

FATE THERAPEUTICS INC  
Form 10-Q  
May 13, 2014  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2014

OR

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT OF 1934**

From the transition period from            to            .

Commission File Number 001-36067

# FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**65-1311552**  
(IRS Employer  
Identification No.)

**3535 General Atomics Court, Suite 200, San Diego, CA**  
(Address of principal executive offices)

**92121**  
(Zip Code)

Registrant's telephone number, including area code: **(858) 875-1800**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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

As of May 9, 2014, there were 20,514,567 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

Table of Contents

FATE THERAPEUTICS, INC.

FORM 10-Q

TABLE OF CONTENTS

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1.</u></b>	<b><u>Financial Statements</u></b> 3
	<u>Condensed Consolidated Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013</u> 3
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013 (unaudited) and the period from April 27, 2007 (inception) through March 31, 2014 (unaudited)</u> 4
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013 (unaudited) and the period from April 27, 2007 (inception) through March 31, 2014 (unaudited)</u> 5
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u> 6
<b><u>Item 2.</u></b>	<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b> 11
<b><u>Item 3.</u></b>	<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b> 18
<b><u>Item 4.</u></b>	<b><u>Controls and Procedures</u></b> 18
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1.</u></b>	<b><u>Legal Proceedings</u></b> 18
<b><u>Item 1A.</u></b>	<b><u>Risk Factors</u></b> 18
<b><u>Item 2.</u></b>	<b><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b> 45
<b><u>Item 3.</u></b>	<b><u>Defaults Upon Senior Securities</u></b> 45
<b><u>Item 4.</u></b>	<b><u>Mine Safety Disclosures</u></b> 45
<b><u>Item 5.</u></b>	<b><u>Other Information</u></b> 45
<b><u>Item 6.</u></b>	<b><u>Exhibits</u></b> 45
<b><u>SIGNATURES</u></b>	46

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Fate Therapeutics, Inc.****(A Development Stage Company)****Condensed Consolidated Balance Sheets****(in thousands, except share and per share data)**

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 47,881	\$ 54,036
Prepaid expenses and other current assets	382	615
Total current assets	48,263	54,651
Property and equipment, net	1,264	810
Restricted cash	122	122
Total assets	\$ 49,649	\$ 55,583
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 1,330	\$ 682
Accrued expenses	1,641	2,039
Current portion of deferred rent	61	53
Repurchase liability for unvested equity awards	82	94
Long-term debt, current portion	1,240	1,732
Total current liabilities	4,354	4,600
Deferred rent	118	135
Commitments and contingencies (Note 4)		
Stockholders equity:		
Preferred stock, \$0.001 par value; authorized shares 5,000,000 at March 31, 2014 and December 31, 2013; no shares issued or outstanding		
Common stock, \$0.001 par value; authorized shares 150,000,000 at March 31, 2014 and December 31, 2013; issued and outstanding shares 20,463,849 at March 31, 2014 and 20,434,080 at December 31, 2013	20	20
Additional paid-in capital	138,646	137,337
Deficit accumulated during the development stage	(93,489)	(86,509)
Total stockholders equity	45,177	50,848
Total liabilities and stockholders equity	\$ 49,649	\$ 55,583

*See accompanying notes.*

Table of Contents**Fate Therapeutics, Inc.****(A Development Stage Company)****Condensed Consolidated Statements of Operations and Comprehensive Loss****(in thousands, except share and per share data)**

	<b>Three Months Ended</b>		<b>Period</b>
	<b>2014</b>	<b>March 31,</b>	<b>From April</b>
		<b>2013</b>	<b>27, 2007</b>
		<b>(unaudited)</b>	<b>(inception)</b>
			<b>to</b>
			<b>March 31,</b>
			<b>2014</b>
			<b>(unaudited)</b>
<b>Revenues:</b>			
Collaboration revenue	\$	\$	209 \$
Grant revenue			263
Total revenue			472
<b>Operating expenses:</b>			
Research and development		4,522	2,531
General and administrative		2,415	1,297
Total operating expenses		6,937	3,828
Loss from operations		(6,937)	(3,356)
<b>Other income (expense):</b>			
Interest income			1
Interest expense		(43)	(100)
Income from 48D tax credit			1,231
Loss on extinguishment of debt			(332)
Change in fair value of warrant liability			12
Change in fair value of exchangeable shares			(105)
Total other expense, net		(43)	(192)
Net loss and comprehensive loss	\$	(6,980)	\$ (3,548) \$ (93,489)
Net loss per common share, basic and diluted	\$	(0.34)	\$ (2.92)
Weighted-average common shares used to compute basic and diluted net loss per share		20,346,856	1,213,286

*See accompanying notes.*

Table of Contents**Fate Therapeutics, Inc.****(A Development Stage Company)****Condensed Consolidated Statements of Cash Flows****(in thousands)**

	<b>Three Months Ended March</b>		<b>Period From</b>
	<b>31,</b>		<b>April 27, 2007</b>
	<b>2014</b>	<b>2013</b>	<b>(inception) to</b>
	<b>(unaudited)</b>		<b>March 31,</b>
			<b>2014</b>
			<b>(unaudited)</b>
<b>Operating activities</b>			
Net loss	\$ (6,980)	\$ (3,548)	\$ (93,489)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	123	157	2,631
Issuances of common stock for technology			57
Stock-based compensation	871	75	3,194
Amortization of discounts	8	18	543
Noncash interest expense	10	22	1,179
Deferred rent	(9)	(59)	179
Deferred revenue		(21)	
Stock-based milestone charges and change in fair value of exchangeable shares	375	105	3,693
Change in fair value of preferred stock warrants		(12)	(35)
Loss on disposal of assets			135
Loss on extinguishment of debt			332
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	304	49	(1,673)
Accounts payable and accrued expenses	43	(719)	3,890
Net cash used in operating activities	(5,255)	(3,933)	(79,364)
<b>Investing activities</b>			
Purchase of property and equipment	(398)	(7)	(4,059)
Proceeds from sale of property and equipment			208
Restricted cash			(122)
Net cash used in investing activities	(398)	(7)	(3,973)
<b>Financing activities</b>			
Issuance of common stock, net of repurchases and issuance costs	(2)		292
Repurchase of common stock for cash			(7)
Proceeds from initial public offering, net of offering costs			40,480
Issuance of convertible promissory notes			32,236
Proceeds from long-term debt			6,400
Payments on long-term debt	(500)	(500)	(6,829)
Issuance of preferred stock for cash, net of offering costs			58,646
Net cash (used in) provided by financing activities	(502)	(500)	131,218
Net change in cash and cash equivalents	(6,155)	(4,440)	47,881
Cash and cash equivalents at beginning of the period	54,036	9,087	
Cash and cash equivalents at end of the period	\$ 47,881	\$ 4,647	\$ 47,881

*See accompanying notes.*





Table of Contents

**Fate Therapeutics, Inc.**

**(A Development Stage Company)**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

**Organization**

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company engaged in the discovery and development of pharmacologic modulators of adult stem cells. Based on the Company's understanding of key biological mechanisms that guide the fate of adult stem cells, the Company has built two platforms that optimize the activity and enhance the therapeutic potential of adult stem cells: its hematopoietic stem cell, or HSC, modulation platform and its muscle satellite stem cell, or Satellite Cell, modulation platform.

As of March 31, 2014, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

**Initial Public Offering**

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

- the conversion of all outstanding shares of the Company's convertible preferred stock into 7,229,590 shares of the Company's common stock;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

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

### **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 the valuation of equity awards and 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.

Table of Contents

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Canada, Fate Therapeutics Ltd., incorporated in the United Kingdom, and Destin Therapeutics Inc., incorporated in Canada. 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, 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, 2013, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed by the Company with the SEC on March 17, 2014. The results for the three months ended March 31, 2014 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) collectibility 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.

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

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 is 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. The Company has not entered into or materially modified any multiple element arrangements subsequent to 2010.

