

ACCELERON PHARMA INC

Form 10-Q

May 15, 2014

[Table of Contents](#)

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

For the transition period from to

Commission File Number: 001-36065

ACCELERON PHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

27-0072226
(I.R.S. Employer
Identification Number)

128 Sidney Street

Cambridge, MA 02139

(617) 649-9200

(Address, including zip code, and telephone number, including
area code, of registrant's principal executive offices)

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 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. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

As of April 30, 2014, there were 31,455,763 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

Table of Contents

TABLE OF CONTENTS

<u>PART I. FINANCIAL INFORMATION</u>	Page
	3
<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>
	3
	<u>Condensed Consolidated Balance Sheets as of March 31, 2014 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</u>
	4
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2014 and 2013</u>
	5
	<u>Notes to Condensed Consolidated Financial Statements</u>
	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	21
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	29
<u>Item 4.</u>	<u>Controls and Procedures</u>
	29
<u>PART II. OTHER INFORMATION</u>	30
<u>Item 1.</u>	<u>Legal Proceedings</u>
	30
<u>Item 1A.</u>	<u>Risk Factors</u>
	30
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	30
<u>Item 6.</u>	<u>Exhibits</u>
	30
<u>SIGNATURES</u>	31
<u>CERTIFICATIONS</u>	1

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Acceleron Pharma Inc.****Condensed Consolidated Balance Sheets**

(amounts in thousands except share and per share data)

(unaudited)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 214,135	\$ 113,163
Collaboration receivables (includes related party amounts of \$2,633 and \$3,616 at March 31, 2014 and December 31, 2013, respectively)	2,633	3,616
Prepaid expenses and other current assets	1,685	2,243
Total current assets	218,453	119,022
Property and equipment, net	3,674	3,705
Restricted cash	913	913
Other assets		92
Total assets	\$ 223,040	\$ 123,732
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,295	\$ 885
Accrued expenses	4,659	6,927
Deferred revenue	1,735	2,031
Deferred rent	499	499
Notes payable, net of discount		16,868
Total current liabilities	9,188	27,210
Deferred revenue, net of current portion	5,241	5,620
Deferred rent, net of current portion	2,212	2,337
Warrants to purchase common stock	25,942	30,753
Total liabilities	42,583	65,920
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Undesignated preferred stock, \$0.001 par value: 25,000,000 shares authorized and no shares issued or outstanding		
Common stock, \$0.001 par value: 175,000,000 shares authorized; 31,339,135, and 28,348,630 shares issued and outstanding at March 31, 2014 and December 31,	32	29

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

2013, respectively

Additional paid-in capital	381,869	250,107
Accumulated deficit	(201,444)	(192,324)
Total stockholders' equity	180,457	57,812
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 223,040	\$ 123,732

See accompanying notes to these condensed consolidated financial statements.

Table of Contents**Acceleron Pharma Inc.****Condensed Consolidated Statements of Operations and Comprehensive Loss**

(amounts in thousands except per share data)

(unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenue:		
Collaboration revenue:		
License and milestone	\$ 674	\$ 12,515
Cost-sharing, net	2,633	2,497
Total revenue(1)	3,307	15,012
Costs and expenses:		
Research and development	11,765	8,780
General and administrative	3,750	3,096
Total costs and expenses	15,515	11,876
(Loss) income from operations	(12,208)	3,136
Other income (expense):		
Other income (expense), net	3,997	(1,066)
Interest income	13	12
Interest expense	(922)	(435)
Total other income (expense), net	3,088	(1,489)
Net (loss) income	\$ (9,120)	\$ 1,647
Comprehensive (loss) income	\$ (9,120)	\$ 1,647
Reconciliation of net loss to net loss applicable to common stockholders:		
Net (loss) income	\$ (9,120)	\$ 1,647
Accretion of dividends, interest, redemption value and issuance costs on redeemable convertible preferred stock		(6,756)
Gain on extinguishment of redeemable convertible preferred stock		2,765
Net loss applicable to common stockholders basic and diluted	\$ (9,120)	\$ (2,344)
Net loss per share applicable to common stockholders basic and diluted: (Note 8)	\$ (0.30)	\$ (0.24)
Weighted-average number of common shares used in computing net income (loss) per share applicable to common stockholders:		
Basic and diluted	30,321	9,740
(1) Includes related party revenue (Note 19)	\$ 3,307	\$ 12,798

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

Acceleron Pharma Inc.

Condensed Consolidated Statements of Cash Flows

(amounts in thousands)

(unaudited)

	Three Months Ended March 31,	
	2014	2013
Operating Activities		
Net (loss) income	\$ (9,120)	\$ 1,647
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	265	224
Stock-based compensation	1,018	428
(Payment) / Accretion of deferred interest	(536)	86
Amortization of deferred debt issuance costs	36	18
Change in fair value of warrants	(3,990)	1,067
Gain on retirement of warrants		(76)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	539	(272)
Collaboration receivables	983	(223)
Related party receivable		(2)
Accounts payable	1,410	(247)
Accrued expenses	(2,278)	(744)
Deferred revenue	(674)	(2,516)
Deferred rent	(125)	(125)
Net cash used in operating activities	(12,472)	(735)
Investing Activities		
Purchases of property and equipment	(150)	(80)
Net cash used in investing activities	(150)	(80)
Financing Activities		
Proceeds from issuance of common stock from initial public offering, net issuance costs	129,166	
Payments of long-term debt	(16,332)	
Payments made to repurchase redeemable convertible preferred stock, common stock and warrants to purchase common stock		(300)
Proceeds from exercise of stock options and warrants to purchase common stock	760	14
Net cash provided by financing activities	113,594	(286)
Net increase (decrease) in cash and cash equivalents	100,972	(1,101)
Cash and cash equivalents at beginning of period	113,163	39,611
Cash and cash equivalents at end of period	\$ 214,135	\$ 38,510
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	\$ 1,574	\$ 435
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
	\$	\$ 6,756

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

Accretion of dividends, interest, redemption value, and issuance costs on preferred stock

Follow-on offering costs included in accounts payable and accrued expense	\$	8	\$	
Reclassification of warrant liability to additional paid-in capital	\$	821	\$	678
Purchase of property and equipment included in accounts payable and accrued expenses	\$	83	\$	

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

Acceleron Pharma Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Acceleron Pharma Inc. (Acceleron or the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of novel protein therapeutics for cancer and rare diseases. The Company's research focuses on the biology of the Transforming Growth Factor-Beta (TGF- β) protein superfamily, a large and diverse group of molecules that regulate the growth and repair of tissues throughout the human body. By coupling its discovery and development expertise, including its proprietary knowledge of the TGF- β superfamily, with internal protein engineering and manufacturing capabilities, the Company has built a highly productive research and development platform that has generated numerous innovative protein therapeutics with novel mechanisms of action. The Company has internally discovered three protein therapeutics that are currently being studied in numerous ongoing Phase 2 clinical trials, focused on the areas of cancer and rare diseases.

The Company is headquartered in Cambridge, Massachusetts and has one wholly-owned subsidiary, Acceleron Pharma Security Corporation.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risk that the Company never achieves profitability, the need for substantial additional financing, risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology and compliance with government regulations.

2. Basis of Presentation

The accompanying interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

The accompanying interim condensed consolidated financial statements are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2013, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2014, and the results of its operations and its cash flows for the three months ended March 31, 2014 and 2013.

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

The results for the three months ended March 31, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2013, and the notes thereto, together with Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

On January 29, 2013 the Company completed a public offering whereby the Company sold 2,760,000 shares of common stock (including 360,000 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option by the underwriters in connection with the offering) at a price of \$50.00 per share. The shares began trading on the Nasdaq Global Select Market on January 24, 2014. The aggregate net proceeds received by the Company from the offering were \$129.0 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

The accompanying interim condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the financial statements. As of March 31, 2014, the Company's significant accounting policies and estimates, which are detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, have not changed.

Table of Contents

3. Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts expensed during the reporting period. Actual results could materially differ from those estimates.

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: revenue recognition, stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of liability-classified warrants, accrued expenses, and the recoverability of the Company's net deferred tax assets and related valuation allowance.

4. Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment. All material long-lived assets of the Company reside in the United States. The Company does use contract research organizations (CROs) and research institutions located outside the United States. Some of these expenses are subject to collaboration reimbursement which is presented as a component of cost sharing, net in the statement of operations and comprehensive loss.

5. Cash and Cash Equivalents and Restricted cash

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value. As of March 31, 2014 and December 31, 2013, the Company maintained letters of credit totaling \$0.9 million held in the form of a money market account as collateral for the Company's facility lease obligations and its credit cards.

