

ACCELERON PHARMA INC
Form 10-Q
November 03, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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 2836 27-0072226
(State or other jurisdiction of (Primary Standard Industrial (I.R.S. Employer
incorporation or organization) Classification Code Number) 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 Smaller reporting company

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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

As of October 31, 2016, there were 37,746,503 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

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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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,016	\$27,783
Collaboration receivables (all amounts are with related party)	3,019	3,628
Prepaid expenses and other current assets	3,676	2,458
Short-term investments	107,279	77,064
Total current assets	144,990	110,933
Property and equipment, net	4,215	3,106
Restricted cash	946	796
Other assets	6	368
Long-term investments	112,728	31,134
Total assets	\$ 262,885	\$146,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,071	\$875
Accrued expenses	12,814	12,400
Deferred revenue	541	555
Deferred rent	766	661
Total current liabilities	16,192	14,491
Deferred revenue, net of current portion	3,839	4,239
Deferred rent, net of current portion	1,146	1,157
Warrants to purchase common stock	12,161	17,187
Total liabilities	33,338	37,074
Commitments and contingencies (Note 14)		
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; 37,700,693 and 33,313,355 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	38	34
Additional paid-in capital	574,834	416,926
Accumulated deficit	(345,203) (307,477)
Accumulated other comprehensive loss	(122) (220)
Total stockholders' equity	229,547	109,263
Total liabilities and stockholders' equity	\$ 262,885	\$146,337

See accompanying notes to these condensed consolidated financial statements.

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Acceleron Pharma Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(amounts in thousands except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue:				
License and milestone	\$ 135	\$ 205	\$ 15,415	\$ 1,008
Cost-sharing, net	2,870	3,950	8,987	13,286
Total revenue (all amounts are with related party)	3,005	4,155	24,402	14,294
Costs and expenses:				
Research and development	17,102	13,335	49,492	42,261
General and administrative	6,411	5,433	19,029	14,796
Total costs and expenses	23,513	18,768	68,521	57,057
Loss from operations	(20,508)	(14,613)	(44,119)	(42,763)
Other (expense) income, net:				
Other (expense) income, net	(794)	2,616	5,026	5,595
Interest income	512	139	1,348	356
Total other (expense) income, net	(282)	2,755	6,374	5,951
Loss before income taxes	(20,790)	(11,858)	(37,745)	(36,812)
Income tax benefit	20	—	20	—
Net loss applicable to common stockholders	\$(20,770)	\$(11,858)	\$(37,725)	\$(36,812)
Net loss per share applicable to common stockholders-basic and diluted (Note 9)	\$(0.55)	\$(0.36)	\$(1.01)	\$(1.12)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders-basic and diluted	37,616	33,097	37,268	32,869
Other comprehensive loss:				
Net loss	\$(20,770)	\$(11,858)	\$(37,725)	\$(36,812)
Unrealized holding (losses) gains on short-term and long-term investments during the period, net of tax of \$0.1 million and \$0.1 million, for the three and nine months ended September 30, 2016, respectively, and zero and zero for the three and nine months ended September 30, 2015, respectively	(374)	41	98	(21)
Comprehensive loss	\$(21,144)	\$(11,817)	\$(37,627)	\$(36,833)

See accompanying notes to these condensed consolidated financial statements.

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Acceleron Pharma Inc.

Condensed Consolidated Statements of Cash Flows

(amounts in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2016	2015
Operating Activities		
Net loss	\$(37,725)	\$(36,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,158	871
Stock-based compensation	13,387	8,295
Change in fair value of warrants	(5,026)	(5,595)
Other non-cash items	(262)	(531)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(1,211)	(99)
Collaboration receivables	609	(583)
Accounts payable	1,196	1,923
Accrued expenses	389	2,037
Restricted cash	(150)	106
Deferred revenue	(414)	(1,008)
Deferred rent	94	(354)
Net cash used in operating activities	(27,955)	(31,750)
Investing Activities		
Purchase of investments	(132,565)	(134,328)
Proceeds from maturities of investments	21,120	30,138
Purchases of property and equipment	(2,246)	(659)
Net cash used in investing activities	(113,691)	(104,849)
Financing Activities		
Proceeds from issuance of common stock from public offering, net issuance costs	140,697	—
Proceeds from exercise of stock options and warrants to purchase common stock	3,524	2,987
Proceeds from issuances of common stock related to employee stock purchase plan	658	590
Net cash provided by financing activities	144,879	3,577
Net increase (decrease) in cash and cash equivalents	3,233	(133,022)
Cash and cash equivalents at beginning of period	27,783	176,460
Cash and cash equivalents at end of period	\$31,016	\$43,438
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Reclassification of warrant liability to additional paid-in capital	\$—	\$465
Purchase of property and equipment included in accounts payable and accrued expenses	\$25	\$82

See accompanying notes to these condensed consolidated financial statements.

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Acceleron Pharma Inc.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

Acceleron Pharma Inc. (Acceleron or the Company) is a Cambridge, Massachusetts-based clinical stage biopharmaceutical company focused on the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. The Company's research focuses on key natural regulators of cellular growth and repair, particularly the Transforming Growth Factor-Beta (TGF-beta) protein superfamily. By combining its discovery and development expertise, including its proprietary knowledge of the TGF-beta superfamily, and its internal protein engineering and manufacturing capabilities, the Company has built a highly productive discovery and development platform that has generated innovative therapeutic candidates with novel mechanisms of action. The Company has four internally discovered therapeutic candidates that are currently in clinical trials.

