

ACCELERON PHARMA INC

Form 10-Q

November 04, 2015

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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, 2015

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 incorporation or organization)

(Primary Standard Industrial Classification Code Number)

(I.R.S. Employer Identification Number)

128 Sidney Street

Cambridge, MA 02139

(617) 649-9200

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

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

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

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

Large accelerated filer

Accelerated filer

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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, 2015, there were 33,253,235 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, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$43,438	\$176,460
Short-term investments	72,459	—
Collaboration receivables (all amounts are with related party)	3,950	3,367
Prepaid expenses and other current assets	2,536	2,480
Total current assets	122,383	182,307
Property and equipment, net	2,945	3,087
Long-term investments	32,253	—
Restricted cash	796	902
Other assets	43	—
Total assets	\$158,420	\$186,296
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$2,647	\$724
Accrued expenses	8,968	6,848
Deferred revenue	596	1,162
Deferred rent	661	519
Total current liabilities	12,872	9,253
Deferred revenue, net of current portion	4,374	4,816
Deferred rent, net of current portion	1,322	1,818
Warrants to purchase common stock	8,064	14,124
Total liabilities	26,632	30,011
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; 33,197,649 and 32,432,025 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	34	33
Additional paid-in capital	412,170	399,835
Accumulated deficit	(280,395)	(243,583)
Accumulated other comprehensive loss	(21)	—
Total stockholders' equity	131,788	156,285
Total liabilities and stockholders' equity	\$158,420	\$186,296

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		Nine Months Ended September	
	30,		30,	
	2015	2014	2015	2014
Revenue:				
Collaboration revenue:				
License and milestone	\$205	\$280	\$1,008	\$1,302
Cost-sharing, net	3,950	3,228	13,286	9,592
Total revenue (all amounts are with related party)	4,155	3,508	14,294	10,894
Costs and expenses:				
Research and development	13,335	11,876	42,261	36,318
Litigation settlement	—	—	—	5,000
General and administrative	5,433	3,023	14,796	10,485
Total costs and expenses	18,768	14,899	57,057	51,803
Loss from operations	(14,613	) (11,391	) (42,763	) (40,909
Other income, net:				
Other income, net	2,616	3,394	5,595	8,130
Interest income	139	25	356	59
Interest expense	—	—	—	(922
Total other income, net	2,755	3,419	5,951	7,267
Net loss applicable to common stockholders	\$(11,858	) \$(7,972	) \$(36,812	) \$(33,642
Net loss per share applicable to common stockholders-basic and diluted (Note 9)	\$(0.36	) \$(0.25	) \$(1.12	) \$(1.18
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders-basic and diluted	33,097	31,855	32,869	28,594
Other comprehensive loss:				
Net loss	\$(11,858	) \$(7,972	) \$(36,812	) \$(33,642
Net unrealized holding gains (losses) on short-term and long-term investments during the period	41	—	(21	) —
Comprehensive loss	\$(11,817	) \$(7,972	) \$(36,833	) \$(33,642

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,	
	2015	2014
Operating Activities		
Net loss	\$(36,812 )	\$(33,642 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	871	832
Loss on disposition of fixed assets	12	—
Stock-based compensation	8,295	3,327
(Payment) / accretion of deferred interest	—	(536 )
Amortization of deferred debt issuance costs	—	36
Change in fair value of warrants	(5,595 )	(8,124 )
Net amortization of premium on investments	(543 )	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(99 )	(1,723 )
Collaboration receivables	(583 )	388
Accounts payable	1,923	2,429
Accrued expenses	2,037	(923 )
Deferred revenue	(1,008 )	(1,302 )
Deferred rent	(354 )	(374 )
Restricted cash	106	11
Net cash used in operating activities	(31,750 )	(39,601 )
Investing Activities		
Purchase of investments	(134,328 )	—
Proceeds from maturities investments	30,138	—
Purchases of property and equipment	(659 )	(498 )
Net cash used in investing activities	(104,849 )	(498 )
Financing Activities		
Proceeds from issuance of common stock from public offering, net issuance costs	—	129,174
Proceeds from exercise of stock options and warrants to purchase common stock	2,987	3,349
Proceeds from issuances of common stock related to employee stock purchase plan	590	—
Payments of long-term debt	—	(16,331 )
Net cash provided by financing activities	3,577	116,192
Net (decrease) increase in cash and cash equivalents	(133,022 )	76,093
Cash and cash equivalents at beginning of period	176,460	113,163
Cash and cash equivalents at end of period	\$43,438	\$189,256
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	\$—	\$1,574
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Reclassification of warrant liability to additional paid-in capital	\$465	\$7,601
Purchase of property and equipment included in accounts payable and accrued expenses	\$82	\$7

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 biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutic candidates that are based on the mechanisms that the human body uses to regulate the growth and repair of its cells and tissues. 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, 2014, 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, 2015, and the results of its operations and its cash flows for the three and nine months ended September 30, 2015 and 2014.

The results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015, 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, 2014, 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, 2014.

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, 2015, 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, 2014, 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 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

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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 novel therapeutic candidates that are based on the mechanisms that the human body uses to regulate the growth and repair of its cells and tissues. All material long-lived assets of the Company reside in the United States. The Company does use contract research organizations (CROs) and research institutions located outside the United States. Some of these expenses are subject to collaboration reimbursement which is presented as a component of cost sharing, net in the 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, 2015 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, 2015 and 2014.