6. Concentrations of Credit Risk and Off-Balance Sheet Risk

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents, restricted cash and collaboration receivables. The Company maintains its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company routinely assesses the creditworthiness of its customers and collaboration partners. The Company has not experienced any material losses related to receivables from individual customers and collaboration partners, or groups of customers. The Company does not require collateral. Due to these factors, no additional credit risk beyond amounts provided for collection losses is believed by management to be probable in the Company's accounts receivable.

Table of Contents**7. Fair Value Measurements**

The following tables set forth the Company's financial instruments carried at fair value using the lowest level of input applicable to each financial instrument as of March 31, 2014 and December 31, 2013 (in thousands):

	March 31, 2014			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$ 213,626	\$	\$	\$ 213,626
Restricted cash	913			913
Total assets	\$ 214,539	\$	\$	\$ 214,539
Liabilities:				
Warrants to purchase redeemable convertible preferred stock	\$	\$	\$	\$
Warrants to purchase common stock			25,942	25,942
Total liabilities	\$	\$	25,942	25,942

	December 31, 2013			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$ 101,394	\$	\$	\$ 101,394
Restricted cash	913			913
Total assets	\$ 102,307	\$	\$	\$ 102,307
Liabilities:				
Warrants to purchase redeemable convertible preferred stock	\$	\$	\$	\$
Warrants to purchase common stock			30,753	30,753
Total liabilities	\$	\$	\$ 30,753	\$ 30,753

Items measured at fair value on a recurring basis include warrants to purchase redeemable convertible preferred stock and warrants to purchase common stock (Note 12). During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs.

The following table sets forth a summary of changes in the fair value of the Company's preferred and common stock warrant liability, which have been classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

Three Months Ended March 31,
2014 2013

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

Beginning balance	\$	30,753	\$	6,651
Change in fair value		(3,990)		1,067
Exercises		(821)		(678)
Repurchases				(83)
Ending balance	\$	25,942	\$	6,957

The money market funds noted above are included in cash and cash equivalents in the accompanying balance sheets. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the three months ended March 31, 2014 or the year ended December 31, 2013 except for the transfer out of the warrants to purchase redeemable convertible preferred stock as described below.

Table of Contents

During the three months ended September 30, 2013, as a result of the closing of the Company's initial public offering (the IPO), the warrants to purchase preferred stock were converted to warrants to purchase common stock. The resulting warrants to purchase common stock meet the criteria to be classified as permanent equity and are no longer required to be measured at fair value at each reporting period.

The fair value of the warrants to purchase preferred stock that were classified as liabilities was estimated using the Black-Scholes option pricing model at the date of issuance and on each re-measurement date. This method of valuation involves using inputs such as the fair value of the Company's various classes of preferred stock, stock price volatility, the contractual term of the warrants, risk free interest rates, and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. See Note 12 for further discussions of the accounting for the warrants, as well as for a summary of the significant inputs and assumptions used to determine the fair value of the warrants.

The fair value of warrants to purchase common stock that are classified as liabilities is estimated using a Monte Carlo model. This method of valuation involves using inputs such as the fair value of a share of common stock, stock price volatility, and the contractual term of the warrants. Due to the nature of these inputs, the valuation for the warrants is considered a Level 3 measurement.

The Company measures eligible assets and liabilities at fair value, with changes in value recognized in earnings. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to remeasure any of its existing financial assets or liabilities, and did not elect the fair value option for any financial assets and liabilities transacted in the three months ended March 31, 2014 or the year ended December 31, 2013.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of March 31, 2014 and December 31, 2013, the Company does not have any significant uncertain tax positions.

8. Net Loss Per Share

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	Three Months Ended March 31,	
	2014	2013
Outstanding stock options	3,844	3,961
Common stock warrants	912	870
Preferred stock		18,030
Preferred stock warrants		141
	4,756	23,002

9. Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, other events, and circumstances from non-owner sources. Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss), which includes certain changes in equity that are excluded from net income (loss). Comprehensive loss has been disclosed in the accompanying condensed consolidated statements of operations and comprehensive (loss) and equals the Company's net loss for all periods presented.

10. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company has evaluated all subsequent events and determined that there are no material recognized or unrecognized subsequent events requiring disclosure, other than those disclosed in this Report on Form 10-Q and as discussed below.

Table of Contents

On May 5, 2014, and pursuant to stock purchase agreements entered into on April 2, 2014, Celgene Corporation completed its purchase of an aggregate of 1,100,000 shares of common stock from five current shareholders of the Company for an aggregate purchase price of \$47.1 million. The selling stockholders and the number of shares sold are as follows: Advanced Technology Ventures (251,584 shares), Flagship Ventures (215,142 shares), Polaris Venture Partners (313,491 shares), Venrock (247,837 shares), and Alkermes, Inc. (71,946 shares). Following this purchase, Celgene beneficially owns approximately 14.6% of the outstanding shares of Common Stock.

11. Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

12. Warrants

Below is a summary of the number of shares issuable upon exercise of outstanding warrants and the terms and accounting treatment for the outstanding warrants (in thousands, except per share data):

	Warrants as of		Weighted-Average Exercise Price Per Share	Expiration	Balance Sheet Classification	
	March 31, 2014	December 31, 2013			March 31, 2014	December 31, 2013
Warrants to purchase Common Stock	14	46	10.92	June 25, 2019	Equity(1)	Equity(1)
Warrants to purchase Common Stock	51	64	12.56	March 18, 2020	Equity(2)	Equity(2)
Warrants to purchase Common stock	834	857	5.88	June 10, 2020 - July 9, 2020	Liability(3) (4)	Liability(3) (4)
Warrants to purchase Common stock	13	13	4.00 - 7.40	March 31, 2015 - December 31, 2017	Equity(5)	Equity(5)
All warrants	912	980	\$ 6.31			

(1) In March 2014, the warrant holders exercised warrants to purchase 32,050 shares of Common Stock on a net basis, resulting in the issuance of 22,955 shares of Common Stock.

(2) In March 2014, the warrant holders exercised warrants to purchase 12,738 shares of Common Stock on a net basis, resulting in the issuance of 9,202 shares of Common Stock.

(3) In March 2014, the warrant holders exercised warrants to purchase 543 shares of Common Stock on a net basis, resulting in the issuance of 456 shares of Common Stock.

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

(4) In March 2014, the warrant holders exercised warrants to purchase 23,445 shares of Common Stock on a cash basis, resulting in the issuance of 23,445 shares of Common Stock.

(5) Warrants to purchase common stock were issued in connection with various debt financing transactions that were consummated in periods prior to December 31, 2012. See discussion below for further details.

In connection with various financing transactions that were consummated in periods prior to December 31, 2013, the Company issued warrants for the purchase of up to 106,500 shares of the Company's Series A redeemable convertible preferred stock (Series A Preferred Stock), 31,891 shares of the Company's Series B redeemable convertible preferred stock (Series B Preferred Stock), 45,786 shares of the Company's Series C-1 redeemable convertible preferred stock (Series C-1 Preferred Stock), and 63,693 shares of the Company's Series D-1 redeemable convertible preferred stock (Series D-1 Preferred Stock). Each warrant was immediately exercisable. The warrants to purchase Series A and Series B Preferred Stock expire seven years from the original date of issuance, while the warrants to purchase Series C-1 and Series D-1 Preferred Stock expire ten years from the original date of issuance. The warrants to purchase shares of the Company's preferred stock have an exercise price equal to the original issuance price of the underlying instrument. Each warrant is exercisable on either a physical settlement or net share settlement basis and the redemption provisions are outside the control of the Company. In connection with the closing of the Company's IPO on September 24, 2013, the outstanding warrants to purchase Series B Preferred Stock, Series C-1 Preferred Stock, and Series D-1 Preferred Stock were converted into warrants to purchase common stock. The exercise prices for each of these warrants remained unchanged.

Table of Contents

The Company follows the provisions of ASC Topic 480, *Issuer's Accounting for Freestanding Warrants and Other Similar Instruments on Shares that Are Redeemable*, which requires that warrants to purchase redeemable preferred stock be classified as liabilities. In addition, the value of the warrants is remeasured to the then-current fair value at each reporting date. Changes in fair value are recorded to other income (expense), net. For the three months ended March 31, 2013 using current assumptions, the remeasurement resulted in an increase in fair value of \$1.1 million, which was recorded in other expense, net in the accompanying consolidated statements of operations and comprehensive loss. As a result of the closing of the IPO and the resulting conversion of the warrants to purchase preferred shares into warrants to purchase common stock, the fair value of the warrant liability at September 24, 2013 was reclassified to permanent equity and therefore, is no longer subject to remeasurement.