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, 2015, 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 September 30, 2016, and the results of its operations and its cash flows for the three and nine months ended September 30, 2016 and 2015.

The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, 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, 2015, 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, 2015.

On January 11, 2016, the Company completed its underwritten public offering of 3,750,000 shares of common stock at a public offering price of \$40.00 per share. The aggregate net proceeds received by the Company, after underwriting discounts and commissions and other offering expenses, were \$140.3 million.

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 September 30, 2016, 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, 2015, have not changed.

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.

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 consolidated 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

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reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the consolidated 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 consolidated 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, which is the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. The Company does use contract research organizations 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 consolidated statements of operations and comprehensive loss.

5. Cash Equivalents and Short-term and Long-term Investments

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 primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified all of its marketable securities at September 30, 2016 as "available-for-sale" pursuant to ASC 320, Investments – Debt and Equity Securities. The Company records available-for-sale securities at fair value, with the unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders' equity. There were no realized gains or losses on marketable securities for the three and nine months ended September 30, 2016 and 2015.

Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

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The following is a summary of cash, cash equivalents and investments as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	\$31,016	\$ —	\$ —	\$31,016
Available-for-sale securities:				
Corporate obligations due in one year or less	42,643	1	(23)	42,621
Corporate obligations due in more than one year	48,203	31	(66)	48,168
U.S. Treasury securities due in one year or less	22,985	10	—	22,995
U.S. Treasury securities due in more than one year	14,048	14	(1)	14,061
Certificates of deposit due in one year or less	20,385	—	—	20,385
Certificates of deposit due in more than one year	10,280	—	(1)	10,279
Mortgage and other asset backed securities due in one year or less	21,278	4	(4)	21,278
Mortgage and other asset backed securities due in more than one year	40,253	1	(34)	40,220
Total available-for-sale securities	220,075	61	(129)	220,007
Total cash, cash equivalents and available-for-sale securities	\$251,091	\$ 61	\$ (129)	\$251,023
	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	\$27,783	\$ —	—\$ —	\$27,783
Available-for-sale securities:				
Corporate obligations due in one year or less	53,243	—	(81)	\$53,162
Corporate obligations due in more than one year	14,112	—	(72)	14,040
U.S. Treasury securities due in one year or less	6,016	—	(4)	6,012
U.S. Treasury securities due in more than one year	4,995	—	(15)	4,980
Certificates of deposit due in one year or less	11,890	—	—	11,890
Certificates of deposit due in more than one year	4,886	—	—	4,886
Mortgage and other asset backed securities due in one year or less	6,010	—	(10)	6,000
Mortgage and other asset backed securities due in more than one year	7,266	—	(38)	7,228
Total available-for-sale securities	108,418	—	(220)	108,198
Total cash, cash equivalents and available-for-sale securities	\$136,201	\$ —	—\$ (220)	\$135,981

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion in interest income. The cost of securities sold is based on the specific identification method. The Company includes in interest income interest and dividends on securities classified as available-for-sale.

The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of September 30, 2016 and December 31, 2015 was \$106.7 million and \$89.7 million, respectively. The aggregate fair value of securities held by the Company in an unrealized loss position for more than twelve months as of September 30, 2016 was \$5.5 million. The aggregate unrealized loss for those securities in an unrealized loss position for more than twelve months is \$5,000.

6. Restricted Cash

As of September 30, 2016 the Company maintained letters of credit totaling \$0.9 million held in the form of certificates of deposit and money market funds as collateral for the Company's facility lease obligations and its credit cards. As of December 31, 2015, the Company maintained letters of credit totaling \$0.8 million held in the form of certificates of deposit.

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

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 primarily consist of cash, cash equivalents, restricted cash, short-term and long-term investments and collaboration receivables. The Company maintains its cash and cash equivalent balances and short-term and long-term investments with financial institutions that management believes are creditworthy. Short-term and long-term investments consist of investment grade corporate obligations, treasury notes, asset backed securities, and certificates of deposit. 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 concentrations 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 collaboration receivables.

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8. 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 September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Quoted Prices in Active Markets for Identifiable (Level 1)	Significant Observable Inputs (Level 2)	Other Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$26,611	\$ —	\$ —	\$26,611
Corporate obligations	—	90,789	—	90,789
U.S. Treasury securities	—	37,057	—	37,057
Certificates of deposit	—	31,154	—	31,154
Mortgage and other asset backed securities	—	61,498	—	61,498
Restricted cash	946	—	—	946
Total assets	\$27,557	\$ 220,498	\$ —	\$248,055
Liabilities:				
Warrants to purchase common stock	\$—	\$ —	\$ 12,161	\$12,161
Total liabilities	\$—	\$ —	\$ 12,161	12,161

	December 31, 2015			
	Quoted Prices in Active Markets for Identifiable (Level 1)	Significant Observable Inputs (Level 2)	Other Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$24,811	\$ —	\$ —	\$24,811
Corporate obligations	—	67,706	—	67,706
U.S. Treasury securities	—	10,991	—	10,991
Certificates of deposit	—	16,776	—	16,776
Mortgage and other asset backed securities	—	13,228	—	13,228
Restricted cash	796	—	—	796
Total assets	\$25,607	\$ 108,701	\$ —	\$134,308
Liabilities:				
Warrants to purchase common stock	\$—	\$ —	\$ 17,187	\$17,187
Total liabilities	\$—	\$ —	\$ 17,187	\$17,187

The money market funds noted above are included in cash and cash equivalents in the accompanying condensed consolidated 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 nine months ended September 30, 2016 or the year ended December 31, 2015.