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

Table of Contents

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. The receivable for reimbursable amounts that have not been collected is reflected in prepaid and other current assets.

**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 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 88,043 shares and 120,822 shares for the three months ended March 31, 2014 and 2013, 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 convertible preferred stock, warrants for the purchase of convertible preferred stock and common stock, exchangeable shares and common stock options outstanding under the Company's stock option plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

For the three months ended March 31, 2014, the Company realized a net loss of \$7.0 million. Shares of potentially dilutive securities totaled approximately 2.5 million for the three months ended March 31, 2014, including options to purchase approximately 2.2 million shares of common stock with an exercise price less than the average quarterly market price of the underlying common shares.

For the three months ended March 31, 2013, the Company realized a net loss of \$3.5 million. Shares of potentially dilutive securities totaled approximately 9.2 million for the three months ended March 31, 2013.

**2. 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.

Table of Contents

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

During the three months ended March 31, 2014, based on the assessed achievement of certain pre-clinical milestones, 38,462 shares of the Company s common stock were deemed earned, but not issued, resulting in a \$0.4 million charge to research and development expense.

In addition to the 38,462 shares of the Company s common stock deemed earned but not issued during the three months ended March 31, 2014, the Company may issue an additional 365,380 shares of the Company s common stock based on the achievement of additional contractual milestones as follows: (i) 38,461 shares for the achievement of certain pre-clinical milestones, (ii) 211,538 shares for the achievement of certain clinical milestones and (iii) 115,381 shares for the achievement of certain commercialization milestones, such that the maximum aggregate number of shares of the Company s common stock that may be issued related to the Verio acquisition is 884,605.

At the date of the achievement of a milestone, the fair value of the additional shares is charged to research and development expense and recorded in additional paid-in capital. Prior to the Company s IPO, at the end of each reporting period, any changes in the fair value of Exchangeable Shares resulting from changes in the fair value of the underlying common stock of the Company were recorded as a component of other income (expense). As of the IPO date, the exchangeable share liability was reclassified into additional paid-in capital.

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

	Common Stock	Fair Value Per Share of Underlying Common Stock	Initial Fair Value of Common Stock
April 2010	138,462	\$ 1.69	\$ 234
March 2011	92,308	1.69	156
May 2011	115,380	1.69	195
April 2012	57,691	1.37	78
July 2013	76,922	4.49	346
March 2014	38,462	9.74	375
	519,225		\$ 1,384

**3. Fair Value Measurements**

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

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

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



Table of Contents

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 March 31, 2014 and December 31, 2013, the carrying amount of cash equivalents was \$46.3 million and \$52.3 million, respectively, which approximates fair value and was determined based upon Level 1 inputs. Cash equivalents primarily consisted of money market funds. As of March 31, 2014 and December 31, 2013, the Company did not hold any Level 2 or Level 3 financial assets that are recorded at fair value on a recurring basis.

Financial liabilities that were measured at fair value on a recurring basis included the preferred stock warrant liability and exchangeable shares for the periods the liabilities were outstanding. None of the Company's non-financial assets or liabilities is recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

As of March 31, 2014 and December 31, 2013, the Company had no liabilities measured at fair value on a recurring basis.

**4. Long-Term Debt, Commitments and Contingencies**

**Long-Term Debt**

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

	March 31, 2014	December 31, 2013
Long-term debt	\$ 1,250	\$ 1,750
Less current portion of long-term debt	(1,250)	(1,750)
Long-term debt, net of current portion	\$	\$
Current portion of long-term debt	\$ 1,250	\$ 1,750
Current portion of debt discount	(10)	(18)
Current portion of long-term debt, net	\$ 1,240	\$ 1,732

**Facility Lease**

The Company leases certain office and laboratory space from a stockholder of the Company under a non-cancelable operating lease. The lease expires in June 2016. The lease is subject to additional charges for common area maintenance and other costs. In connection with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit in the amount of \$0.1 million. As of March 31, 2014, future minimum payments under the operating lease are \$2.1 million.

**5. 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, 2013	1,726,991	\$ 2.30
Granted	743,376	6.73
Canceled	(47,677)	5.13
Exercised	(29,769)	1.89
Balance at March 31, 2014	2,392,921	\$ 3.63

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

### Table of Contents

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

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Research and development	\$ 565	\$ 38
General and administrative	306	37
	<b>\$ 871</b>	<b>\$ 75</b>

As of March 31, 2014, the outstanding options included 161,689 performance-based options for which the achievement of the performance-based vesting provisions was determined not to be probable. The aggregate grant date fair value of these unvested options at March 31, 2014 was \$0.7 million.

As of March 31, 2014, the unrecognized compensation cost related to outstanding options (excluding those with performance-based conditions) was \$5.0 million and is expected to be recognized as expense over approximately 3.3 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:

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	2.0%	1.1%
Expected volatility	94.5%	89.7%
Expected term (in years)	6.07	6.06
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:

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	2.2%	1.3%
Expected volatility	94.5%	89.7%
Remaining contractual term (in years)	6.7	8.29
Expected dividend yield	0.0%	0.0%

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

*The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2013 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 17, 2014.*

*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, and the additional risks and other factors described under the caption Risk Factors under Item 1A of the Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with Securities and Exchange Commission on March 17, 2014. 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.*

Table of Contents

**Overview**

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of pharmacologic modulators of adult stem cells to treat orphan diseases, including certain hematologic malignancies, lysosomal storage disorders, or LSDs, and muscular dystrophies. Our novel approaches utilize established pharmacologic modalities, including small molecules and therapeutic proteins, and target well-characterized biological mechanisms to enhance the therapeutic potential of adult stem cells. Based on our deep understanding of key biological mechanisms that guide the fate of adult stem cells, we have built two stem cell modulation platforms that optimize the activity of adult stem cells using both *ex vivo* and *in vivo* techniques: our hematopoietic stem cell, or HSC, modulation platform and our muscle satellite stem cell, or Satellite Cell, modulation platform. We believe that the product candidates generated by our stem cell modulation platforms have significant potential as life-changing or curative therapeutics across a broad range of orphan indications.

Since our inception in 2007, we have devoted substantially all of our resources to the development of our stem cell modulation platforms, the clinical and preclinical advancement of our product candidates, the creation, licensing and protection of related intellectual property and the provision of general and administrative support for these operations. To date, we have funded our operations primarily through the public sale of common stock, the private placement of preferred stock and convertible notes and through commercial bank debt. In October 2013, we completed our initial public offering, or IPO, whereby we received net proceeds of \$40.5 million.

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 initial product candidates;
- continue our research and development efforts;
- manufacture preclinical study and clinical trial materials;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and technical personnel to conduct our clinical trials;

- hire additional scientific personnel to support our product development efforts;
- implement operational, financial and management systems; and
- add general and administrative personnel to operate as a public company.

We do not expect to generate any revenues from therapeutic product sales 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 impact 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 facility in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Fate Canada that were outstanding at March 31, 2014 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.

Table of Contents

***Revenue***

To date, we have not generated any revenues from therapeutic product sales. Our revenues have been derived from collaboration activities and grant revenues.

Collaboration revenues have been generated exclusively from our collaboration arrangement 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 ending in September 2013. We are eligible to receive certain commercialization milestones and royalties on the sale of iPSC reagent products. In connection with the arrangement with BD, we recognized \$0.2 million for the three months ended March 31, 2013 as collaboration revenue in our consolidated statements of operations. Our three-year joint development period under our license and collaboration agreement with BD concluded in September 2013. We do not anticipate generating any significant revenues under the arrangement with BD in the future.

Grant revenue has been primarily generated 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-inducing hearing loss. All funding under the TATRC grant was expended in full as of May 2013.

***Research and Development Expenses***

Research and development expenses consist of development costs associated with our platforms and programs. These costs are expensed as incurred and include:

- compensation and employee-related costs;
  
- 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 for laboratory supplies;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- 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.