In December 2012, the Company modified the warrant to purchase 106,500 shares of Series A Preferred Stock and extended the expiration date from December 21, 2012 to February 28, 2013. During the three months ended March 31, 2013, the holder of the warrant exercised the warrant on a net basis, resulting in the issuance of 46,668 shares of Series A Preferred Stock. Upon exercise, the Company re-measured the fair value of the warrant and recorded the resulting increase in fair value of \$0.1 million as other expense in the accompanying consolidated statement of operations and comprehensive loss for the three months ended March 31, 2013.

In connection with the Series E redeemable convertible preferred stock (Series E Preferred Stock) financing transactions that took place in June 2010 and July 2010, the Company issued warrants to purchase up to 871,580 shares of common stock. Each warrant was immediately exercisable and expires ten years from the original date of issuance. The warrants to purchase shares of the Company's common stock have an exercise price equal to the estimated fair value of the underlying instrument as of the initial date such warrants were issued. Each warrant is exercisable on either a physical settlement or net share settlement basis from the date of issuance. The warrant agreement contains a provision requiring an adjustment to the number of shares in the event the Company issues common stock, or securities convertible into or exercisable for common stock, at a price per share lower than the warrant exercise price. The Company concluded the anti-dilution feature required the warrants to be classified as liabilities under ASC Topic 815, *Derivatives and Hedging - Contracts in Entity's Own Equity* (ASC 815). The warrants are measured at fair value, with changes in fair value recognized as a gain or loss to other income (expense) in the statements of operations and comprehensive income (loss) for each reporting period thereafter. The fair value of the common stock warrants were recorded as a discount to the preferred stock issued of \$3.0 million, and the preferred stock was being accreted to the redemption value. At the end of each reporting period, the Company remeasured the fair value of the outstanding warrants, using current assumptions, resulting in an increase (decrease) in fair value of \$(4.0) million, and \$0.8 million, respectively, which was recorded in other expense in the accompanying consolidated statements of operations and comprehensive loss for the three months ended March 31, 2014 and 2013. The Company will continue to re-measure the fair value of the liability associated with the warrants to purchase common stock at the end of each reporting period until the earlier of the exercise or the expiration of the applicable warrants. On March 31, 2013, the Company retired 13,994 warrants to purchase common stock as a consequence of a repurchase of shares from an investor. All remaining outstanding warrants were fully vested and exercisable as of March 31, 2014 and December 31, 2013.

13. Commitments and Contingencies

Legal Proceedings

On October 18, 2012, the Salk Institute for Biological Studies (Salk) filed a complaint in the Massachusetts Superior Court for Suffolk County, alleging that the Company breached one of the Company's two licensing agreements with Salk. The licensing agreement in dispute provides the Company with a license with respect to certain of Salk's U.S. patents related to the ActRIIB activin receptor proteins. Salk contends that, under the licensing agreement, the Company owed Salk a greater share of the upfront payment that it received under its now-terminated agreement with Shire AG regarding ACE-031 and a share of the upfront payment and development milestone payments that the Company has received under its ongoing collaboration agreement with Celgene regarding ACE-536. Salk is seeking a total of approximately \$10.5 million plus interest

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

in payment and a 15% share of future development milestone payments received under the agreement with Celgene regarding ACE-536. The Company contends that no additional amounts are due to Salk and that it has complied with all of its payment obligations under the applicable Salk license agreement.

The Company moved to dismiss the complaint on December 3, 2012. The Court denied the Company's motion on February 28, 2013. On March 14, 2013, Acceleron answered the complaint and asserted patent invalidity counterclaims. On the basis of those counterclaims, Acceleron removed the action on March 28, 2013 to the United States District Court for the District of Massachusetts. The parties have since reached an agreement on a stipulation as to certain patent issues raised in the action, and Acceleron has dismissed its counterclaims. The Court held an initial scheduling conference on May 30, 2013, and

Table of Contents

the fact discovery is now closed. The case is currently scheduled for trial in September 2014. The Company intends to defend its position vigorously.

The Company evaluated the suit under ASC Topic 450, *Contingencies*, as a loss contingency. The estimated loss from a loss contingency shall be accrued if information available before the financial statements are issued indicates that it is probable a liability had been incurred at the date of the financial statements, and the amount of loss can be reasonably estimated. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established a reserve with respect to the dispute as of March 31, 2014 or December 31, 2013.

The Company's estimates can be affected by various factors. As of March 31, 2014 and December 31, 2013, management has determined a loss is reasonably possible. Although the Company believes it would successfully defend the lawsuit, the Company has in the past participated in settlement discussions with Salk. Accordingly, the Company has estimated the range of possible losses as of March 31, 2014 and December 31, 2013 to be between \$0 and \$10.5 million plus interest.

Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met at March 31, 2014 and December 31, 2013, or royalties on future sales of specified products. No milestone or royalty payments under these agreements are expected to be payable in the immediate future. See Note 14 for discussion of these arrangements.

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

14. Significant Agreements

Celgene

Overview

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

On February 20, 2008 the Company entered into a collaboration, license, and option agreement (the Sotatercept Agreement) with Celgene Corporation (Celgene) relating to sotatercept. On August 2, 2011, the Company entered into a second collaboration, license and option agreement with Celgene for ACE-536 (the ACE-536 Agreement), and also amended certain terms of the Sotatercept Agreement. These agreements provide Celgene exclusive licenses for Sotatercept and ACE-536 in all indications, as well as exclusive rights to obtain a license to certain future compounds. Celgene is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases.

Sotatercept Agreement

Under the terms of the Sotatercept Agreement, the Company and Celgene collaborate worldwide for the joint development and commercialization of sotatercept. The Company also granted Celgene an option to license three discovery stage compounds. Under the terms of the agreement, the Company and Celgene will jointly develop, manufacture and commercialize sotatercept. Celgene paid \$45.0 million of nonrefundable, upfront license and option payments to the Company upon the closing of the Sotatercept Agreement.

The Company retained responsibility for research and development through the end of Phase 2a clinical trials, as well as manufacturing the clinical supplies for these trials. These activities were substantially completed in 2011. Celgene is conducting the ongoing Phase 2 trials for myelodysplastic syndromes (MDS), chronic kidney disease, and α -thalassemia and will be responsible for any Phase 3 clinical trials, as well as additional Phase 2 clinical trials, and will be responsible for overseeing the manufacture of Phase 3 and commercial supplies by third party contract manufacturing organizations. Under the agreement, the Company was eligible to receive clinical milestones of up to \$88.0 million, regulatory milestones of up to \$272.0 million, and commercial milestones of up to \$150.0 million for sotatercept. Clinical milestone payments are triggered

Table of Contents

upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon the acceptance of the marketing application and upon the approval to market a product candidate by the Food and Drug Administration (FDA) or other global regulatory authorities. Commercial milestone payments are triggered when an approved pharmaceutical product reaches certain defined levels of net sales by Celgene in countries outside of North America. In addition, to the extent sotatercept is commercialized, the Company would be entitled to receive tiered royalty payments in the low-to-mid twenty percent range of net sales from sales generated from all geographies. Royalty payments are subject to certain reductions, including for entry of a generic product onto the market.

Additionally, for three named discovery stage option programs the Company was eligible to receive option fees of up to \$30.0 million, clinical milestones of up to \$53.3 million, regulatory milestones of up to \$204.0 million, and commercial milestones of up to \$150.0 million for each option program. Clinical milestone payments are triggered upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon the acceptance of the marketing application and upon the approval to market a product candidate by the FDA or other global regulatory authorities. Commercial milestone payments are triggered when an approved pharmaceutical product reaches certain defined levels of net sales by Celgene in countries outside of North America. Option fee payments are triggered upon license of any of the option programs by Celgene. In addition, to the extent an option compound is commercialized, the Company would be entitled to receive tiered royalty payments in the low-to-mid twenty percent range of net sales from sales generated from all geographies. Royalty payments are subject to certain reductions, including for entry of a generic product onto the market. None of the three discovery stage programs has advanced to the stage to achieve payment of a milestone.

In connection with entering into the Sotatercept Agreement, Celgene purchased 457,875 shares of Series C-1 Preferred Stock at the aggregate purchase price of \$5.0 million. The Series C-1 Preferred Stock was purchased at an amount that was deemed to represent fair value at the time of purchase. Per our agreement and concurrent with the IPO, Celgene purchased 666,667 shares of Common Stock at the IPO offer price of \$15.00 per share for \$10.0 million.