Items measured at fair value on a recurring basis include warrants to purchase common stock (Note 13). 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 common stock warrant liability, which has been classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

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	Nine Months Ended September 30,	
	2016	2015
Beginning balance	\$17,187	\$14,124
Change in fair value	(5,026)	(5,595)
Exercises	—	(465)
Ending balance	\$12,161	\$8,064

The fair value of the warrants to purchase common stock on the date of issuance and on each re-measurement date for those warrants classified as liabilities was estimated using either the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock, or for certain re-measurement dates, when the warrants are deeply in the money, the Black-Scholes option pricing model. At each reporting period the Company evaluates the best valuation methodology, and at September 30, 2016, the Black-Scholes option pricing model was used. Due to the nature of these inputs, the valuation of 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 re-measure 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 nine months ended September 30, 2016 or the year ended December 31, 2015.

9. 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 their inclusion would have had an anti-dilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Outstanding stock options	3,193	3,328	3,193	3,328
Common stock warrants	397	398	397	398
Shares issuable under employee stock purchase plan	18	19	18	19
Restricted stock units	670	524	670	524
	4,278	4,269	4,278	4,269

10. 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. Accumulated other comprehensive income (loss) is presented separately on the consolidated balance sheets and consists of cumulative unrealized gains and losses from short-term and long-term investments and the tax expense associated with the gains as of September 30, 2016.

11. 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.

12. 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.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective for the Company on January 1,

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2018. The Company is currently evaluating the method of adoption and the potential impact that Topic 606 may have on its financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40). The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of the financial statements. The accounting standard is effective for interim and annual periods ending after December 15, 2016, and will not have a material impact on the consolidated financial statements, but may impact the Company's footnote disclosures.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810), Amendments to the Consolidation Analysis, which updated accounting guidance on consolidation requirements. This update changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. This guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015, with early adoption permitted. The Company adopted this standard on January 1, 2016 and the adoption did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as non-current in a classified statement of financial position. The new standard will be effective for the Company on January 1, 2017. The Company is currently evaluating the method of adoption and the potential impact that Topic 740 may have on its financial position and results of operations.

In February 2016 the FASB issued ASU 2016-02, Leases (Topic 842), Amendments to the FASB Accounting Standards Codification, which replaces the existing guidance for leases. ASU 2016-02 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a twelve month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. In addition, ASU 2016-02 requires the use of the modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. This guidance is effective for annual and interim periods beginning after December 15, 2018 and requires retrospective application. The Company is currently assessing the impact that adopting ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In March 2016 the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share based payments, including income tax consequences, classification of awards as either equity, or liabilities, an option to make a policy election to recognize gross share based compensation expense with actual forfeitures recognized as they occur as well as certain classification changes on the statement of cash flows. This guidance is effective for annual and interim reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is currently assessing the impact that adopting ASU 2016-09 will have on its consolidated financial statements and related disclosures.

13. 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	
September 30, 2016	December 31, 2015			September 30, 2016	December 31, 2015

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Warrants to purchase common stock	393	393	\$ 5.88	June 10, 2020 - July 9, 2020	Liability	Liability
Warrants to purchase common stock	4	5	4.00 - 7.40	March 28, 2017 - December 31, 2017	Equity(1) (2)	Equity(2)
All warrants	397	398	\$ 5.88			

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(1) In March 2016, the warrant holders exercised warrants to purchase 1,317 shares of Common Stock on a net basis, resulting in the issuance of 1,109 shares of Common Stock.

(2) 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 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 or through the life of the instrument, the Company re-measured the fair value of the outstanding warrants, using current assumptions, resulting in an increase in fair value of \$0.8 million and a decrease of \$2.6 million for the three months ended September 30, 2016 and 2015, respectively, and a decrease in fair value of \$5.0 million and \$5.6 million for the nine months ended September 30, 2016 and 2015, respectively, which was recorded in other (expense) income in the accompanying consolidated statements of operations and comprehensive loss. 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. All remaining outstanding warrants were fully vested and exercisable as of September 30, 2016 and December 31, 2015.

14. Commitments and Contingencies

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the three months ended September 30, 2016, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met at September 30, 2016 and December 31, 2015, or royalties on future sales of specified products. No royalty payments under these agreements are expected to be payable in the immediate future. See Note 15 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.

15. Significant Agreements

Celgene

Overview

On February 20, 2008 the Company entered into a collaboration, license, and option agreement with Celgene Corporation (Celgene) relating to sotatercept (the Sotatercept Agreement). On August 2, 2011, the Company entered into a second collaboration, license and option agreement with Celgene for luspatercept (the Luspatercept Agreement), and also amended certain terms of the Sotatercept Agreement. These agreements provide Celgene exclusive licenses for sotatercept and luspatercept in all indications, as well as exclusive rights to obtain a license to certain future compounds. Celgene is an

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integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

There have been no material changes to the key terms of the Sotatercept and Luspatercept Agreements since December 31, 2015. For further information on the terms of the agreements as well as the historical accounting analysis, please see the notes to the consolidated financial statements included in the Company's Form 10-K for the year ended December 31, 2015.