From inception through March 31, 2014, we have incurred \$61.5 million in research and development expenses. We plan to increase our current level of research and development expenses for the foreseeable future as we continue the development of our stem cell modulation platforms and our initial therapeutic product candidates. Our current planned research and development activities include the following:

- advancing ProHema in a Phase 2 clinical trial in the setting of adult patients with orphan hematologic malignancies in 2014 to examine its safety and its curative potential in allogeneic hematopoietic stem cell transplants, or HSCT;
- initiating in 2014 a clinical trial of ProHema in pediatric patients with orphan hematologic malignancies to examine its safety and curative potential in allogeneic HSCT in children;
- initiating in 2014 a clinical trial of a pharmacologically-modulated HSC product candidate in pediatric patients with lysosomal storage disorders, or LSDs, to evaluate its safety and its curative potential in LSDs; and
- conducting in 2014 investigational new drug, or IND, enabling studies of a Wnt7a protein analog product candidate to evaluate its safety and its potential to promote muscle regeneration.



Table of Contents

We cannot determine with certainty the timing of initiation, the duration and the completion costs of current or future preclinical studies and clinical trials of our therapeutic product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our programs, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued development of our product candidates, including ProHema. Clinical and preclinical development timelines, the probability of success and development costs 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):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
HSC modulation platform	\$ 2,150	\$ 1,158
Other preclinical programs and technologies	1,587	786
Total direct research and development expenses	3,737	1,944
Unallocated expenses	785	587
Total research and development expenses	\$ 4,522	\$ 2,531

We do not allocate general equipment and supply costs, or facilities, depreciation and other miscellaneous expenses to specific programs as these expenses are deployed across all of our programs.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

***Other Income (Expense), Net***

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

Other income (expense), net consists primarily of interest income earned on cash and cash equivalents; interest expense on convertible notes and on amounts outstanding under our credit facility; changes in fair value of the exchangeable share liability while outstanding relating to the total exchangeable shares held by the prior stockholders of Verio; and changes in fair value of the warrant liability while outstanding relating to our preferred stock warrants.

### **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.

Table of Contents

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, 2013 continue to be our critical accounting policies. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2014.

**Results of Operations***Comparison of the Three Months Ended March 31, 2014 and 2013*

The following table summarizes the results of our operations for the three months ended March 31, 2014 and 2013 (in thousands):

	Three Months Ended March 31,		
	2014	2013	Increase / (Decrease)
Collaboration revenue	\$	\$	209 \$ (209)
Grant revenue			263 (263)
Research and development expense	4,522	2,531	1,991
General and administrative expense	2,415	1,297	1,118
Total other income (expense), net	(43)	(192)	149

*Revenue.* We did not generate any revenue for the three months ended March 31, 2014, compared to a total of \$0.5 million of revenue generated for the three months ended March 31, 2013. The decrease was due to the completion of our TATRC grant in May 2013 and the expiration of the three-year joint development period under our license and collaboration agreement with BD in September 2013. We do not expect to generate any significant revenue under these agreements in the future.

*Research and development expenses.* Research and development expenses were \$4.5 million for the three months ended March 31, 2014, compared to \$2.5 million for the three months ended March 31, 2013. The \$2.0 million increase in research and development expenses primarily reflects the following:

- \$0.8 million increase in compensation and benefits expense, including stock-based compensation expense, to support the clinical development of ProHema and the preclinical development of our other product candidates;
- \$0.5 million increase in third-party professional consultant and service provider expenses relating to our preparation for, and the commencement of, our Phase 2 clinical trial of ProHema in adult patients undergoing HSCT for the treatment of hematologic malignancies (the PUMA study) in March 2014; and

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- \$0.4 million increase from the non-cash share charge related to the achievement of a pre-clinical milestone under our agreement with the former Verio stockholders.

*General and administrative expenses.* General and administrative expenses were \$2.4 million for the three months ended March 31, 2014, compared to \$1.3 million for the three months ended March 31, 2013. The \$1.1 million increase in general and administrative expenses primarily reflects the following:

- \$0.5 million increase in compensation and benefits expense, including stock-based compensation expense, associated with the expansion of our financial and administrative resources; and
- \$0.4 million increase in third-party financial and legal professional service provider and insurance expenses to support operations as a public company.

*Other income (expense), net.* Other income (expense), net was \$(43,000) for the three months ended March 31, 2014, compared to \$(0.2) million for the three months ended March 31, 2013. The increase in other income (expense), net, was primarily due to a fair value charge on the exchangeable share liability of \$0.1 million during the three months ended March 31, 2013 related to the total exchangeable shares held by the former stockholders of Verio that did not reoccur during the three months ended March 31, 2014.

### **Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations since inception. As of March 31, 2014, we had an accumulated deficit of \$93.5 million and anticipate that we will continue to incur net losses for the foreseeable future.

Table of Contents

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net cash used in operating activities	\$ (5,255)	\$ (3,933)
Net cash used in investing activities	(398)	(7)
Net cash used in financing activities	(502)	(500)
Net change in cash and cash equivalents	\$ (6,155)	\$ (4,440)

***Operating Activities***

Cash used in operating activities increased \$1.4 million from \$3.9 million for the three months ended March 31, 2013 to \$5.3 million for the three months ended March 31, 2014. The primary driver of operating cash requirements was our net loss in each period. During the three months ended March 31, 2014, we used cash from operating activities of \$5.3 million while our net loss was \$7.0 million. The difference was a result of \$0.3 million net change in our operating assets and liabilities and \$1.4 million of non-cash charges and deferrals, including \$0.9 million of stock-based compensation, a \$0.4 million non-cash exchangeable share charge related to the achievement of a pre-clinical milestone under our agreement with the former stockholders of Verio, and \$0.1 million of depreciation expense.

***Investing Activities***

During the three months ended March 31, 2014 and 2013, investing activities used cash of \$0.4 million and \$7,000, respectively, for the purchase of property and equipment.

***Financing Activities***

Financing activities used cash of \$0.5 million for each the three months ended March 31, 2014 and 2013 related to the pay down of principal on our outstanding long-term debt.

From our inception through March 31, 2014, we have funded our consolidated operations primarily through the public sale of our common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of March 31, 2014, we had cash and cash equivalents of \$47.9 million. Our IPO on October 4, 2013 resulted in net proceeds of \$40.5 million. We also repaid a total of \$1.7 million in cash of outstanding principal and accrued interest on convertible notes in connection with the IPO.

In 2009, we entered into a \$3.0 million loan and security agreement collateralized by substantially all of our assets, excluding certain intellectual property. We drew the full \$3.0 million available under the loan and security agreement in 2009. In August 2011, the loan and security agreement was amended to: (i) increase the available credit under the loan and security agreement to \$4.0 million, (ii) add an additional payment upon maturity equal to 5% of the maximum loan amount and (iii) repay the remaining \$0.6 million of outstanding principal related to the original \$3.0 million loan. We accessed the full \$4.0 million of available credit under the amended loan and security agreement by taking a term advance of \$2.0 million in August 2011 and a term advance of \$2.0 million in December 2011, each of which are scheduled to be fully paid by August 2014 and December 2014, respectively. The term advances require interest-only payments during the first 12 months from access and equal monthly principal and interest payments during the final 24 months from access. The interest rate on the term advances is fixed at 7.0% per annum for their entire 36-month term of the debt. As of March 31, 2014, the aggregate outstanding principal was \$1.3 million.

### *Operating Capital Requirements*

To date, we have not generated any revenues from therapeutic product sales. We do not know when, or if, we will generate any revenue from therapeutic product sales. We do not expect to generate significant revenue from therapeutic product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We have incurred, and will continue to incur, additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Table of Contents

We believe our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we may require additional capital for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates.

