FATE THERAPEUTICS INC
Form 10-Q
May 13, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

OR

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

From the transition period from to .

Commission File Number 001-36067

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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FATE THERAPEUTICS, INC.

FORM 10-Q

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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)

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
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
Liabilities and stockholders equity		
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.

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Fate Therapeutics, Inc.

(A Development Stage Company)

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended March 31,		Period From April 27, 2007 (inception) to March 31, 2014
	2014	2013	
	(unaudited)		(unaudited)
Revenues:			
Collaboration revenue	$	$ 209	$ 2,927
Grant revenue		263	2,084
Total revenue		472	5,011
Operating expenses:			
Research and development	4,522	2,531	61,508
General and administrative	2,415	1,297	33,125
Total operating expenses	6,937	3,828	94,633
Loss from operations	(6,937)	(3,356)	(89,622)
Other income (expense):			
Interest income		1	192
Interest expense	(43)	(100)	(2,684)
Income from 48D tax credit			1,231
Loss on extinguishment of debt			(332)
Change in fair value of warrant liability		12	35
Change in fair value of exchangeable shares		(105)	(2,309)
Total other expense, net	(43)	(192)	(3,867)
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.

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Fate Therapeutics, Inc.

(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,		Period From April 27, 2007 (inception) to March 31, 2014
	2014	2013	
	(unaudited)		(unaudited)
Operating activities			
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)
Investing activities			
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)
Financing activities			
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.

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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;

- 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.

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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.

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

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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.

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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

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:

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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

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

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

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:

	Three Months Ended March 31,	
	2014	2013
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:

	Three Months Ended March 31,	
	2014	2013
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.

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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.

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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;

- 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.

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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):

	Three Months Ended March 31,	
	2014	2013
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

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.

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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,		Increase / (Decrease)
	2014	2013	
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

- $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.

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

	Three Months Ended March 31,	
	2014	2013
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.

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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.

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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.

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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.

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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

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.

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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;

- 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;

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- 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;

- 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.

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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;

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- 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