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.

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 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.

Through September 30, 2016, the Company has received \$43.5 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 chronic kidney disease.

Luspatercept Agreement

Under the terms of the Luspatercept Agreement, the Company and Celgene collaborate worldwide for the joint development and commercialization of luspatercept. The Company also granted Celgene an option for future products for which Acceleron files an Investigational New Drug application for the treatment of anemia. 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 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 luspatercept 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.

Through September 30, 2016, the Company has received \$84.5 million in research and development funding and milestone payments for luspatercept. The next likely milestone payment would be \$25.0 million and result from U.S. Food and Drug Administration or European Medical Association acceptance of a Biologics Licensing Application or equivalent for luspatercept in either myelodysplastic syndromes or beta-thalassemia.

Both Agreements

The Company and Celgene shared development costs under the Sotatercept and Luspatercept Agreements through December 31, 2012. As of January 1, 2013, Celgene has been 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, luspatercept and future products under both agreements in North America. Celgene's option to buy down royalty rates for sotatercept and luspatercept expired unexercised and, therefore, the Company will receive tiered royalties in the low-to-mid twenty percent range on net sales of sotatercept and luspatercept. The royalty schedules for sotatercept and luspatercept are the same.

Accounting Analysis

During the three months ended September 30, 2016 and 2015, the Company recognized \$0.1 million and \$0.2 million, respectively, and during the nine months ended September 30, 2016 and 2015, \$0.4 million and \$1.0 million, respectively, of the total deferred revenue as license and milestone revenue in the accompanying consolidated

statements of operations and comprehensive loss.

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As noted above, under the terms of the Luspatercept Agreement the Company retained 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 luspatercept 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 are 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 Luspatercept 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 luspatercept until December 31, 2012 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. The Company recorded net cost-sharing revenue of \$2.9 million and \$3.9 million during the three months ended September 30, 2016 and 2015, respectively, and \$9.0 million and \$13.3 million during the nine months ended September 30, 2016 and 2015, respectively.

Other AgreementsOther

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 Company also agreed to pay specified development milestone payments totaling up to \$2.0 million for sotatercept and \$0.7 million for luspatercept. 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 September 30, 2016 and 2015, the Company expensed zero and zero, respectively, and during the nine months ended September 30, 2016 and 2015, respectively, the Company expensed \$1.0 million and \$0.1 million of 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, the Company is 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 the Company sublicenses its patent rights, it will owe a percentage of sublicensing revenue, excluding payments based on the level of sales, profits or other levels of commercialization. During the three and nine months ended September 30, 2016 and 2015, 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 relating to dalantercept totaling up to \$1.0 million. 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 and nine months ended September 30, 2016 and 2015, the Company did not reach any milestones defined under the agreement and, therefore, no amounts have been paid or expensed.

In May 2014, the Company executed a collaboration agreement with a research technology company. The Company paid an upfront research fee of \$0.3 million upon execution of the agreement. The Company also received an option to obtain a commercial license to the molecules developed during the collaboration. During the three months ended September 30, 2016 and 2015, the Company expensed \$0.4 million and \$0.2 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company expensed \$0.9 million and \$1.0 million, respectively, of milestones and fees, which is recorded as research and development expense.

16. Stock-Based Compensation

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The Company recognized stock-based compensation expense related to stock options, restricted stock units and the 2013 Employee Stock Purchase Plan (2013 ESPP) totaling \$4.6 million, \$3.1 million, \$13.4 million and \$8.3 million during the three months ended September 30, 2016 and 2015 and the nine months ended September 30, 2016 and 2015, 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):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Research and development	\$ 1,942	\$ 1,201	\$ 5,617	\$ 3,302
General and administrative	2,646	1,863	7,770	4,993
	\$ 4,588	\$ 3,064	\$ 13,387	\$ 8,295

Stock Options

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

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Expected volatility	65.4%	66.0%	64.5%	67.1%
Expected term (in years)	6.0	6.0	5.9	6.0
Risk-free interest rate	1.2 %	1.7 %	1.4 %	1.7 %
Expected dividend yield	— %	— %	— %	— %

The following table summarizes the stock option activity under the Company's 2003 Stock Option and Restricted Stock Plan and 2013 Equity Incentive Plan during the nine months ended September 30, 2016 (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, 2015	3,191	\$ 18.85	6.31	
Granted	639	\$ 28.69		
Exercised	(606)	\$ 5.82		
Canceled or forfeited	(31)	\$ 36.28		
Outstanding at September 30, 2016	3,193	\$ 23.12	6.69	\$ 46,294
Exercisable at September 30, 2016	1,932	\$ 16.72	5.37	\$ 39,724
Vested and expected to vest at September 30, 2016 (2)	3,147	\$ 22.97	6.65	\$ 46,058

(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 September 30, 2016.

This represents the number of vested options at September 30, 2016, plus the number of unvested options expected (2) to vest at September 30, 2016, based on the unvested options outstanding at September 30, 2016, adjusted for the estimated forfeiture rate.