Until we can generate a sufficient amount of revenue from our therapeutic products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. In any event, we do not expect to achieve significant revenue from therapeutic product sales prior to the use of our existing cash and cash equivalents. Additional capital may not be available 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 development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity 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. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and 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 design, initiation, progress, size, timing, duration, costs and results of preclinical studies and clinical trials for our product candidates;
- the outcome, timing and cost of 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;
- 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 effect of competing technological and market developments; and
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

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

#### **Contractual Obligations and Commitments**

The Company did not enter into any material contractual obligations during the three months ended March 31, 2014. The Company has 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.



Table of Contents

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

*Interest Rate Risk*

Our cash and cash equivalents as of March 31, 2014 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 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 March 31, 2014.

*Changes in Internal Control over Financial Reporting*

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

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are currently not a party to any material legal proceedings or aware of any pending material legal proceedings, 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 results of operations or financial condition. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities.

**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 Our Limited Operating History and the Discovery, Development and Regulation of Our Product Candidates**

*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. Since inception, we have devoted substantially all of our resources to the development of our stem cell modulation platforms, the clinical and preclinical advancement of our product candidates, the creation, licensing and protection of related intellectual property rights and the provision of general and administrative support for these operations. We have not yet obtained regulatory approval for any product candidates or generated any revenues from therapeutic product sales. If ProHema or any of our other product candidates fails in clinical trials or preclinical development, or does not gain regulatory approval, or if our product candidates do not achieve market acceptance, we may never become profitable.

Table of Contents

We have incurred net losses in each year since our inception and as of March 31, 2014, we had an accumulated deficit of approximately \$93.5 million. We expect to continue to incur losses for the foreseeable future, including in connection with our ongoing Phase 2 clinical trial of ProHema using our nutrient-rich media, or NRM, formulation in adult patients undergoing hematopoietic stem cell transplant, or HSCT, for the treatment of hematologic malignancies, or the PUMA study, and our other ongoing and planned preclinical and clinical development activities for ProHema and our Wnt7a analogs, and we expect these losses to increase as we continue our development of, and seek regulatory approval for, our product candidates. In addition, if we receive approval to market any of our product candidates, we will incur additional losses as we build an internal sales and marketing organization to commercialize any approved products. We also expect our expenditures to increase as we add infrastructure and personnel to support our operations as a public company. 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 U.S. Food and Drug Administration, or 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 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.

***We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development activities and operations.***

We are currently advancing ProHema through clinical development and our Wnt7a analogs through preclinical development. Developing biological products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional capital in order to complete the clinical development of, and to commercialize, ProHema, and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals would likely be delayed. Raising funds in the current economic environment may be difficult and additional funding may not be available on acceptable terms, or at all.

The amount and timing of our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the progress, costs, results and timing of the PUMA study and our planned Phase 1b clinical trials of ProHema;
- the progress, costs, results and timing of our additional preclinical studies and planned clinical trials of our Wnt7a analogs;
- our ability to initiate, and the size, progress, costs, results and timing of additional future clinical trials, including any registrational clinical trials for ProHema or for Wnt7a analogs, that will be necessary to support any application for regulatory approval of our product candidates; and

- 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.

Some of these factors are outside of our control. 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. This period could be shortened if there are any significant or unanticipated increases in spending on development programs. In addition, our current cash position will not be sufficient to complete the advanced clinical development, including Phase 3 clinical trials, of ProHema or clinical trials of our Wnt analogs that would be necessary to support an application for regulatory approval. Accordingly, we will continue to require substantial additional capital. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

If we are required to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or curtail our operations, which will have a material adverse effect on our business, operating results and prospects.

Table of Contents

***If we fail to complete preclinical development and clinical trials, obtain regulatory approval, or successfully commercialize our product candidates from our hematopoietic stem cell, or HSC, and Satellite Cell modulation platforms, our business would be significantly harmed.***

We have not completed clinical development for any of our product candidates and will only obtain regulatory approval to commercialize 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 safe, pure and potent, and effective, and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex and extremely expensive processes with uncertain results. A failure of one or more clinical trials may occur at any stage.

We have never obtained marketing approval from the FDA or any comparable foreign regulatory authority for any product candidate. 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 issues that do not potentially outweigh the therapeutic benefit of the product candidates, and whether the regulatory agencies agree that the data from our clinical trials are sufficient to support approval for any of our product candidates. 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 more preclinical studies and clinical trials than we currently anticipate. Even if we do receive FDA or other regulatory agency approval, we may not be successful in commercializing approved product candidates. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

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

In March 2014, we initiated enrollment of the PUMA study using our NRM formulation in adult patients undergoing double umbilical cord blood transplant for hematologic malignancies, following our submission to the FDA of manufacturing and product data incorporating our NRM formulation for the manufacture of ProHema, where such data was generated using the NRM formulation intended for clinical use. We originally initiated a Phase 2 trial in December 2012 using standard processing media for the manufacture of ProHema, or the ProHema-03 study, and notified the FDA in May 2013 of our election to pause enrollment of the ProHema-03 study to incorporate the use of our improved NRM formulation in the manufacture of ProHema. In August 2013, we submitted to the FDA preclinical and product development data supporting the use of our NRM formulation in the manufacture of ProHema and that its use should not result in additional safety risks. We also submitted an amended protocol defining how we planned to resume our clinical development of ProHema using our NRM formulation.

In addition, we submitted an amendment to our current IND for ProHema, and have received permission from the FDA to proceed with conducting a clinical trial of ProHema for the treatment of hematologic malignancies in pediatric patients, or the PROMPT study, under this amended IND application. Our IND amendment details the clinical protocol for the conduct of the PROMPT study and information on how we plan to conduct the clinical trial with a formulation of ProHema having a reduced volume for the treatment of pediatric patients. We plan to submit product development data supporting our reduced volume formulation of ProHema to the FDA prior to initiating enrollment in the PROMPT study.

While we have initiated enrollment in the PUMA study and received FDA permission to initiate enrollment in the PROMPT study, the FDA may require us to generate additional preclinical, product or clinical data to support the use of our NRM formulation in the PUMA study or the PROMPT study, or any other planned or subsequent clinical trials of ProHema, or may impose additional requirements for our clinical

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

development activities for ProHema. Additionally, the FDA may in the future have comments, or impose requirements, on our protocols for conducting the PUMA study or the PROMPT study, or any other planned or subsequent clinical trials of ProHema. Additional comments, requirements or impositions by the FDA may cause delays in the conduct of the PUMA study or PROMPT study, or other planned or subsequent clinical trials of ProHema, or other 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. Specifically, any comments, requirements or impositions by the FDA may cause delays in the availability of data from the PUMA study and the PROMPT study. Any inability to advance ProHema or any other product candidate through clinical development would have a material adverse effect on our business.

Table of Contents

***We will need to file a new IND application to initiate our planned clinical trial of ProHema for the treatment of lysosomal storage disorders, or LSDs, in pediatric patients.***

In addition to the PROMPT study, we plan to conduct a clinical trial of ProHema for the treatment of LSDs in pediatric patients. Based on feedback from the FDA, we will need to file a new IND application to evaluate ProHema for the treatment of LSDs in pediatric patients. Our clinical and product development plans, including our plans to file a new IND application to evaluate ProHema for the treatment of LSDs in pediatric patients, may change in response to a variety of factors, including the results of additional preclinical research and our discussions with key opinion leaders, regulatory authorities and/or third-party service providers. If we change our clinical and product development plans or are required to submit additional data or new IND applications, this may delay our timeline, require additional resources and data and create uncertainty and additional complexity in our ability to obtain regulatory approval for these indications.