Commensurate with the execution of the ACE-536 Agreement described below, the Company and Celgene agreed to modify the terms of the Sotatercept Agreement. The modified terms included: (1) a change to the responsibility for development costs to align with the ACE-536 Agreement, with Celgene responsible for more than half of the worldwide costs through December 31, 2012, and 100% of the development costs thereafter, (2) future contingent development milestones for sotatercept were amended to a two-category (oncology and non-oncology) structure with potential future clinical milestones of \$27.0 million and regulatory milestones of \$190.0 million from a four-category (various cancer indications) structure and, (3) future contingent development milestones for option compounds were amended to a two-category (oncology and non-oncology) structure with potential future clinical milestones of \$25.5 million and regulatory milestones of \$142.5 million from a four-category (various cancer indications) structure, and (4) an option to buy down tiered royalty payments on both Sotatercept and ACE-536 with a one-time \$25.0 million payment on or prior to January 1, 2013. The potential commercial milestones remained unchanged. To date, the Company has received \$41.8 million in research and development funding and milestone payments for sotatercept under the original and modified agreements. The next likely clinical milestone payment would be \$10.0 million and result from Celgene's start of a Phase 3 study in MDS or β -thalassemia.

The Sotatercept Agreement will expire on a country-by-country basis on the occurrence of both of the following: (1) the expiration of the royalty term with respect to all license products in such country, and (2) the exercise or forfeiture by Celgene of its option with regard to each option compound. The royalty term for each licensed product in each country outside North America is the period commencing with first commercial sale of the applicable licensed product in the applicable country and ending on the latest of expiration of specified patent coverage or a specified period of years. The royalty term for each licensed product in North America is the period commencing with the first commercial sale in North America and ending, on a licensed product and country-by-country basis on the date which commercialization of such licensed product has ceased. The term for each option compound runs for a specified period of years unless Celgene exercises its option, in which case the compound becomes a licensed product, or forfeits its option by failing to make certain payments following the achievement of certain milestones in early clinical development of the option compound.

Celgene has the right to terminate the agreement with respect to one or more licensed targets or in its entirety, upon 180 days' notice (or 45 days' notice if the licensed product has failed to meet certain end point criteria with respect to clinical trials or other development activities). The agreement may also be terminated in its entirety by either Celgene or the Company in the event of a material breach by the other party or in the event of a bankruptcy filing of the other party. There are no cancellation, termination or refund provisions in this arrangement that contain material financial consequences to the Company.

Table of Contents

ACE-536 Agreement

Under the terms of the ACE-536 Agreement, the Company and Celgene collaborate worldwide for the joint development and commercialization of ACE-536. The Company also granted Celgene an option for future products for which Acceleron files an Investigational New Drug application for the treatment of anemia. Celgene paid \$25.0 million on the closing of the ACE-536 Agreement in August, 2011.

The Company retains responsibility for research and development through the end of Phase 1 and initial Phase 2 clinical trials, as well as manufacturing the clinical supplies for these studies. Celgene will conduct subsequent Phase 2 and Phase 3 clinical studies. Acceleron will manufacture ACE-536 for the Phase 1 and Phase 2 clinical trials and Celgene will be responsible for overseeing the manufacture of Phase 3 and commercial supplies by third party contract manufacturing organizations. The Company is eligible to receive clinical milestones of up to \$32.5 million, regulatory milestones of up to \$105.0 million and commercial milestones of up to \$80.0 million for ACE-536. The Company will receive additional, lower development, regulatory, and commercial milestones for any additional products for the treatment of anemia on which Celgene exercises an option. Clinical milestone payments are triggered upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon the acceptance of the marketing application and upon approval to market a protein therapeutic candidate by the FDA or other global regulatory authorities. Commercial milestone payments are triggered when an approved pharmaceutical product reaches certain defined levels of net sales by Celgene in countries outside of North America. In addition, to the extent ACE-536 is commercialized, the Company would be entitled to receive tiered royalty payments in the low-to-mid twenty percent range of net sales from sales generated from all geographies. Royalty payments are subject to certain reductions, including for entry of a generic product onto the market.

Through March 31, 2014, the Company has received \$35.3 million in research and development funding and milestone payments for ACE-536. The next likely clinical milestone payment would be \$15.0 million and result from the start of a Phase 3 study in MDS or α -thalassemia. The Company has not yet identified additional compounds for the treatment of anemia. Accordingly, there is no assurance that the Company will generate future value from additional programs.

The ACE-536 Agreement will expire on a country-by-country basis on the occurrence of both of the following: (1) the expiration of the royalty term with respect to all license products in such country, and (2) the end of the option term. The royalty term for each licensed product in each country outside North America is the period commencing with first commercial sale of the applicable licensed product in the applicable country and ending on the latest of expiration of specified patent coverage or a specified period of years. The royalty term for each licensed product in North America is the period commencing with the first commercial sale in North America and ending, on a licensed product and country-by-country basis on the date which commercialization of such licensed product has ceased. The option term runs until the later of (1) the date on which no development or commercialization activities are ongoing or are expected to commence for any licensed products under the ACE-536 Agreement; (2) the date on which no development or commercialization activities are ongoing or are expected to commence for any licensed products under the Sotatercept Agreement and all option rights under the Sotatercept Agreement have been forfeited with respect to each option compound where Celgene has made a payment with respect to such compound; and (3) the royalty term for all licensed products under the ACE-536 Agreement and the Sotatercept Agreement has ended; provided that if at the time the option term would otherwise end any option compounds under the ACE-536 Agreement are in clinical development the option term shall continue until Celgene's rights to such compound are either exercised or forfeited.

Celgene has the right to terminate the ACE-536 Agreement with respect to one or more licensed targets or in its entirety, upon 180 days' notice (or 45 days' notice if the licensed product has failed to meet certain end point criteria with respect to clinical trials or other development activities), provided that Celgene may not terminate the ACE-536 Agreement prior to the completion of the on-going ACE-536 α -thalassemia and ACE-536 MDS Phase 2 clinical trials, except under certain conditions. The agreement may also be terminated in its entirety by either Celgene or the Company in the event of a material breach by the other party or in the event of a bankruptcy filing of the other party. There are no

cancellation, termination or refund provisions in this arrangement that contain material financial consequences to the Company.

Both Agreements

The Company and Celgene shared development costs under the Sotatercept and ACE-536 Agreements through December 31, 2012. As of January 1, 2013, Celgene is responsible for paying 100% of worldwide development costs under both agreements. Celgene will be responsible for all commercialization costs worldwide. The Company has the right to co-promote sotatercept, ACE-536 and future products under both agreements in North America. Celgene's option to buy down royalty rates for sotatercept and ACE-536 expired unexercised and, therefore, the Company will receive tiered royalties in the low-to-mid twenty percent range on net sales of sotatercept and ACE-536. The royalty schedules for sotatercept and ACE-536 are the same.

Table of Contents

Accounting Analysis

Prior to 2011, the Company accounted for the Sotatercept Agreement, as a multiple element arrangement under ASC 605-25 (prior to the amendments of ASU 2009-13). The Company identified the following deliverables under the arrangement; (1) the license to the ActRIIA compound, (2) right to license option program compounds, (3) participation in the joint development committee, (4) participation in the joint commercialization committee and (5) research and development activities. Under the provisions of ASC 605-25, applicable to the arrangement, since the Company could not establish VSOE for the undelivered elements, the Company was required to recognize the initial consideration, consisting of the \$45.0 million of nonrefundable upfront license and option payments, over the period the undelivered elements were to be delivered, which was initially estimated to be 15 years. As of the date of the modification of the agreement, there was approximately \$34.7 million of deferred revenue under the arrangement.

As a result of the material modifications to the cost sharing obligations, milestone payments structure and royalty payment structure, the Company concluded the modification represented a significant modification under ASU 2009-13, which required the Company to apply the updated provisions of ASU 2009-13 subsequent to the modification.

Because the ACE-536 Agreement and the amendment to the Sotatercept Agreement were negotiated in contemplation of each other, and the Company had not yet completed all of its obligations pursuant to the Sotatercept Agreement, the agreements were considered one arrangement for accounting purposes. The deliverables under the combined arrangement include: (1) licenses to develop and commercialize sotatercept and ACE-536, (2) performance of research and development services, (3) participation on the joint development committees, and (4) the performance of manufacturing services to provide clinical material to Celgene. The Company has determined the option to future products related to the treatment of anemia represents a substantive option. The Company is under no obligation to discover, develop or deliver any new compounds that modulate anemia and Celgene is not contractually obligated to exercise the option. As a result, the Company is at risk as to whether Celgene will exercise the option.

All of these deliverables identified in the arrangement were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC 605-25. Factors considered in making this determination included, among other things, the subject of the licenses, the nature of the research and development services, and the capabilities of Celgene.