During the nine months ended September 30, 2016, the Company granted stock options to purchase an aggregate of 639,070 shares of its common stock, with a weighted-average grant date fair value of options granted of \$28.69.

During the nine months ended September 30, 2016, current and former employees of the Company exercised a total of 605,558 options, resulting in total proceeds of \$3.5 million.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2016 was \$16.7 million.

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As of September 30, 2016, there was \$21.5 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over a weighted-average period of 2.43 years.

Restricted Stock Units

The following table summarizes the restricted stock unit (RSU) activity under the 2013 Equity Incentive Plan during the nine months ended September 30, 2016 (in thousands):

	Number of Grants	Weighted- Average Grant Date Fair Value
Unvested balance at December 31, 2015	521	\$ 31.57
Granted	158	30.17
Vested	—	—
Forfeited	(9)	34.01
Unvested balance at September 30, 2016	670	\$ 31.22

During the nine months ended September 30, 2016, the Company issued 133,980 RSUs to employees. These RSUs are subject to time-based vesting. As of September 30, 2016, there was approximately \$4.7 million of unrecognized compensation cost related to the time-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.23 years. 181,710 restricted stock units remained unvested and outstanding at September 30, 2016.

During the nine months ended September 30, 2016, the Company issued 23,977 performance-based RSUs in addition to the 464,000 issued in 2015. The vesting of these performance-based RSUs is accelerated upon the occurrence of certain milestone events, but otherwise these RSUs vest in September 2019. As a result, when probable, compensation cost is recognized over the estimated period of achievement. If achievement is not considered probable the expense is recognized over the vesting period. As of September 30, 2016, there was approximately \$9.5 million of unrecognized compensation cost related to the performance-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.08 years. All 487,977 of these performance-based RSUs remained outstanding at September 30, 2016.

Employee Stock Purchase Plan

During the three months ended September 30, 2016 and 2015, the Company recorded \$0.1 million and \$0.1 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company recorded \$0.2 million and \$0.2 million, respectively, of stock-based compensation expense related to the 2013 ESPP.

17. Income Taxes

For the three and nine months ended September 30, 2016, the Company recognized an income tax benefit of \$20,000 and \$20,000 and tax expense in other comprehensive income of \$53,000 and \$53,000 related to the unrealized gain on available for sale securities. As of September 30, 2016, the Company recorded an accrued tax provision of \$17,000 related to this tax benefit included within accrued expenses and other current liabilities in the condensed consolidated balance sheet, which is expected to be generated from continued operations.

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 September 30, 2016 and December 31, 2015.

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, 2012 through December 31, 2015. 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.

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 September 30, 2016 and December 31, 2015, the Company did not have any significant uncertain tax positions.

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18. Related Party Transactions

Celgene Corporation

In connection with prior arrangements, Celgene owned 12.9% and 12.3% of the Company's fully diluted equity as of September 30, 2016 and December 31, 2015, respectively. Refer to Note 15 for additional information regarding this collaboration arrangement.

During the three and nine months ended September 30, 2016 and 2015, all revenue recognized by the Company was recognized under the Celgene collaboration arrangement and, as of September 30, 2016, the Company had \$4.4 million of deferred revenue related to the Celgene collaboration arrangement.

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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 statements 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, 2015.

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 "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "project," "should," "strategy," "target," "will," "would," or, in each case, the negative or other variations thereon or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- our ongoing and planned preclinical studies and clinical trials;
- clinical trial data and the timing of results of our ongoing clinical trials;
- our plans to develop and commercialize dalantercept and ACE-083, and our and Celgene's plans to develop and commercialize luspatercept and sotatercept;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;
- the timing of anticipated milestone payments under our collaboration agreements with Celgene;
- the timing of, and our and Celgene's ability to, obtain and maintain regulatory approvals for our therapeutic candidates;
- the rate and degree of market acceptance and clinical utility of any approved therapeutic candidate, particularly in specific patient populations;
- our ability to quickly and efficiently identify and develop therapeutic candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding our operating capital requirements, results of operations, financial condition, liquidity, capital requirements, prospects, growth and strategies.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and industry changes and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. 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 events in the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statements, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the section "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, press releases, and our website.

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

Overview

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We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. Our research focuses on key natural regulators of cellular growth and repair, particularly the Transforming Growth Factor-Beta, or TGF-beta, protein superfamily. We are a leading company in discovering and developing therapeutic candidates that regulate cellular growth and repair. By combining our discovery and development expertise, including our proprietary knowledge of the TGF-beta superfamily, and our internal protein engineering and manufacturing capabilities, we have built a highly productive discovery and development platform that has generated innovative therapeutic candidates with novel mechanisms of action. These differentiated therapeutic candidates have the potential to significantly improve clinical outcomes for patients across many fields of medicine, and we have focused our discovery and development efforts on treatments for cancer and rare diseases.

We have four internally discovered therapeutic candidates that are currently in clinical trials: luspatercept, sotatercept, dalantercept and ACE-083.