***Our Wnt7a analogs are still in preclinical development, which may not be successful. If we are unable to successfully complete preclinical studies and clinical trials of our Wnt7a analogs, our business will be harmed.***

Our Wnt7a analogs are still in preclinical development. To our knowledge, there are no Wnt proteins currently undergoing clinical development, primarily due to certain molecular characteristics that hinder their effective development as biologic therapeutics. Although we believe we are the first company to produce an analog of a Wnt protein that is amenable to manufacture, formulation and administration for *in vivo* therapeutic use, we may later encounter difficulties in manufacturing, formulating or administering our Wnt7a analogs, or we may otherwise observe undesirable safety or efficacy profiles in these product candidates as our development activities progress. Subject to our selection of a lead candidate, the completion of IND-enabling studies and our proposed pre-IND meeting with the FDA, we plan to file an IND application with the FDA and initiate a Phase 1 clinical trial of a Wnt7a analog. We may delay or cancel our ongoing and planned preclinical and clinical development activities for our Wnt7a analogs for a variety of reasons, including:

- the results of our ongoing or future preclinical studies or clinical trials may not support further development of, or may require us to significantly modify our development plans for, our Wnt7a analogs;
- the FDA may require us to conduct additional preclinical studies or generate additional data before we are allowed to proceed with clinical development;
- an inability to manufacture Wnt7a analogs in a sufficient quantity or supply, or to formulate Wnt7a analogs in a suitable form for administration, for use in our planned preclinical studies or clinical trials;
- difficulty in establishing or maintaining manufacturing relationships with third parties on acceptable terms, or in establishing or maintaining our own manufacturing capability, to produce and supply our Wnt7a analogs;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- an inability to reach a consensus with regulatory agencies on clinical trial design, or to reach agreement on acceptable terms with prospective clinical research organizations and clinical trial sites, or to obtain required institutional review board, or IRB, approval at each clinical trial site, or to recruit suitable and sufficient numbers of patients, for the conduct of clinical trials for our Wnt7a analogs; or
- the occurrence of adverse events associated with our Wnt7a analogs in clinical trials that are viewed to outweigh their potential benefits.

Any delay in, or cessation of, our Wnt7a analog development activities could materially harm our business.

*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. Our current and future clinical trials of ProHema and our other product candidates may be delayed, unsuccessful or terminated as a result of many factors, including:

- delays in our ability to enroll patients in the PUMA study;
- the introduction of our NRM formulation into the PUMA study may not produce the benefits that we currently anticipate or may result in unanticipated adverse effects;



Table of Contents

- delays in designing appropriate clinical trial protocols and reaching agreement on trial design with investigators and regulatory authorities;
- delays or failure in reaching agreement on acceptable clinical trial contracts or protocols with prospective sites;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy or guidelines;
- delays in reaching agreement on acceptable terms with third-party service providers to manage various aspects of our clinical trials, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and trial sites;
- failure of third-party service providers and clinical trial sites to ensure the proper and timely conduct of our clinical trials;
- failure of clinical trial sites to manufacture ProHema consistently under the correct conditions at their on-site cell processing facilities for use in our clinical trials;
- failure of third-party manufacturers to manufacture to the appropriate specifications the critical reagents necessary for the manufacture of ProHema;
- the commercial availability of other materials necessary for the manufacture of ProHema;
- delays in achieving study endpoints and completing data analysis for a trial;
- regulators or IRBs may not authorize us to commence or recommence a clinical trial;
- data safety monitoring committees may recommend suspension, termination or a clinical hold for various reasons, including concerns about patient safety;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- regulators or IRBs may suspend or terminate the trial or impose a clinical hold for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- patients in our clinical trials have serious, life-threatening diseases and may die or suffer other adverse medical events for reasons that may not be related to our product candidates;
- participating patients may be subject to unacceptable health risks;
- patients not completing clinical trials due to safety issues, side effects, or other reasons;
- our product candidates may demonstrate a lack of safety or efficacy during clinical trials; and
- changes in regulatory requirements and guidance that require us to amend clinical trial protocols to reflect these changes.

The FDA has indicated that we will need to standardize the process for manufacturing ProHema across the multiple cell processing facilities at the clinical sites participating in our trials, and any delays in, or inability to, establish manufacturing protocols acceptable to the FDA will result in further delays to our clinical development plans. Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Moreover, our development costs will increase because we will be required to complete additional or larger clinical trials for product candidates from our HSC and Satellite Cell modulation platforms prior to FDA or other regulatory approval. We may not have adequate capital or other resources to commence or complete these additional or larger trials. 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 may significantly harm our business, financial condition and prospects.

Table of Contents

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

We will be required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates. Each indication for which we plan to evaluate our current product candidates represents a rare disease or condition with limited patient populations from which to draw participants in clinical trials. Due to our focus on the development of product candidates for the treatment of orphan hematologic malignancies, rare genetic diseases and muscular dystrophies, we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner. In addition, there are currently only a limited number of specialized transplant centers that perform HSCTs, and among physicians who perform HSCTs, some may not choose to perform these procedures under conditions that fall within our protocols, which would have an adverse effect on our development of ProHema. Our ability to enroll patients in our clinical trials is affected by factors including:

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

- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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

***Results from preclinical studies and earlier clinical trials do not ensure that future clinical trials will be successful.***

All of our product candidates are still in an early stage of development, and we cannot be assured that these trials will ultimately be successful. For example, although the results of our Phase 1b clinical trial of ProHema in adults with hematologic malignancies undergoing double umbilical cord blood transplant demonstrated human proof-of-concept, we may not achieve or duplicate these results in the PUMA study or planned additional clinical trials of ProHema for a variety of reasons, including:

- the use of our NRM formulation may not produce the potency and efficacy benefits observed in preclinical studies, or may result in unanticipated side effects in comparison to the standard processing media used in our Phase 1b clinical trial;
- later-stage trials that enroll a larger number of patients may not produce the same or similar results as earlier trials with fewer patients;
- the expansion in the number of participating clinical centers and the variabilities among the centers may result in complexities in conducting clinical trials, which we may be unable to manage adequately;

Table of Contents

- we may be unable to ensure the consistent manufacture of ProHema, which is required to be manufactured at cell processing facilities at each clinical center, across all participating clinical centers in the PUMA study or in any future clinical trials that we may conduct;
- differences in the design of the Phase 2 clinical trial, such as additional conditioning regimens, expanded eligibility criteria, potential patient population changes based on additional clinical centers that are more geographically dispersed, and the addition of a concurrent control arm;
- our efforts to standardize and automate our ProHema manufacturing process to make it acceptable to FDA for entry into Phase 2 clinical trials, may make it less effective than the product manufactured during our Phase 1b trial or otherwise adversely affect ProHema; and
- we have not previously evaluated ProHema in pediatric patients, and pediatric patients may experience side effects or other adverse events not observed in adult patients.

Additionally, because our Wnt7a analogs are still in preclinical development, we cannot assure you that any product candidates selected from our Satellite Cell modulation platform will demonstrate the safety, purity and potency profile necessary to support further preclinical study or clinical development or regulatory approval.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stages of development. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and initial results from a clinical trial do not necessarily predict final results. Even if early stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to demonstrate the required characteristics to support marketing approval for our product candidates in our planned and future clinical trials would substantially harm our business and prospects.

***Our planned clinical development activities for ProHema present operational, technical and timing issues related to pediatric clinical trials.***

Many clinical centers that could potentially participate in our pediatric clinical trials of ProHema are distinct and separate from the centers participating in our adult trials, and finding sufficient, capable centers that would be interested in participating in our pediatric trials may take additional time. There will be fewer eligible patients with hematologic malignancies and rare genetic disorders for our planned clinical trials in pediatric patients because the total number of pediatric patients with such diseases and disorders is lower than it is in adults. This may increase the time to enroll our planned pediatric clinical trials in hematologic malignancies and rare genetic disorders and could also further limit our ability to enroll patients in our planned Phase 1 clinical trials of ProHema in pediatric patients.