The total arrangement consideration of \$77.7 million under the ACE-536 Agreement and amended Sotatercept Agreement consisted of (1) the \$25.0 million up-front payment for the license of ACE-536, (2) the remaining deferred revenue from the Sotatercept Agreement of \$34.7 million, and (3) estimated payments for development activities and manufacturing services of \$18.0 million. The Company used its BSP for each of the undelivered elements as the Company did not have VSOE or TPE of selling price for each deliverable. The Company's BSP considered its development plan for the compounds, expected manufacturing services, and reimbursement from Celgene (reimbursement of more than half of development expenses through December 31, 2012 and 100% thereafter). The Company determined its BSP for each of the undelivered elements under the arrangements as of the arrangement execution date as follows:

- \$18.8 million for research and development services
- \$2.9 million for the sotatercept joint development committee

- \$3.7 million for the ACE 536 joint development committee
- \$2.8 million for the manufacturing services

After determining the BESP of the undelivered elements, the remaining consideration of \$49.5 million was recognized upon execution of the arrangements. The difference between the estimated payments of \$18.0 million and the estimated selling prices which totaled \$28.2 million, using BESP, for undelivered elements was \$10.2 million. This amount was deferred at inception and will be recognized as the undelivered elements are delivered, using the proportional performance method, or ratably in the case of performance on the Joint Development Committee.

As noted above, the total arrangement consideration includes estimated payments for development activities and manufacturing services identified at the outset of the ACE-536 Agreement and amended Sotatercept Agreement. At the end of each reporting period, the Company reassesses the estimated payments to be received related to these services and the BESP of the undelivered elements based upon the Company's current estimates. The Company accounts for such changes as a change in accounting estimate and the cumulative impact of any change is reflected in the period of change.

Table of Contents

During 2011, the Company achieved a \$7.5 million clinical milestone under its ACE-536 Agreement, related to the dosing of the first patient in a multiple-dose clinical trial. The Company evaluated the milestone and determined that it was not substantive, as there was no significant uncertainty to achieving the milestone upon execution of the ACE-536 Agreement. As such, the Company allocated the \$7.5 million payment based on the allocation of arrangement consideration determined at the execution date of the ACE-536 Agreement and amended Sotatercept Agreement. Based on this allocation, the Company recognized \$4.8 million of the payment upon achievement, with the remaining \$2.7 million recognized as revenue as the undelivered elements are delivered, consistent with the treatment of the up-front payment. During January 2013, the Company achieved a \$10.0 million clinical milestone under its ACE-536 Agreement, related to the dosing of the first patient for a Phase 2 clinical trial. The Company evaluated the milestone and deemed it to be substantive and consistent with the definition of a milestone included in ASU 2010-17 and, accordingly, recognized the \$10.0 million payment in revenue during the three months ended March 31, 2013. The remaining development milestones under the ACE-536 and Sotatercept Agreements were deemed to be substantive and consistent with the definition of a milestone included in ASU 2010-17 and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when such milestone is achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve the milestones, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone. During the three months ended March 31, 2014 and 2013, the Company recognized, \$0.7 million and \$0.6 million, respectively, of the total deferred revenue as license and milestone revenue in the accompanying consolidated statements of operations and comprehensive loss.

As noted above, under the terms of the ACE-536 Agreement the Company retains responsibility for certain research and development activities through the completion of Phase 1 and initial Phase 2 clinical trials, as well as manufacturing the clinical supplies for these studies. Celgene is responsible for the conduct of subsequent Phase 2 and Phase 3 clinical studies. In November, 2013, the Company agreed to conduct additional activities for the benefit of the ACE-536 program including certain clinical and non-clinical services such as multiple toxicology studies and associated assay development and sample testing, clinical extension studies, and market development work. These activities will be reimbursed under the same terms and rates of the existing Agreements. The Company evaluated the additional services to be provided and determined that as the Company is under no obligation to conduct these additional activities, these services do not represent a deliverable under or modification to the ACE-536 Agreement, but rather, represent a separate services arrangement which should be accounted for as the services are delivered.

Pursuant to the terms of the agreement, Celgene and the Company shared development costs, with Celgene responsible for substantially more than half of the costs for sotatercept and ACE-536 until December 31, 2013 and 100% of the costs from January 1, 2013 and thereafter. Payments from Celgene with respect to research and development costs incurred by the Company are recorded as cost-sharing revenue. Payments by the Company to Celgene for research and development costs incurred by Celgene are recorded as a reduction to cost-sharing revenue. During the three months ended March 31, 2014 and 2013, the Company recorded net cost-sharing revenue of \$2.6 million and \$2.2 million, respectively.

Table of Contents

Other Agreements

Shire License

In September 2010, the Company entered into a license and collaboration agreement granting Shire AG the exclusive right to develop, manufacture and commercialize ActRIIB compounds in territories outside North America. Shire also received the right to conduct research and manufacture commercial supplies in North America for ActRIIB compounds. The lead ActRIIB compound was designated ACE-031. Under the initial development plan, the companies share the costs associated with developing and commercializing ACE-031, in Duchenne Muscular Dystrophy. In September 2010, Shire made a nonrefundable, up-front license payment to the Company of \$45.0 million. In accordance with the Company's revenue recognition policy prior to the adoption of ASU 2009-13, the up-front license payment of \$45.0 million was deferred, and was to be recognized as revenue ratably over three years, which represented the original period over which the Company expected to perform and deliver research and development and manufacturing services. On February 8, 2011, the FDA placed ACE-031 on clinical hold. The Company re-assessed the duration of its deliverables under the license agreement and estimated the new term to be approximately five years. The adjustment was treated as a change in accounting estimate with the remaining deferred revenue of \$38.8 million at February 8, 2011, recognized prospectively over the new period of research and development and manufacturing services. In April 2013, the Company and Shire determined not to further pursue development of ACE-031 and Shire sent the Company a notice of termination for the ACE-31 collaboration. The collaboration terminated effective June 30, 2013. Upon the effectiveness of the termination of the Shire Agreement in the second quarter of 2013, the Company accelerated the recognition of \$22.4 million of remaining deferred revenue from upfront non-refundable payments received under the Shire Agreement as it had no further obligation for deliverables under the Shire Agreement. During the three months ended March 31, 2014 and 2013, the Company recognized zero and \$1.9 million, respectively of the up-front, non-refundable payments as license and milestone revenue in the accompanying consolidated statements of operations and comprehensive loss.

The agreement also included contingent milestone payments, based on the achievement of development milestones totaling \$223.8 million and commercial milestones of \$228.8 million for ActRIIB compounds. The milestones under the Shire Agreement were deemed to be substantive and consistent with the definition of a milestone included in ASU 2010-17 and, accordingly, the Company recognized payments related to the achievement of such milestones, if any, when such milestone was achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve the milestones, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

Pursuant to the terms of the agreement, Shire and the Company shared development costs, with Shire responsible for 65% of the costs for ACE-031 and 55% of the costs for licensed compounds other than ACE-031. Payments from Shire with respect to research and development costs incurred by the Company are recorded as cost-sharing revenue. Payments by the Company to Shire for research and development costs incurred by Shire are recorded as a reduction to cost-sharing revenue. During the three months ended March 31, 2014 and 2013, the Company recorded net cost-sharing revenue of zero and \$0.3 million, respectively, which includes payments to Shire of zero and \$0.2 million, respectively, which are recorded as contra-revenue in the accompanying consolidated statements of operations and comprehensive loss.

Other

In 2004, the Company entered into a license agreement with a non-profit institution for an exclusive, sublicensable, worldwide, royalty-bearing license to certain patents developed by the institution (Primary Licensed Products). In addition, the Company was granted a non-exclusive, non-sub- licensable license for Secondary Licensed Products. As compensation for the licenses, the Company issued 62,500 shares of its common stock to the institution, the fair value of which was \$25,000, and was expensed during 2004, to research and development expense. The

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

Company also agreed to pay specified development milestone payments totaling up to \$2.0 million for sotatercept and \$0.7 million for ACE-536. In addition, the Company is obligated to pay milestone fees based on the Company's research and development progress, and U.S. sublicensing revenue ranging from 10%-25%, as well as a royalty ranging from 1.0%-3.5% of net sales on any products under the licenses. During the three months ended March 31, 2014 and 2013, the Company did not pay or expense any milestones and fees defined under the agreement.

In 2004, the Company entered into another license agreement with certain individuals for an exclusive, sublicensable, worldwide, royalty-bearing license to certain patents developed by the individuals. The Company agreed to pay specified development and sales milestone payments aggregating up to \$1.0 million relating to the development and commercialization of dalantercept. In addition, we are required to pay royalties in the low single-digits on worldwide net product sales of dalantercept, with royalty obligations continuing at a 50% reduced rate for a period of time after patent expiration. If we sublicense our patent rights, we will owe a percentage of sublicensing revenue, excluding payments based on the level of sales,

Table of Contents

profits or other levels of commercialization. During the three months ended March 31, 2014 and 2013, the Company did not reach any milestones defined under the agreement and, therefore, no amounts have been paid or expensed.