Luspatercept, our lead program, and sotatercept, are partnered with Celgene Corporation, or Celgene. Luspatercept is designed to promote red blood cell production through a novel mechanism, and we are developing luspatercept with Celgene to treat anemia and associated complications in myelodysplastic syndromes (MDS) and beta-thalassemia. In 2015, Celgene initiated two Phase 3 clinical trials for luspatercept for the treatment of MDS and beta-thalassemia. We and Celgene are developing sotatercept to treat patients with chronic kidney disease. Sotatercept has the potential to treat several complications of chronic kidney disease including mineral-bone disorder, vascular calcification and anemia. Celgene is responsible for paying 100% of the development costs for all clinical trials for luspatercept and sotatercept, including our ongoing earlier stage clinical trials for these therapeutic candidates. We may receive up to an additional \$545.0 million of potential development, regulatory and commercial milestone payments and, if these therapeutic candidates are commercialized, we will receive a royalty on net sales in the low-to-mid 20% range. We will co-promote luspatercept and sotatercept, if approved, in North America for which our commercialization costs will be entirely funded by Celgene.

We wholly own dalantercept and ACE-083, and we are independently developing these therapeutic candidates. We are currently evaluating dalantercept in a Phase 2 clinical trial for the treatment of patients with renal cell carcinoma. ACE-083 is designed for the treatment of focal muscle disorders, such as facioscapulohumeral muscular dystrophy, and we have completed a Phase 1 clinical trial with ACE-083 in healthy volunteers. We have reported data from the Phase 1 clinical trial of ACE-083 showing marked increases in the volume of muscles treated with ACE-083, and we intend to advance ACE-083 into a Phase 2 clinical trial in patients with facioscapulohumeral muscular dystrophy. In addition to our clinical programs, we are conducting research to identify new therapeutic candidates to bring forward into clinical trials. To this end, in 2015 we implemented a new platform technology, IntelliTrap™, which is accelerating our discovery efforts. We have nominated an IntelliTrap™ molecule, ACE-2494, as a candidate for clinical development and will initiate investigational new drug-enabling activities in 2016.

As of September 30, 2016, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$337.3 million from public investors, \$96.2 million in equity investments from our collaboration partners and \$258.1 million in upfront payments, milestones, and net research and development payments from our collaboration 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 and ACE-083;
- continue our preclinical studies and potential clinical development efforts of our existing preclinical therapeutic candidates;
- continue research activities for the discovery of new therapeutic candidates;
- manufacture therapeutic candidates for our preclinical studies and clinical trials;
- seek regulatory approval for our therapeutic candidates; 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 therapeutic candidates. We expect that this will take a number

of years and is subject to significant uncertainty. All current and future development and commercialization costs for sotatercept and luspatercept are paid by Celgene. If we obtain regulatory approval for dalantercept, ACE-083 or any future 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

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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 therapeutic candidates.

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 therapeutic candidates and potentially begin to commercialize any approved products. For a description of the numerous risks and uncertainties associated with product development, see "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 therapeutic candidates. 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 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 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.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our therapeutic candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our 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 therapeutic candidates. The duration, costs and timing of clinical trials and development of our 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

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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 therapeutic candidate could mean a significant change in the costs and timing associated with the development of that therapeutic candidate. For example, if the U.S. Food and Drug Administration, 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 our therapeutic candidates, 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 September 30, 2016, we have incurred \$446.0 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-beta platform therapeutic candidates, the discovery and development of preclinical therapeutic candidates, and the development of sotatercept, luspatercept, dalantercept and ACE-083. As of January 1, 2013, expenses associated with sotatercept and luspatercept are reimbursed 100% by Celgene. These reimbursements are recorded as revenue. We are expensing the costs of seven Phase 2 clinical trials for luspatercept, dalantercept and ACE-083, of which the four for luspatercept are reimbursed by Celgene, and we are also expensing the costs of a Phase 1 clinical trial for ACE-083. With respect to the luspatercept Phase 3 clinical trials directly conducted by Celgene, we do not incur and are not reimbursed for expenses related to these development activities.

We manage certain activities such as clinical trial operations, manufacture of therapeutic candidates, and preclinical animal toxicology studies through third-party CROs. The only costs we track by each therapeutic candidate are external costs such as services provided to us by CROs, manufacturing of preclinical and clinical drug product, 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 during the three and nine months ended September 30, 2016 and 2015 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2016	2015	2016	2015
Luspatercept ⁽¹⁾	\$1,693	\$2,418	\$5,012	\$7,647
Dalantercept	1,128	2,463	5,215	6,555
ACE-083	1,820	291	3,434	2,058
Total direct research and development expenses	4,641	5,172	13,661	16,260
Other expenses ⁽²⁾	12,461	8,163	35,831	26,001
Total research and development expenses	\$17,102	\$13,335	\$49,492	\$42,261

As of January 1, 2013, expenses associated with sotatercept and luspatercept are reimbursed 100% by Celgene.

(1) These reimbursements are recorded as revenue and are presented as cost-sharing, net. In the periods presented, Celgene conducted most of the development activities for sotatercept, and we do not incur and are not reimbursed for expenses related to development activities directly conducted by Celgene.

(2) Other expenses include unallocated employee and contractor-related expenses, facility expenses, lab supplies, miscellaneous expenses and expenses associated with preclinical programs.

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 continue to incur expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, 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 therapeutic candidates. Additionally, if and when we believe regulatory approval of a therapeutic candidate appears likely, to the extent that we are undertaking commercialization of such therapeutic candidate ourselves, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations.