As we have not previously evaluated ProHema in pediatric patients, we will have to modify the current formulation of ProHema to one that is suitable for children, due to their smaller size and requirement for smaller infusion volume. We submitted an amendment to our current IND

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

application for ProHema that details our planned use of a reduced volume formulation of ProHema for the treatment of pediatric patients with hematologic malignancies, and plan to submit data supporting our reduced volume formulation of ProHema to the FDA prior to initiating enrollment of pediatric patients. The FDA will have the opportunity to review the details regarding the reduced volume formulation and data supporting the formulation of ProHema, and may require us to generate additional preclinical, product, or clinical data to support the use of any reduced volume formulation of ProHema for our PROMPT trial or 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 our planned pediatric clinical trials. In addition, the FDA will need to review and approve our specific clinical plans to conduct trials in pediatric patients with rare genetic disorders, and may present additional requirements, including additional data in adult patients, before we can proceed with our planned pediatric clinical trials. Any delays in our planned clinical development activities for pediatric patients could have an adverse effect on our business operations.

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

Our product candidates are based on our novel HSC and Satellite Cell modulation platforms, and unexpected problems related to this new technology may arise that can cause us to delay, suspend or terminate our development efforts. 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 to our and regulatory agencies' lack of experience with them.

Table of Contents

Stem cell therapies 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 stem cell products. 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 how long it will take or how much it will cost to obtain regulatory approvals for ProHema or any of our other modulated HSC product candidates in the United States and elsewhere. Furthermore, the requirement that ProHema is manufactured at cell processing facilities in close proximity to transplant centers within a short period of time before transplantation may present unprecedented additional complexities associated with ensuring consistent manufacture across all sites, the degree of qualification testing necessary for cell-based therapies both pre- and post-administration, and ProHema's rapid release nature, all of which contribute to regulatory uncertainty.

Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. 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. In addition, adverse developments in clinical trials of potential stem cell therapies conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. These regulatory authorities and advisory groups and the 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 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. Delay or failure to obtain, or unexpected costs in obtaining, 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, good manufacturing practices, or GMP requirements relating to 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.

In addition, later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;

- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- requirements to institute a risk evaluation and mitigation strategy, or REMS, to monitor safety of the product post-approval;
- requirements to individually license clinical cell processing facilities for the manufacture of ProHema;
- warning letters issued by the FDA or other regulatory authorities;



Table of Contents

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products, fines, restitution or disgorgement of profits or revenue;
- suspension, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to product candidates granted breakthrough therapy or fast track designation by the FDA.***

We are evaluating the possibility of seeking breakthrough therapy or fast track designation for some of our product candidates, although we may elect not to do so. A breakthrough therapy program is for a product candidate intended to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. In contrast, a fast track program is for a product candidate that treats a serious or life-threatening condition, and nonclinical or clinical data demonstrate the potential to address an unmet medical need. Although we believe some of our product candidates may qualify under either or both of the breakthrough therapy and fast track programs, we may elect not to pursue either of these programs, and the FDA has broad discretion whether or not to grant these designations. Accordingly, even if we believe a particular product candidate is eligible for breakthrough therapy or fast track designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track designation if it believes that the product no longer meets the qualifying criteria. In addition, the breakthrough therapy program is a relatively new program. As a result, we cannot be certain whether any of our product candidates can or will qualify for breakthrough therapy designation. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

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

We expect to rely heavily on orphan drug exclusivity for our product candidates, including ProHema. Orphan drug status confers seven years of marketing exclusivity under the Federal Food, Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication. We have been granted orphan drug designation in the United States for human allogeneic HSCs *ex vivo* modulated with FT1050 for the enhancement of stem cell engraftment and in the European Union for ProHema for the treatment of acute myelogenous leukemia through the *ex vivo* modulation of allogeneic umbilical cord blood cells. 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, the 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, 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 the 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.

Table of Contents

*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 fraud and abuse laws, including, without limitation, the federal anti-kickback statute. 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. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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. 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 third-party suppliers for various components of our improved NRM formulation for the manufacture of ProHema and do not have supply arrangements for certain of these components to complete clinical development.*

We currently rely, and expect to continue to rely, on third-party suppliers for components that enable us to develop and use our NRM formulation for the manufacture of ProHema in the Phase 2 PUMA study, the PROMPT study, and any subsequent clinical trials of ProHema. We have not entered into, and may not be able to enter into, clinical supply agreements for certain of the components necessary to produce our NRM formulation and may therefore fail to secure an adequate and reliable supply of these components to complete our planned clinical development of ProHema through to commercialization. Even if we are able to secure such clinical supply agreements, we may be limited to a sole manufacturer for certain of the components required in our NRM formulation. Accordingly, we cannot guarantee that we will have an

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

adequate supply of NRM to complete our planned clinical development of ProHema, including our Phase 3 clinical trial or any other future clinical trials. In addition, if we are unable to secure adequate quantities of these components from our preferred suppliers, we may be required to identify alternate suppliers of these components, or to modify our NRM formulation. If we are required to change suppliers of our components, or modify our NRM formulation, the efficacy and potency of ProHema may be adversely affected. We also may be required to make further changes to our trial protocol or provide additional data to the FDA regarding the use of alternative components for our NRM formulation or a modified NRM formulation, which could delay our clinical development plans for ProHema and increase the costs required to complete our planned clinical development of ProHema.

***We rely on a single third-party supplier for the FT1050 starting material required for the manufacture of ProHema and depend on third-party suppliers for other components necessary for the manufacture of ProHema.***

To date, we have obtained our supplies of 16, 16-dimethyl prostaglandin E2, which we refer to as FT1050, for the manufacture of ProHema in our preclinical studies and clinical trials from a single third-party manufacturer. This manufacturer supplies FT1050 to us for our clinical trials on a purchase order basis under a clinical supply manufacturing agreement, and we do not have any current contractual relationships for the commercial manufacture and supply of bulk FT1050 substance for manufacturing ProHema. Additionally, to date, we have acquired, or our clinical cell processing facilities have acquired, other equipment, materials and disposables necessary for the manufacture of ProHema from third parties. These materials include but are not limited to automated cell washing devices, automated cell warming units, commercially available media, cord blood transfer and wash sets, and other

Table of Contents

disposables. We do not have any current contractual relationships for the commercial supply of these materials for manufacturing ProHema and rely on their general commercial availability. Although we believe that we have alternate suppliers for FT1050 and the other components necessary for the manufacture of ProHema should our current third-party manufacturers or suppliers become unavailable to us for any reason, we may incur delays associated with identifying and qualifying replacement suppliers and negotiating the terms of any supply contracts with the replacement suppliers. These delays could adversely impact our clinical development plans 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.

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 only used unlicensed CBUs in the manufacture of ProHema for our clinical trials, the FDA may later prohibit the use of unlicensed CBUs for transplantation. 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 impact our ability to develop and commercialize ProHema.

***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 commercialize ProHema, if approved.***

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 to maximize consistency across the multiple clinical cell processing facilities, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. Although we are responsible for ensuring compliance with GMPs 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. The clinical cell processing facilities at which ProHema is manufactured must be approved by applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after a BLA, or comparable foreign regulatory marketing application is submitted. We do not control the manufacturing process for ProHema and are completely dependent on third parties for compliance with the FDA's requirements and proper execution of the protocol for the manufacture of ProHema. Because of the requirement that ProHema be manufactured in close proximity to the transplant center within a short period of time before

Table of Contents

transplant, if the applicable clinical cell processing facilities are unable to manufacture ProHema in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we will not be able to secure backup manufacturing capabilities. For example, to comply with GMPs and other regulatory requirements and our manufacturing protocols, the clinical cell processing facility may be required to possess or obtain certain equipment necessary for the manufacture of ProHema 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, for the compliant manufacture of ProHema. Clinical cell processing facilities may be unwilling or unable to comply with these requirements, which could restrict or prohibit a given clinical center from manufacturing ProHema and making it available for administration to patients within the required timeframes. 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 impact on our business.