During 2012, the Company executed a license agreement with a research institution for an exclusive, sublicensable, worldwide, royalty-bearing license. The Company is obligated to pay development milestones and commercial milestone fees totaling up to \$1.0 million. Under the agreement, if the Company engages the inventors in the clinical research, the development milestones are waived and commercial milestones shall change to \$0.8 million plus any waived milestones. The Company will also pay \$25,000 annually upon first commercial sale as well as royalties of 1.5% of net sales on any products developed under the patents. During the three months ended March 31, 2014 and 2013, the Company did not reach any milestones defined under the agreement and, therefore, no amounts have been paid or expensed.

15. Stock-Based Compensation

The Company recognized stock-based compensation expense totaling \$1.0 million and \$0.4 million during the three months ended March 31, 2014 and 2013, respectively.

Total compensation cost recognized for all stock-based compensation awards in the consolidated statements of operations and comprehensive loss is as follows (in thousands):

		2014	Three Months Ended March 31,	2013	
Research and development	\$		400	\$	151
General and administrative			618		277
	\$		1,018	\$	428

The fair value of each option issued to employees was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions (in thousands):

	2014	Three Months Ended March 31,	2013	
Expected volatility		71.5%		n/a
Expected term (in years)		6		n/a
Risk-free interest rate		1.8%		n/a
Expected dividend yield		%		n/a

The Company did not grant any stock options during the three months ended March 31, 2013.

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

The following table summarizes the stock option activity under the 2003 Plan during the three months ended March 31, 2014 (in thousands):

	Number of Grants	Weighted- Average Exercise Price Per Share	Weighted- Average Contractual Life (in years)	Aggregate Intrinsic Value(1)
Outstanding at December 31, 2013	3,942	\$ 7.05	6.43	
Granted	114	\$ 45.30		
Exercised	(172)	\$ 3.62		
Canceled or forfeited	(40)	\$ 19.80		
Outstanding at March 31, 2014	3,844	\$ 8.20	6.34	\$ 102,318
Exercisable at March 31, 2014	2,521	\$ 4.41	5.06	\$ 75,860
Vested and expected to vest at March 31, 2014(2)	3,768	\$ 8.00	6.28	\$ 100,978

Table of Contents

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money at March 31, 2014.

(2) This represents the number of vested options at March 31, 2014, plus the number of unvested options expected to vest at March 31, 2014, based on the unvested options outstanding at March 31, 2014, adjusted for the estimated forfeiture rate.

During the three months ended March 31, 2014, the Company granted stock options to purchase an aggregate of 113,950 shares of its common stock, with a weighted-average grant date fair value of options granted of \$45.30.

During the three months ended March 31, 2014, current and former employees of the Company exercised a total of 172,005 options, resulting in total proceeds of \$0.6 million.

The aggregate intrinsic value of options exercised during the three months ended March 31, 2014 was \$6.4 million.

As of March 31, 2014, there was \$12.0 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over a weighted-average period of 2.6 years.

16. Income Taxes

For the three months end March 31, 2014 and 2013, the Company did not record a current or deferred income tax expense or benefit.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of March 31, 2014 and December 31, 2013.

The Company files income tax returns in the United States, and various state and foreign jurisdictions. The federal, state and foreign income tax returns are generally subject to tax examinations for the tax years ended December 31, 2009 through December 31, 2012. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state or foreign tax authorities to the extent utilized in a future period.

17. Long-Term Debt

On June 7, 2012, the Company entered into a loan and security agreement (the Loan Agreement) with three lenders, pursuant to which the Company received a loan in the aggregate principal amount of \$20.0 million. The Company was required to repay the aggregate principal balance under the Loan Agreement in 42 months. The first 12 payments were interest only and the remaining 30 payments were equal monthly installments of principal plus interest. The Loan Agreement provided that the interest only period could be extended under certain circumstances. The Company did not trigger the requirements and began paying principal in July 2013.

Per annum interest was payable at the 8.5%. The Loan Agreement also included a closing fee of \$0.2 million. The Company amortized the cost over the 42 months of loan. The Loan Agreement was also subject to an additional deferred payment of \$1.2 million due with the final payment. The Company recorded the deferred payment to interest expense over the term of the Loan Agreement. The resulting effective interest rate is approximately 11.8%. The Company was not subject to any financial covenants and the Loan Agreement is secured by a lien on all of the Company's personal property as of, or acquired after, the date of the Loan Agreement, except for intellectual property.

On March 12, 2014, the Company repaid the outstanding balance of the Loan Agreement. At the time of repayment the Company recognized interest expense related to the remaining \$0.6 million of the \$1.2 million deferred payment due with the final payment. The Company also recognized \$0.3 million in prepayment fees as additional expense.

Table of Contents**18. Related Party Transactions****Celgene Corporation (Celgene)**

In connection with its entry into the collaboration agreement with Celgene, on February 2008, the Company sold Celgene 457,875 shares of its Series C-1 Preferred Stock. As part of the Company's June 2010 Series E financing, Celgene purchased 36,496 shares of Series E Preferred Stock and received warrants to purchase 38,979 shares of common stock. As part of the Company's December 2011 Series F financing, Celgene purchased 1,990,446 shares of Series F Preferred Stock. In connection with the Company's September 2013 initial public offering, Celgene purchased 666,667 shares of common stock. In connection with the Company's January 2014 public offering, Celgene purchased 300,000 shares of common stock. As a result of these transactions, Celgene owned 9.7% and 9.7% of the Company's fully diluted equity as of March 31, 2014 and December 31, 2013, respectively. Refer to Note 14 for additional information regarding this collaboration agreement.

During the three months ended March 31, 2014, the Company recognized \$3.3 million in collaboration revenue under the Celgene collaboration arrangement and, as of March 31, 2014, had \$7.0 million of deferred revenue related to the Celgene collaboration arrangement.

The Company recognized revenue from Celgene during the three months ended March 31, 2014 and 2013 as follows (in thousands):

		Three Months Ended March 31,	
	2014		2013
License and milestone	\$	674	\$ 10,631
Cost sharing, net		2,633	2,166
	\$	3,307	\$ 12,797

Table of Contents

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

The following information should be read in conjunction with the unaudited condensed consolidated financial information and the notes thereto included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2013.

Certain matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may, will, expect, anticipate, estimate, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of the factors included under the section Item 1A. Risk Factors in our Annual Report on Form 10-K.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

You should read the following discussion and analysis of financial condition and results of operations together with Part I Item 1 Financial Information and our financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of novel protein therapeutics for cancer and rare diseases. Our research focuses on the biology of the Transforming Growth Factor-Beta (TGF- β) protein superfamily, a large and diverse group of molecules that are key regulators in the growth and repair of tissues throughout the human body. We are leaders in understanding the biology of the TGF- β superfamily and in targeting these pathways to develop important new medicines. By coupling our discovery and development expertise, including our proprietary knowledge of the TGF- β superfamily, with our internal protein engineering and manufacturing capabilities, we have built a highly productive research & development platform that has generated innovative protein therapeutic

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

candidates with novel mechanisms of action. These differentiated protein therapeutic candidates have the potential to significantly improve clinical outcomes for patients with cancer and rare diseases.

We have three internally discovered protein therapeutic candidates that are currently being studied in numerous ongoing Phase 2 clinical trials, focused on cancer and rare diseases. Our two most advanced protein therapeutic candidates, sotatercept and ACE-536, promote red blood cell production through a novel mechanism. Together with our collaboration partner, Celgene Corporation, which we refer to as Celgene, we are developing sotatercept and ACE-536 to treat anemia and associated complications in patients with β -thalassemia and myelodysplastic syndromes (MDS), red blood cell disorders that are generally unresponsive to currently approved drugs. Sotatercept is also being developed to treat patients with other disorders associated with anemia including chronic kidney disease. Our third clinical stage protein therapeutic candidate, dalantercept, is designed to inhibit blood vessel formation through a mechanism that is distinct from, and potentially synergistic with, the dominant class of cancer drugs that inhibit blood vessel formation, the vascular endothelial growth factor (VEGF) pathway inhibitors. We are developing dalantercept primarily for use in combination with these successful products to produce better outcomes for cancer patients.

In addition to our clinical stage programs, we are developing a novel protein therapeutic candidate, ACE-083, for a first-in-human clinical trial that we expect to initiate by the end of 2014. ACE-083 has been designed to promote muscle

Table of Contents

growth in those muscles in which the drug is injected with minimal systemic effect. We are focused on the development of ACE-083 for diseases in which increases in the size and function of specific muscles may provide a clinical benefit.