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Other (Expense) Income, Net

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

To estimate the fair value of our liability classified warrants, we use either the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock, or for certain re-measurement dates, due to the warrants being deeply in the money, the Black-Scholes option pricing model. We base the estimates in the pricing models, in part, on subjective assumptions, including stock price volatility, risk-free interest rate, dividend yield, and the fair value of the preferred stock or common stock underlying the warrants. The Black-Scholes option pricing model was used at September 30, 2016.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. 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 liability-classified warrants to purchase 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, 2015. 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, 2015.

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Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

(in thousands)	Three Months Ended		Increase (Decrease)
	September 30, 2016	2015	
Revenue:			
Collaboration revenue:			
License and milestone	\$ 135	\$ 205	\$ (70)
Cost-sharing, net	2,870	3,950	(1,080)
Total revenue	3,005	4,155	(1,150)
Costs and expenses:			
Research and development	17,102	13,335	3,767
General and administrative	6,411	5,433	978
Total costs and expenses	23,513	18,768	4,745
Loss from operations	(20,508)	(14,613)	(5,895)
Other (expense) income, net	(282)	2,755	(3,037)
Loss before income taxes	(20,790)	(11,858)	(8,932)
Income tax benefit	20	—	20
Net loss	\$(20,770)	\$(11,858)	\$(8,912)

Revenue. We recognized revenue of \$3.0 million in the three months ended September 30, 2016, compared to \$4.2 million in the same period in 2015. All of the revenue in both periods was derived from the Celgene agreements. This \$1.2 million decrease was primarily due to a decrease in cost sharing revenue of \$1.1 million due to lower expenses for luspatercept clinical trials and toxicology studies compared to the prior year and increased luspatercept expenses during Q3 2015 related to a bulk drug substance manufacturing campaign.

Research and Development Expenses. Research and development expenses were \$17.1 million in the three months ended September 30, 2016, compared to \$13.3 million in the same period in 2015. This \$3.8 million increase was primarily due to an increase in personnel expenses totaling \$2.7 million, to support development of our wholly owned therapeutic candidates and preclinical programs, which includes an increase in stock-based compensation expense of \$0.7 million. Other increases include miscellaneous research and drug supply expenses of \$2.3 million. These increases were partially offset by a decrease in clinical trial and toxicology expenses totaling \$1.2 million.

General and Administrative Expenses. General and administrative expenses were \$6.4 million in the three months ended September 30, 2016, compared to \$5.4 million for the same period in 2015. This \$1.0 million increase was primarily due to an increase in stock-based compensation expense of \$0.8 million and an increase in professional fees of \$0.3 million.

Other (Expense) Income, Net. Other expense, net was \$0.3 million in the three months ended September 30, 2016, compared to other income, net of \$2.8 million for the same period in 2015. This \$3.1 million change was primarily due to a \$3.4 million increase in expense due to marking the common warrant liability to market in each period, offset by a \$0.3 million increase in interest income in the three months ended September 30, 2016 due to changes in the total investments held in each period and the mix of investments.

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Comparison of the Nine Months Ended September 30, 2016 and 2015

(in thousands)	Nine Months Ended		Increase
	September 30, 2016	2015	(Decrease)
Revenue:			
Collaboration revenue:			
License and milestone	\$ 15,415	\$ 1,008	\$ 14,407
Cost-sharing, net	8,987	13,286	(4,299)
Total revenue	24,402	14,294	10,108
Costs and expenses:			
Research and development	49,492	42,261	7,231
General and administrative	19,029	14,796	4,233
Total costs and expenses	68,521	57,057	11,464
Loss from operations	(44,119)	(42,763)	(1,356)
Other income, net	6,374	5,951	423
Loss before income taxes	(37,745)	(36,812)	(933)
Income tax benefit	20	—	20
Net loss	\$(37,725)	\$(36,812)	\$(913)

Revenue. We recognized revenue of \$24.4 million in the nine months ended September 30, 2016, compared to \$14.3 million in the same period in 2015. All of the revenue in both periods was derived from the Celgene agreements. This \$10.1 million increase was primarily due to the receipt of a \$15.0 million milestone payment from Celgene for the initiation of a Phase 3 clinical trial with luspatercept, offset by a decrease in cost sharing revenue of \$4.3 million primarily due to lower expenses for luspatercept clinical trials and toxicology studies compared to the prior year and increased luspatercept expenses during 2015 related to a bulk drug substance manufacturing campaign. Deferred revenue also decreased \$0.6 million as we complete our deliverables under the Celgene agreements.

Research and Development Expenses. Research and development expenses were \$49.5 million in the nine months ended September 30, 2016, compared to \$42.3 million in the same period in 2015. This \$7.2 million increase was primarily due to an increase in personnel expenses totaling \$5.8 million, to support development of our wholly owned therapeutic candidates and preclinical programs, which includes an increase in stock-based compensation expense of \$2.3 million. Other increases include licensing expense related to the achievement of our milestone totaling \$0.9 million and miscellaneous research and drug supply expenses of \$3.8 million. These increases were offset in part by a decrease in clinical trial and toxicology expenses totaling \$3.3 million.

General and Administrative Expenses. General and administrative expenses were \$19.0 million in the nine months ended September 30, 2016, compared to \$14.8 million for the same period in 2015. This \$4.2 million increase was primarily due to an increase in personnel expenses of \$3.4 million, which includes an increase in stock-based compensation expense of \$2.8 million, as well as an increase in professional fees of \$0.8 million.