***We will be substantially dependent on third parties for the manufacture of our clinical supplies of our Wnt7a analogs.***

We expect to rely on third-party manufacturers for clinical supplies of our Wnt7a analogs and other product candidates that we may develop. These third-party manufacturers will be required to comply with current GMPs 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 other 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, Wnt proteins have specific molecular characteristics that make their manufacture for therapeutic application difficult, and it is possible that any third-party manufacturers that we engage may experience difficulties in such manufacture. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our Wnt7a analogs and adversely affect our business.

***We currently rely on third parties to support the conduct of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to 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 to monitor and manage data for our ongoing and planned clinical programs. We rely on these parties for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and our third-party service providers are required to 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 GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party service providers or clinical trial sites fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. 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 clinical trials must be conducted with product produced under applicable GMP requirements. We also rely on third parties to assist in conducting our preclinical studies, including IND-enabling studies, in accordance with good laboratory practices, or GLP. Failure by our third-party service providers to comply with applicable legal, regulatory or scientific standards in our clinical trials or our preclinical studies could negatively impact the results obtained in these trials or studies, and may require us to suspend or terminate ongoing preclinical studies or clinical trials, or repeat nonclinical and clinical trials or preclinical studies, which would harm our ability to complete the development of, and obtain regulatory approval for, our product candidates.

Our third-party service providers are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If third-party service providers do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical or preclinical data they obtain is compromised due to the failure to adhere to our clinical or preclinical protocols, regulatory requirements or for other reasons, our 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. 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.



Table of Contents

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Although we carefully manage our relationships with our third-party service providers, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

*If we lose our relationships with our third-party service providers, our product development efforts could be delayed.*

We rely on third-party service providers for clinical trials and preclinical activities related to our product development efforts. Switching or adding additional third-party service providers involves additional cost and timing considerations and requires management time and focus. Some of our third-party service providers have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our third-party service providers have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new service provider commences work and the new provider may not provide the same type or level of services as the original provider. If any of our relationships with our third-party service providers terminate, we may not be able to enter into arrangements with alternative service providers or to do so on commercially reasonable terms.

**Risks Related to Our Intellectual Property**

*It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.*

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. We are the owner of record of various patent applications pending in the United States and in certain foreign jurisdictions relating to ProHema and other therapeutic compositions of stem cells that have been pharmacologically modulated to enhance their therapeutic properties, and methods of manufacturing the cellular compositions. In addition, we own a number of patent applications pending in the United States and in certain foreign jurisdictions relating to our Wnt analogs, covering compositions of matter, processes for preparing such Wnt proteins and formulations, and the modulation of satellite cells. To date, no patents have been issued to us specifically covering our product candidates, and we cannot be certain that any patents will issue with claims that cover our ProHema and Wnt product candidates.

Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in foreign jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently, or may in the future, own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

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

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

Table of Contents

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make therapeutics or compounds that are similar to our product candidates, but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;
- the claims of our issued patents or patent applications when issued may not cover our products or product candidates;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- any granted patents may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

***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 impact our business and operations.***

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

We are the exclusive licensee of over 80 issued or pending U.S. and non-U.S. patents or patent applications relating to ProHema and other therapeutic compositions of stem cells that have been pharmacologically modulated to enhance their therapeutic properties, methods of manufacturing the cellular compositions, and methods of promoting hematopoietic reconstitution, expansion and self-renewal using modulators that increase prostaglandin signaling activity.

We have exclusive licenses to over 30 patents and patent applications relating to our Wnt analogs, covering compositions of matter, processes for preparing such Wnt proteins and formulations, and the modulation of satellite cells.

As a licensee of third parties, we rely on these third parties 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 patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our 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.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in the parent patent application.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.***

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. For example, under our exclusive license agreements with various universities and research institutions, we are required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and must satisfy specified milestone and royalty payment obligations. If we fail to comply with our obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part, increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired. Additionally, we may be subject to royalty obligations to multiple licensors with respect to the same product.

Table of Contents

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

***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. In addition, 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. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

*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. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, 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. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of the relevant product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the

Table of Contents

presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, 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.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours that claims priority to an application filed prior to March 16, 2013, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, changes enacted on March 15, 2013 to the U.S. patent laws resulted in the United States changing from a first to invent country to a first to file country. As a result, we may lose the ability to obtain issued patent if a third party files with the patent office first. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.***

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Furthermore, some of our license agreements require us to notify, and in some cases license back to the licensor, certain additional proprietary information or intellectual property that we developed using the rights licensed to us under these agreements. Any such licenses back to the licensor could allow our licensors to use that proprietary information or intellectual property in a manner that could harm our business. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***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 impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.



Table of Contents

**Risks Related to the Commercialization of Our Product Candidates**

*If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.*

We have no experience selling and marketing any products. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If any of our initial product candidates are approved for marketing, we intend to build an internal sales and marketing organization to commercialize these products in highly specialized target markets, where patient and physician communities are concentrated and product adoption is driven by key opinion leaders. However, we may not have adequate financial resources or expertise to build an effective sales and marketing organization.

We may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities in larger target markets, but we may be unable to enter into these arrangements on favorable terms, if at all. If we are unable to develop adequate marketing capabilities on our own or effectively partner with third parties, we will be unable to generate revenues from our approved products. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

Ethical, social and legal concerns about stem cell therapies could result in additional regulations restricting or prohibiting the use of our product candidates. Even with the requisite approvals, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payers accepting stem cell therapies in general, and our product candidates in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. 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 product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and other advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from the chemotherapy and myeloablative treatments associated with the procedure by which ProHema or any other HSC therapeutics that we may develop are administered;

- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapeutics and of physicians to prescribe these therapeutics;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources and may never be successful. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

Table of Contents

*If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.*

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced or uncertain protection for our intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- complexity and difficulty in coordinating the communications and operations of our business; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

*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 HSC 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 these candidates 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. In addition, there are currently no approved products for the treatment of muscular dystrophies, and it is difficult to predict the level of reimbursement, if any, that would be available for any product candidates that we may develop in these indications. If pricing is set at unsatisfactory levels, our ability to successfully market and sell our product candidates will be adversely affected.

We may experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly in the area of orphan drug products, has become very intense. These pricing pressures have imposed significant barriers to the entry of new products.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, which may adversely affect our ability to generate profit from the sales of our product candidates.

Table of Contents

***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 ability to market any product that we may develop and decrease our ability to generate revenue.***

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 stem cell transplants. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In particular, there is no body of established practices and precedents for reimbursement of modulated 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. Stem cell transplant procedures are typically covered by one-time reimbursement, generally available for a limited number of days after transplant. 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 impact 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 hematologic malignancies, rare genetic disorders and muscular dystrophies. 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 HSC and Satellite Cell modulation platforms and our product candidates is substantially dependent on developments within the emerging field of stem cell therapies, some of which are beyond our control.***

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

Our HSC and Satellite Cell modulation platforms and our product candidates are designed to optimize the biological activity of adult stem cells, which represents a novel development within the field of stem cell therapeutics. Stem cell therapies in turn represent a relatively new therapeutic area that presents a number of scientific, clinical, regulatory and ethical challenges. Any adverse developments in the field of stem cell therapeutics generally, and in the practice of HSCT in particular, will negatively impact our ability to develop and commercialize our product candidates. In particular, we currently anticipate that ProHema and any additional product candidates that we develop from our HSC modulation platform would be adopted into the current standard of care for HSCT procedures. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the development and commercialization of therapies targeted at the underlying cause of diseases addressed by ProHema obviate the need for patients to undergo HSCT procedures, our business prospects will be significantly harmed.