We are developing sotatercept and ACE-536 through our exclusive worldwide collaborations with Celgene. As of January 1, 2013, Celgene became responsible for paying 100% of worldwide development costs for both programs. We may receive up to \$560.0 million of potential development, regulatory and commercial milestone payments still outstanding and, if these protein therapeutic candidates are commercialized, we will receive a royalty on net sales in the low-to-mid 20% range. We also will co-promote sotatercept and ACE-536 in North America, if approved, for which our commercialization costs will be entirely funded by Celgene. We have not entered into a partnership for dalantercept and retain worldwide rights to this program.

To date, our operations have been primarily funded by \$105.1 million in equity investments from venture investors prior to the IPO, \$219.3 million from public investors, \$64.2 million in equity investments from our partners and \$207.3 million in upfront payments, milestones, and net research and development payments from our strategic partners.

We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- conduct clinical trials for dalantercept;
- continue our preclinical studies and potential clinical development efforts of our existing preclinical protein therapeutic candidates;
- continue research activities for the discovery of new protein therapeutics;
- manufacture protein therapeutics for our preclinical studies and clinical trials;
- seek regulatory approval for our protein therapeutics; and
- operate as a public company.

We will not generate revenue from product sales unless and until we or a partner successfully complete development and obtain regulatory approval for one or more of our protein therapeutic candidates, which we expect will take a number of years and is subject to significant

uncertainty. All current and future development and commercialization costs for sotatercept and ACE-536 are paid by Celgene. If we obtain regulatory approval for dalantercept or any future protein therapeutic candidate, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such costs are not paid by future partners. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential additional collaborations. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our protein therapeutics.

Our ability to generate product revenue and become profitable depends upon our and our partners' ability to successfully commercialize products. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our protein therapeutics and potentially begin to commercialize any approved products.

Financial Operations Overview

Revenue

Collaboration Revenue

We have not generated any revenue from the sale of products. Our revenue to date has been predominantly derived from collaboration revenue, which includes license and milestone revenues and cost sharing revenue, generated through collaboration and license agreements with partners for the development and commercialization of our protein therapeutics. Cost sharing revenue represents amounts reimbursed by our collaboration partners for expenses incurred by us for research and development activities and, potentially, co-promotion activities, under our collaboration agreements. Cost sharing revenue is

Table of Contents

recognized in the period that the related activities are performed. To the extent that we reimburse collaborators for costs incurred in connection with activities performed by them, we record these costs as a reduction of cost-sharing revenue.

Costs and Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs directly incurred by us for the development of our protein therapeutic candidates, which include:

- direct employee-related expenses, including salaries, benefits, travel and stock-based compensation expense of our research and development personnel;
- expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that will conduct our clinical trials;
- the cost of acquiring and manufacturing preclinical and clinical study materials and developing manufacturing processes;
- allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, insurance and other supplies;
- expenses associated with obtaining and maintaining patents; and
- costs associated with preclinical activities and regulatory compliance.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our protein therapeutic candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our protein therapeutic candidates for which we or any partner obtain regulatory approval. We or our partners may never succeed in achieving regulatory approval for any of our protein therapeutic candidates. The duration, costs and timing of clinical trials and development of our protein therapeutic candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a protein therapeutic candidate could mean a significant change in the costs and timing associated with the development of that protein therapeutic candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of protein therapeutics, or if we experience significant delays in the enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through March 31, 2014, we have incurred \$299.0 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of our TGF- β platform protein therapeutics, the discovery and development of preclinical protein therapeutics, and the development of sotatercept, ACE-536 and dalantercept. Beginning January 1, 2013, expenses associated with sotatercept and ACE-536 are reimbursed 100% by Celgene. These reimbursements are recorded as revenue. Of the Phase 2 clinical trials that are underway for sotatercept, ACE-536 and dalantercept, we are expensing the costs of six clinical trials of ACE-536 and dalantercept, of which the two for ACE-536 are reimbursed by Celgene.

Table of Contents

We manage certain activities such as clinical trial operations, manufacture of protein therapeutic candidates, and preclinical animal toxicology studies through third-party CROs. The only costs we track by each protein therapeutic candidate are external costs such as services provided to us by CROs, manufacturing of preclinical and clinical drug substance, and other outsourced research and development expenses. We do not assign or allocate to individual development programs internal costs such as salaries and benefits, facilities costs, lab supplies and the costs of preclinical research and studies. Our external research and development expenses for sotatercept, ACE-536, dalantercept and ACE-031 (for which development was suspended in April 2013) during the three months ended March 31, 2014 and 2013 are as follows:

(in thousands)	Three Months Ended March 31,	
	2014	2013
ACE-536(1)	\$ 1,519	\$ 703
Dalantercept	1,428	1,076
ACE-031(2)	6	502
ACE-083	1,355	
Total direct research and development expenses	4,308	2,281
Other expenses(3)	7,457	6,499
Total research and development expenses	\$ 11,765	\$ 8,780

(1) Beginning January 1, 2013, expenses associated with sotatercept and ACE-536 are reimbursed 100% by Celgene. These reimbursements are recorded as revenue and are presented as cost-sharing, net.

(2) In April 2013, we and Shire AG, which we refer to as Shire, determined not to further advance the development of ACE-031, and Shire terminated our collaboration agreement, effective June 30, 2013.

(3) Other expenses include unallocated employee and contractor-related expenses, facility expenses and miscellaneous expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, and human resource functions and other general and administrative expenses including directors' fees and professional fees for accounting and legal services.

We anticipate that we will continue to experience increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, director and officer insurance premiums, and investor relations costs associated with being a public company. 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 protein therapeutics. Additionally, if and when we believe regulatory approval of a protein therapeutic candidate appears likely, to the extent that we are undertaking commercialization of such protein therapeutic candidate ourselves, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations.

Other Expense, Net

Other expense, net consists primarily of interest expense from our venture debt facility, interest income earned on cash and cash equivalents, and the re-measurement gain or loss associated with the change in the fair value of our preferred stock and common stock warrant liabilities.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and stock-based compensation. We also utilize significant estimates and assumptions in determining the fair value of our common stock prior to the completion

Table of Contents

of our initial public offering and the fair value of our liability-classified warrants to purchase preferred stock and common stock. 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.

There have been no material changes to our critical accounting policies since December 31, 2013. For further information on our critical and other significant accounting policies, see the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2013.

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

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	
	2014	2013		
Revenue:				
Collaboration revenue:				
License and milestone	\$ 674	\$ 12,515	\$	(11,841)
Cost-sharing, net	2,633	2,497		136
Total revenue	3,307	15,012		(11,705)
Costs and expenses:				
Research and development	11,765	8,780		2,985
General and administrative	3,750	3,096		654
Total costs and expenses	15,515	11,876		3,639
Loss from operations	(12,208)	3,136		(15,344)
Other income (expense), net	3,088	(1,489)		4,577
Net loss	\$ (9,120)	\$ 1,647	\$	(10,767)

Revenue. We recognized revenue of \$3.3 million in the three months ended March 31, 2014, compared to \$15.0 million in the same period in 2013. This \$11.7 million decrease was primarily due the achievement of a \$10.0 million milestone in January 2013. During the three months ended March 31, 2013 the Company also recognized \$2.2 million of collaboration revenue associated with the Shire collaboration arrangement, however, in 2014 no such amounts were recognized due to the termination of the Shire collaboration arrangement in June 2013. These decreases were partially offset by a \$0.5 million increase in Celgene cost sharing revenue during 2014 due to an increase in spend for ACE-536 clinical and toxicology studies.

The following table shows revenue from all sources for the periods presented.

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	
	2014	2013		

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

Collaboration revenue:						
Celgene:						
License and milestone	\$	674	\$	10,631	\$	(9,957)
Cost-sharing, net		2,633		2,166		467
Total Celgene		3,307		12,797		(9,490)
Shire:						
License and milestone				1,884		(1,884)
Cost-sharing, net				331		(331)
Total Shire				2,215		(2,215)
Total collaboration revenue		3,307		15,012		(11,705)
Total revenue	\$	3,307	\$	15,012	\$	(11,705)

Research and Development Expenses. Research and development expenses were \$11.8 million in the three months ended March 31, 2014, compared to \$8.8 million in the same period in 2013. This \$3.0 million increase was primarily due to an

Table of Contents

increase in clinical and toxicology studies totaling \$1.8 million, an increase in personnel expenses of \$0.7 million, an increase in patent costs of \$0.2 million, and an increase in miscellaneous research and development expenses associated with drug supply of \$0.3 million.

General and Administrative Expenses. General and administrative expenses were \$3.8 million in the three months ended March 31, 2014, compared to \$3.1 million for the same period in 2013. This \$0.7 million increase was primarily related to higher professional fees and insurance totaling \$0.8 million and higher total personnel expenses totaling \$0.5 million offset by a decrease in legal expenses of \$0.6 million for lower litigation costs.

