, in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates. We own and have exclusive licenses to patent portfolios for our product candidates, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

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Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

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

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

Certain rights to our key technologies and product candidates, including intellectual property relating to ProHema and our induced pluripotent stem cell (iPSC) technology, are licensed from third parties. As a licensee of third party intellectual property, we rely on our licensors to file and prosecute patent applications and maintain patents, and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our licensed patents, patent applications and other intellectual property rights, and we cannot be certain that such activities will result in valid and enforceable patents and other intellectual property rights. Additionally, our licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and we cannot be certain that our licensors will allocate sufficient resources or prioritize enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

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

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and

would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. There is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party s activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of ProHema or any other product candidates that we develop will not infringe third-party patents.

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

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

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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 ProHema and any other product candidates that we may develop. If pricing policies for our product candidates are unfavorable, our commercial success will be impaired.

Due to the targeted indication of HSCT procedures in general and our hematopoietic cell product candidates in particular, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular therapeutic product candidates that we develop will be relatively high due to their anticipated use in a one-time, potentially life-saving procedure with curative intent, the biopharmaceutical industry has recently experienced significant pricing pressures, including in the area of orphan drug products. Additionally, because our target patient populations are relatively small, the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. If pricing is set at unsatisfactory levels, our ability to successfully market and sell our product candidates will be adversely affected.

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

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

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

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

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

Risks Related to Our Business and Industry

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

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

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from biotechnology and pharmaceutical companies, universities, and other research institutions, and many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. In particular, there are several companies and institutions developing products that may obviate the need for HSCT, or may be competitive to products in our research and development pipeline, or may 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 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;

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- enter into transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

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

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

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

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

In addition, during the term of our research activities under the agreement, we have agreed to collaborate exclusively with Juno on the research and development of small molecule modulators with respect to T cells that have been genetically-engineered to express chimeric antigen receptors or T-cell receptors against certain targets designated by Juno. Furthermore, during the term of the agreement, we will be unable to

conduct, or enable third parties to conduct, research, development and commercialization activities using small molecule modulators to program T-cell product candidates that have been genetically-engineered to express chimeric antigen receptors or T-cell receptors directed against certain targets selected by Juno. These restrictions may prevent us from exploiting our small molecule modulators or impair our ability to pursue research, development and commercialization opportunities that we would otherwise deem to be beneficial to our business.

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

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

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

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- reprioritize our development programs and even cease development and commercialization of our product candidates; or

- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

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

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

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

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

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

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

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

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

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

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

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

We are a clinical-stage biopharmaceutical discovery and development company, formed in 2007, with a limited operating history. We have not yet obtained regulatory approval for any product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and as of September 30, 2015 we had an accumulated deficit of approximately $134.9 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of ProHema and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our development of, and seek regulatory approval for, our product candidates, in-license or acquire new product development opportunities, implement additional infrastructure and internal systems and hire additional scientific, clinical, and marketing personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders equity and working capital.

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

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

- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others;

- developments related to the FDA or to regulations applicable to cellular therapeutics generally or our product candidates in particular, including but not limited to regulatory pathways and clinical trial requirements for approvals;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

- developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- additions or departures of key management or scientific personnel;

- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;

- developments of technological innovations or new therapeutic products by us or others in the field of stem cell therapeutics or immunotherapeutics;

- announcements or expectations of additional equity or debt financing efforts;

- sales of our common stock by us, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., or by our insiders or our other stockholders;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

- comments by securities analysts;

- fluctuations in our operating results; and

- general economic and market conditions.

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

Our principal stockholders exercise significant control over our company.

As of October 30, 2015, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 58% of our outstanding voting stock. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company or affecting the liquidity and volatility of our common stock, and might affect the market price of our common stock.

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

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

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

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

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

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

- a classified board of directors with limitations on the removal of directors;

- advance notice requirements for stockholder proposals and nominations;

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- the inability of stockholders to act by written consent or to call special meetings;

- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and

- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

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

Our ability to use our net operating loss carryforwards may be subject to limitation and may result in increased future tax liability to us.

Generally, a change of more than 50% in the ownership of a corporation s stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company s ability to use its net operating loss carryforwards attributable to the period prior to such change. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code has occurred after each of our previous private placements of preferred stock or after the issuance of shares of common stock in connection with our IPO, our private placement of common stock to Juno in May 2015, or our follow-on public offering in May 2015. In the event we have undergone an ownership change under Section 382, 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.

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SIGNATURES

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

Fate Therapeutics, Inc.

Date: November 3, 2015	By:	/s/ Christian Weyer Christian Weyer President and Chief Executive Officer (Principal Executive Officer)
	By:	/s/ J. Scott Wolchko J. Scott Wolchko Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)

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Index to Exhibits

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.2 to the registrant s Registration Statement on Form S-1/A (File No. 333-190608) filed with the SEC on August 29, 2013 and incorporated herein by reference).
3.2	Amended and Restated Bylaws (filed as Exhibit 3.4 to the registrant s Registration Statement on Form S-1/A (File No. 333-190608) filed with the SEC on August 29, 2013 and incorporated herein by reference).
4.1	Specimen Common Stock Certificate (filed as Exhibit 4.1 to the registrant s Registration Statement on Form S-1/A (File No. 333-190608) filed with the SEC on August 29, 2013 and incorporated herein by reference).
31.1	Certification of Principal Executive 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.
31.2	Certification of 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.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document