Table of Contents

*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 major multinational pharmaceutical companies, established and early-stage biotechnology companies, and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing treatments in the rare disease indications that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Table of Contents

There are several clinical-stage development programs that seek to improve human umbilical cord blood transplantation through the use of *ex vivo* expansion technologies to increase the quantity of HSCs for use in HSCT or the use of *ex vivo* differentiation technologies to increase the quantity of hematopoietic progenitor cells for use in HSCT. Although there are currently no approved pharmaceutical products specifically for the treatment of muscular dystrophies, we are aware of several other companies with product candidates in various stages of development for the treatment of muscular dystrophies. In addition, many universities and private and public research institutes may develop technologies of interest to us, but license them to our competitors. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than ProHema or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our preclinical studies and clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to protect and develop intellectual property rights related to our products;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;



## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- market perception and acceptance of stem cell therapeutics;
- acceptance of our product candidates by physicians and institutions that perform HSCTs;
- the price of our products;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare; and
- our ability to manufacture and sell commercial quantities of any approved products to the market.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. Any inability to successfully compete effectively will adversely impact our business and financial prospects.

***We may need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.***

As we increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the requisite expertise and experience;
- manage our clinical programs effectively;
- if we receive regulatory approval for any product candidate, develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures, including those related to being a public company.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.



Table of Contents

*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 attract or retain 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 attract and retain 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.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Christian Weyer, our President and Chief Executive Officer; J. Scott Wolchko, our Chief Financial Officer and Chief Operating Officer; Pratik S. Multani, our Chief Medical Officer; Daniel D. Shoemaker, our Chief Technology Officer; and Peter Flynn, our Senior Vice President, Early Program Development. If we lose one or more of our executive officers or key consultants, our ability to implement our business strategy successfully could be seriously harmed. While we have entered into employment contracts with each of our executive officers, any of them could leave our employment at any time, as all of our employees are at-will employees. Replacing key personnel and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

We rely on our scientific founders and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

*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 have begun implementing our system of internal controls over financial reporting and preparing the documentation necessary to perform the evaluation needed to comply with Section 404(a) of the Sarbanes-Oxley Act. However, we will need to retain additional finance capabilities and build our financial infrastructure as we continue to operate as a public company, including complying with the requirements of Section 404 of the Sarbanes-Oxley Act and continuing to improve our financial infrastructure with the retention of additional financial and accounting capabilities, the enhancement of internal controls and additional training for our financial and accounting staff. Management oversight will be required as part of the process and as a result, management's attention may be diverted from other business concerns, which could harm our business and results of operations.

***Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, products liability and directors' and officers' insurance.

Table of Contents

We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

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

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

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

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

*We face potential product liability and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.*

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 and any products for which we obtain marketing approval. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance of \$5.0 million per occurrence and \$5.0 million aggregate limit. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. 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 product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large

Table of Contents

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 reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact 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 may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

***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. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research, development and production efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

*Our business is subject to the risks of earthquakes, fire, power outages, floods and other catastrophic events, and to interruption by manmade problems such as terrorism.*

A significant natural disaster, such as an earthquake, fire or a flood, or a significant power outage could have a material adverse impact on our business, operating results and financial condition. Our corporate headquarters are located in San Diego, California, a region known for seismic activity. In addition, natural disasters could affect our third-party service providers' ability to perform services for us on a timely basis. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented. In addition, if a catastrophe such as an earthquake, fire, flood or power loss should affect one of the third parties on which we rely, our business prospects could be harmed. For example, if a central laboratory holding all of our clinical study samples were to suffer a catastrophic loss of their facility, we would lose all of our samples and would have to repeat our studies. In addition, acts of terrorism could cause disruptions in our business or the business of our third-party service providers, partners, customers or the economy as a whole.



Table of Contents

*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. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee 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. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

**Risks Related to Ownership of Our Common Stock**

*Market volatility may affect our stock price and the value of your investment.*

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

- the timing of the initiation or completion of our clinical trials and preclinical studies;
- the results of our clinical trials and preclinical studies;
- the results of clinical trials of our competitors' product candidates or of other stem cell therapeutics in general;
- developments concerning our owned or licensed intellectual property rights;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- changes in laws or regulations applicable to stem cell therapeutics generally or our product candidates in particular, including but not limited to clinical trial requirements for approvals;
- changes in the markets for HSCT products and in the field of stem cell therapeutics, or changes in the markets for the treatment of muscular dystrophies and other diseases targeted by our product candidates;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;

Table of Contents

- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements or expectations of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

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

***Our principal stockholders exercise significant control over our company.***

As of April 7, 2014, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 67% of our outstanding voting stock. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company 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 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 impact on our stockholders' rights as well as on our operations. Any equity financing, or any issuance of securities that may be converted, exercised or exchanged for shares of our capital stock, will result in dilution to our stockholders and may cause the market price of our stock to decline, and any debt financing may impose restrictive covenants on our operations or otherwise adversely affect the holdings or the rights of our stockholders. In addition, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

*Future sales of shares by existing stockholders could cause our stock price to decline.*

In March 2014, approximately 12.4 million shares of our common stock became eligible for sale by our shareholders in the public market upon the expiration of lock-up agreements that were entered into in connection with our IPO, although a portion of such shares held by our affiliates will be subject to volume limitations and other conditions pursuant to Rule 144 of the Securities Act. Certain holders of our common stock have the right to require us to register these shares under the Securities Act pursuant to an investor rights agreement. In addition, a number of our employees, including executive officers, have adopted and may continue to adopt stock trading plans pursuant to which they have arranged to sell shares of our common stock from time to time in accordance with the guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended. Further, the shares subject to outstanding options under our equity incentive plans will, and the shares reserved for future issuance under our equity incentive plans may, become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If our existing stockholders, including our employees and executive officers, sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business. Actual or potential sales by our existing stockholders, including our employees and executive officers, could also be viewed negatively by other investors.

Table of Contents

***We will have broad discretion in how we use our existing cash. We may not use our existing cash effectively, which could affect our results of operations and cause our stock price to decline.***

We will have considerable discretion in the application of our existing cash, including the net proceeds from our IPO. We expect to use our existing cash to fund research and development activities and for working capital and general corporate purposes, including funding the costs of operating as a public company. We may use these proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash resources in a manner that does not produce income or that loses value.

***The requirements of being a public company may strain our resources and divert management's attention.***

As a public company, we have incurred, and will continue to incur, significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, laws, regulations and standards applicable to public companies relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC and The NASDAQ Stock Market, impose various requirements on public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, and could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We have invested, and intend to continue to invest, resources to comply with new and evolving laws, regulations and standards applicable to public companies, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Further, stockholder activism in public companies, the political climate, and the risk of governmental or regulatory proceedings could make it more expensive for us to secure and maintain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

***Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, 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, which will be effective upon the completion of this offering, 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;

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

- 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.

The affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class, is generally necessary to amend or repeal the above provisions that are contained in our amended and restated certificate of incorporation. In addition, absent approval of our board of directors, our amended and restated bylaws may only be amended or repealed by the affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which limits business combination transactions with stockholders of 15% or more of our outstanding voting stock that our board of directors has not approved. These provisions and other similar provisions make it more difficult for stockholders or potential acquirers to acquire us without negotiation. These provisions may apply even if some stockholders may consider the transaction beneficial to them.

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.

Table of Contents

***We are an emerging growth company and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.***

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline significantly if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

***We currently do not intend to pay dividends on our common stock and, consequently, an investor's only opportunity to achieve a return on the investment is if the price of our common stock appreciates.***

We currently do not plan to declare dividends on shares of our common stock in the foreseeable future. Consequently, an investor's only opportunity to achieve a return on the investment in us will be if the market price of our common stock appreciates and the investor sells shares at a profit. There is no guarantee that the price of our common stock in the market will ever exceed the price that an investor paid.

***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 initial public offering. 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.



Table of Contents

**SIGNATURES**

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

**Fate Therapeutics, Inc.**

Date: May 13, 2014

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)

## Edgar Filing: FATE THERAPEUTICS INC - Form 10-Q

### Table of Contents

### **Index to Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
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).
10.1#	Senior Executive Cash Incentive Bonus Plan (1)
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

---

\* In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

# Indicates a management contract or any compensatory plan, contract or arrangement.

(1) Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-36076), filed with the SEC on January 10, 2014 and incorporated herein by reference.