Other Income (Expense), Net. Other income, net was \$3.1 million in the three months ended March 31, 2014, compared to an expense of \$1.5 million for the same period in 2013. This \$4.6 million increase was primarily due a \$5.1 million difference in the effect of marking the common warrant liability to market in each period. The increase was offset in part by an additional \$0.5 million in interest expense for recognition of the remaining deferred payment due upon repayment of long term debt during March 2014.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in June 2003, and as of March 31, 2014, we had an accumulated deficit of \$201.4 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of equity, debt financings or other sources, including potential additional collaborations.

To date, our operations have been funded by \$105.1 million in equity investments from venture investors prior to the IPO, \$219.3 million from public investors, \$64.2 million in equity investments from our partners, and \$207.3 million in upfront payments, milestones, and net research and development payments from our partners.

As of March 31, 2014, we had \$214.1 million in cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in money market mutual funds consisting of U.S. government-backed securities.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

(in thousands)	Three Months Ended	
	March 31,	2013
	2014	
Net cash provided by (used in):		
Operating activities	\$ (12,472)	\$ (735)
Investing activities	(150)	(80)
Financing activities	113,594	(286)
Net increase (decrease) in cash and cash equivalents	\$ 100,972	\$ (1,101)

Operating Activities. The significant increase in net cash used in operating activities for the three months ended March 31, 2014, compared to the three months ended March 31, 2013, is primarily due to the receipt of a \$10.0 million milestone payment from Celgene in the first quarter of 2013.

Net cash used in operating activities was \$12.5 million for the three months ended March 31, 2014, and consisted primarily of a net loss of \$9.1 million adjusted for non-cash items including an decrease in fair value of warrants of \$4.0 million, stock-based compensation expense of \$1.0 million, depreciation and amortization of \$0.3 million, payments of deferred interest of \$0.5 million, and a net decrease due to changes in operating assets and liabilities of \$0.1 million. The significant items in the change in operating assets and liabilities include a decrease in deferred revenue of \$0.7 million due primarily to the effect of the Shire collaboration which was terminated effective June 30, 2013. Other components of the change in operating assets and liabilities include a decrease in accrued expenses of \$2.3 million, a decrease in collaboration receivables of \$1.0 million, a decrease in prepaid expenses of \$0.5 million, a decrease in deferred rent of \$0.1 million and an increase in accounts payable of \$1.4 million.

Table of Contents

Net cash used in operating activities was \$0.7 million for the three months ended March 31, 2013 and consisted primarily of net income of \$1.6 million adjusted for non-cash items including an increase in fair value of warrants of \$1.1 million, stock-based compensation expense of \$0.4 million, depreciation and amortization of \$0.2 million, accretion of deferred interest of \$0.1 million, and a net decrease due to changes in operating assets and liabilities of \$4.1 million. The significant items in the change in operating assets and liabilities include a decrease in deferred revenue of \$2.5 million due to the ongoing recognition of revenue deferred in connection with up-front payments for the Celgene and Shire collaboration agreements, a decrease in accounts payable of \$0.2 million and an increase in prepaid expenses and other current assets of \$0.3 million. Other components of the change in operating assets and liabilities include an increase in collaboration receivables of \$0.2 million, an decrease in accrued expenses of \$0.7 million and a decrease in deferred rent of \$0.1 million.

Investing Activities.

Net cash used in investing activities was \$0.2 million for the three months ended March 31, 2014 and \$0.1 million for the three months ended March 31, 2013 and consisted of purchases of property and equipment.

Financing Activities.

Net cash provided by financing activities was \$113.6 million for the three months ended March 31, 2014 and consisted of \$129.2 million in net proceeds received from the company's follow on public offering and \$0.8 million for the exercise of stock options and warrants, offset by \$16.3 million of principal repayment to pay off our venture debt line. Net cash used in financing activities was \$0.3 million for the three months ended March 31, 2013 and consisted primarily of \$0.3 million payment we made to repurchase and retire redeemable convertible preferred stock, common stock and warrants to purchase common stock.

Operating Capital Requirements

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

We believe that the net proceeds we received from our initial public offering and the concurrent private placement, as well as our follow-on public offering together with receipt of anticipated milestone payments and our existing cash and cash equivalents will be sufficient to fund our projected operating requirements into the second half of 2017. However, we will require additional capital for the further development of our existing protein therapeutic candidates and may also need to raise additional funds sooner to pursue other development activities related to additional protein therapeutic candidates.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to fund our operations through a combination of equity offerings, or debt financings or other sources including potential additional collaborations. Additional capital may not be available on favorable 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 protein therapeutic candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations, and these securities may have rights 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. We may not be able to enter into new collaboration arrangements for any of our proprietary protein therapeutic candidates. 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

Table of Contents

sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the achievement of milestones under our agreement with Celgene;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our protein therapeutic candidates and potential protein therapeutic candidates;
- the number and characteristics of protein therapeutic candidates that we pursue;
- the progress, costs and results of our clinical trials;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the costs and timing of procuring clinical and commercial supplies of our protein therapeutic candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and

- the costs involved in defending and prosecuting litigation regarding in-licensed intellectual property including our litigation with the Salk Institute (see further information in Part II. Item 1. Legal Proceedings).

Net Operating Loss (NOL) Carryforwards

We had deferred tax assets of approximately \$66.1 million as of December 31, 2013, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal and state tax net operating loss, or NOL, carryforwards and research and development tax credit carryforwards. As of December 31, 2013, we had federal NOL carryforwards of approximately \$141.0 million and state NOL carryforwards of \$122.9 million available to reduce future taxable income, if any. These federal NOL carryforwards expire at various times through 2033 and the state NOL carryforwards expire at various times through 2033. In general, if we experience a greater than 50 percent aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state laws. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. If we experience a Section 382 ownership change in connection with this offering or as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carryforwards may be limited or lost.

Contractual Obligations and Commitments

During the three months ended March 31, 2014, there were material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2013. On March 12, 2014, the Company paid off the remaining principal outstanding under the Loan Agreement, the deferred fees and early repayment fees, totaling \$16.0 million. With the repayment, we have no continuing obligations to service the debt line.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, see Recently Issued and Adopted Accounting Standards in the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Table of Contents

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 Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. As of March 31, 2014 and December 31, 2013, we had cash and cash equivalents of \$214.1 million and \$113.2 million, respectively. Our cash equivalents are invested primarily in money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. We contract with CROs and manufacturers internationally. Transactions with these providers are predominantly settled in U.S. dollars and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of March 31, 2014, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Edgar Filing: ACCELERON PHARMA INC - Form 10-Q

During the quarter ended March 31, 2014, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated herein by reference to Notes to Condensed Consolidated Financial Statements Note 13. Commitments and Contingencies in Part I, Item 1, of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Initial Public Offering of Common Stock

On September 24, 2013, we completed the initial public offering (IPO) of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-190417), which was declared effective by the SEC on September 18, 2013, and a registration statement filed pursuant to Rule 462(b) of the Securities Act (File No. 333-191245).

On January 28, 2014, we completed a follow-on public offering of our common stock pursuant to a registration statement on Form S-1 (File No. 333-193252) and a registration statement filed pursuant to Rule 462(b) of the Securities Act (File No. 333-193495).

As of March 31, 2014, we have used \$43.8 million of the net offering proceeds from our IPO to fund operations, capital expenditures, working capital and other general corporate purposes and for debt repayment. On March 12, 2014, the Company paid off the remaining principal outstanding under the Loan Agreement, the deferred fees and early repayment fees, totalling \$16.0 million. None of the net proceeds have been paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We are holding the balance of the net proceeds from the offering in prime money market funds. Except for the early repayment of the Loan Agreement, there has been no material change in our planned use of the balance of the net proceeds from the offering described in our final prospectus filed with the SEC on September 19, 2013 pursuant to Rule 424(b) under the Securities Act.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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.

ACCELERON PHARMA INC.

Date: May 15, 2014

By: /s/ JOHN L. KNOPF, PH.D.
John L. Knopf, Ph.D.
Chief Executive Officer and President

Date: May 15, 2014

By: /s/ KEVIN F. MCLAUGHLIN
Kevin F. McLaughlin
Chief Financial Officer

Table of Contents

Exhibit number	Description of exhibit
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	Ex. 101.INS* XBRL Instance Document
	Ex. 101.SCH* XBRL Taxonomy Extension Schema Document
	Ex. 101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
	Ex. 101.LAB* XBRL Taxonomy Extension Label Linkbase Document
	Ex. 101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document
	Ex. 101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

*In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall be deemed to be furnished and not filed.