Other Income, Net. Other income, net was \$6.4 million in the nine months ended September 30, 2016, compared to \$6.0 million for the same period in 2015. This \$0.4 million increase was primarily due to an increase of \$1.0 million in interest income in the nine months ended September 30, 2016 due to changes in the total investments held in each period and the mix of investments. This was offset by an increase in the common warrant liability of \$0.6 million due to the effect of marking the common warrant liability to market in each period.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in June 2003, and as of September 30, 2016, we had an accumulated deficit of \$345.2 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.

As of September 30, 2016, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$337.3 million from public investors, \$96.2 million in equity investments from our collaboration partners and \$258.1 million in upfront payments, milestones, and net research and development payments from our collaboration partners.

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As of September 30, 2016, we had \$251.0 million in cash, cash equivalents and investments. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements into the second half of 2019.

Cash Flows

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

(in thousands)	Nine Months Ended	
	September 30, 2016	2015
Net cash provided by (used in):		
Operating activities	\$(27,955)	\$(31,750)
Investing activities	(113,691)	(104,849)
Financing activities	144,879	3,577
Net increase (decrease) in cash and cash equivalents	\$3,233	\$(133,022)

Operating Activities

Net cash used in operating activities was \$28.0 million for the nine months ended September 30, 2016 compared to \$31.8 million during the same period in 2015. The change was driven primarily by an increase in net loss of \$0.9 million, which includes an increase in operating expenses of \$11.5 million. This was partially offset by the receipt of a \$15.0 million milestone payment during the nine months ended September 30, 2016. Non-cash changes in the nine months ended September 30, 2016 compared to the same period in 2015 include a \$0.6 million decrease in the gain associated with marking the common warrants to market, a \$5.1 million increase in stock-based compensation expense, a \$0.3 million decrease for net amortization of premium paid for investments, a \$0.3 million increase in depreciation and amortization expense, and a \$1.6 million net decrease in operating assets and liabilities.

Investing Activities

Net cash used in investing activities was \$113.7 million for the nine months ended September 30, 2016 compared to \$104.8 million for the nine months ended September 30, 2015. Our net cash used in investing activities during the nine months ended September 30, 2016 was due to us investing the proceeds from our public offering in January 2016, in which we raised net proceeds of \$140.3 million, compared to during the nine months ended September 30, 2015, which was due to the implementation of our investment policy pursuant to which we began to invest in marketable securities.

Financing Activities

Net cash provided by financing activities was \$144.9 million for the nine months ended September 30, 2016 compared to \$3.6 million for the same period in 2015. The increase is due to the net proceeds from our January 2016 public offering of \$140.3 million, as well as a \$0.6 million increase in cash proceeds from the exercise of stock options and the issuance of common stock related to the employee stock purchase plan.

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 therapeutic candidates. 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, ACE-083 and any future therapeutic candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of therapeutic candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Since the closing of our initial public offering, we have incurred, and expect to continue 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 our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements into the second half of 2019. However, we will require additional capital for the further development of

our existing therapeutic candidates and may also need to raise additional funds sooner to pursue other development activities related to additional therapeutic candidates.

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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, 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 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 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 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 therapeutic candidates and potential therapeutic candidates;
- the number and characteristics of 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 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.

Net Operating Loss (NOL) Carryforwards

We had deferred tax assets of approximately \$109.8 million as of December 31, 2015, 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, 2015, we had federal NOL carryforwards of approximately \$276.1 million and state NOL carryforwards of \$229.8 million available to reduce future taxable income, if any. These federal and state NOL carryforwards expire at various times through 2035. 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 our public offerings 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. For additional information about our taxes, see Note 13 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015.

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Contractual Obligations and Commitments

During the three months ended September 30, 2016, there were no 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, 2015.

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.

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 September 30, 2016 and December 31, 2015, we had cash, cash equivalents and investments of \$251.0 million and \$136.0 million, respectively. Our cash equivalents are invested primarily in bank deposits and money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. We do not enter into financial instruments for trading or speculative purposes. Due to the duration of our investment portfolio and the low risk profile of our investments, we do not believe an immediate 100 basis point change in interest rates would have a material effect on the fair market value of our portfolio. We have the ability to hold our investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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 Exchange Act of 1934, or the Exchange Act, 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 September 30, 2016, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2016, the design and operation of our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

While we are not currently a party to any material legal proceedings, we could become subject to legal proceedings in the ordinary course of business. We do not expect any such potential items to have a significant impact on our financial position.

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, 2015.

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.

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SIGNATURES

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

ACCELERON PHARMA INC.

Date: November 3, 2016 By: /s/ JOHN L. KNOPF, PH.D.

John L. Knopf, Ph.D.

Chief Executive Officer and President

Date: November 3, 2016 By: /s/ KEVIN F. MCLAUGHLIN

Kevin F. McLaughlin

Senior Vice President, Chief Financial Officer and Treasurer

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EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Amendment No. 1 to Amended and Restated Bylaws of Acceleron Pharma Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (001-36065), filed on September 12, 2016).
10.1*	Employment Agreement, by and between Habib J. Dable and Acceleron Pharma Inc., dated as of September 23, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (001-36065), filed on September 27, 2016).
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

*Management contract or compensatory plan or arrangement.