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 adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include 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 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 available-for-sale securities as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	\$43,438	\$—	\$—	\$43,438
Available-for-sale securities:				
Corporate obligations due in one year or less	51,881	5	(17	) 51,869
Corporate obligations due in more than one year	14,925	3	(16	) 14,912
U.S. Treasury securities due in one year or less	6,026	4	—	6,030
U.S. Treasury securities due in more than one year	—	—	—	—
Certificates of deposit due in one year or less	6,555	—	—	6,555
Certificates of deposit due in more than one year	7,565	—	—	7,565
Mortgage and other asset backed securities due in one year or less	8,004	1	—	8,005
Mortgage and other asset backed securities due in more than one year	9,777	1	(2	) 9,776
Total available-for-sale securities	\$104,733	\$14	\$(35	) \$104,712
Total cash, cash equivalents and available-for-sale securities	\$148,171	\$14	\$(35	) \$148,150
	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	\$176,460	\$—	\$—	\$176,460
Available-for-sale securities:				
Total available-for-sale securities	—	—	—	—
Total cash, cash equivalents and available-for-sale securities	\$176,460	\$—	\$—	\$176,460

**6. Restricted Cash**

As of September 30, 2015 and December 31, 2014, the Company maintained letters of credit totaling \$0.8 million and \$0.9 million respectively held in the form of certificates of deposit as collateral for the Company's facility lease obligations and its credit cards.

**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 equivalents 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, management believes no additional credit risk beyond amounts provided for collection losses are 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, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			Total
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Observable Inputs (Level 2)	Other Significant Unobservable Inputs (Level 3)	
Assets:				
Money market funds	\$40,905	\$—	\$—	\$40,905
Corporate obligations	—	66,781	—	66,781
U.S. Treasury securities	—	6,030	—	6,030
Certificates of deposit	—	14,120	—	14,120
Mortgage and other asset backed securities	—	17,781	—	17,781
Restricted cash	796	—	—	796
Total assets	\$41,701	\$104,712	\$—	\$146,413
Liabilities:				
Warrants to purchase common stock	\$—	\$—	\$8,064	\$8,064
Total liabilities	\$—	\$—	\$8,064	8,064

	December 31, 2014			Total
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Observable Inputs (Level 2)	Other Significant Unobservable Inputs (Level 3)	
Assets:				
Money market funds	\$169,679	\$—	\$—	\$169,679
Restricted cash	902	—	—	902
Total assets	\$170,581	\$—	\$—	\$170,581
Liabilities:				
Warrants to purchase common stock	\$—	\$—	\$14,124	\$14,124
Total liabilities	\$—	\$—	\$14,124	\$14,124

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 have been classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

	Nine Months Ended September 30,	
	2015	2014
Beginning balance	\$14,124	\$30,753
Change in fair value	(5,595)	(8,124)
Exercises	(465)	(7,601)
Ending balance	\$8,064	\$15,028

The money market funds noted above are included in cash and cash equivalents in the accompanying balance sheets. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the nine months ended September 30, 2015 or the year ended December 31, 2014.

The fair value of the warrants to purchase common stock on the date of issuance and on each re-measurement date for those warrants to purchase common stock classified as liabilities was estimated using either the Black-Scholes option pricing

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model, due to the warrants being deeply in the money, or the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock. At each reporting period the Company evaluates the best valuation methodology, and at September 30, 2015, the Monte Carlo simulation framework 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, 2015 or the year ended December 31, 2014.

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, 2015 and December 31, 2014, the Company did not have any significant uncertain tax positions.

#### 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		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Outstanding stock options	3,328	3,459	3,328	3,459
Common stock warrants	398	610	398	610
Shares issuable under employee stock purchase plan	19	15	19	15
Restricted stock units	524	—	524	—
	4,269	4,084	4,269	4,084

#### 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 loss is presented separately on the consolidated balance sheets and consists entirely of cumulative unrealized gains and losses from short-term and long-term investments as of September 30, 2015.

#### 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, 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.



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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 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 does not expect adoption of this guidance will have a material impact on our financial statements.

## 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, 2015	December 31, 2014			September 30, 2015	December 31, 2014
Warrants to purchase common stock	393	409	5.88	June 10, 2020 - July 9, 2020	Liability(2)	Liability(2)
Warrants to purchase common stock	5	13	4.00 - 7.40	March 31, 2016 - December 31, 2017	Equity(1) (3) (4)	Equity(1) (3) (4)
All warrants	398	422	\$5.87			

(1) In March 2015, the warrant holders exercised warrants to purchase 5,029 shares of Common Stock on a net basis, resulting in the issuance of 4,519 shares of Common Stock.

(2) In May 2015, the warrant holders exercised warrants to purchase 16,665 shares of Common Stock on a net basis, resulting in the issuance of 13,588 shares of Common Stock.

(3) In August 2015, the warrant holders exercised warrants to purchase 2,399 shares of Common Stock on a net basis, resulting in the issuance of 2,075 shares of Common Stock.

(4) 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 remeasured the fair value of the outstanding warrants, using current assumptions, resulting in a decrease in fair value of \$2.6 million and \$3.4 million for the three months ended September 30, 2015 and 2014, respectively, and a decrease in fair value of \$5.6 million and \$8.1 million for the nine months ended September 30, 2015 and 2014, respectively, which was recorded in other 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, 2015 and December 31, 2014.

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### 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, 2015, 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, 2015 and December 31, 2014, 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 a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. There have been no material changes to the key terms of the Sotatercept and Luspatercept Agreements since December 31, 2014. For further information on our 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, 2014.

##### 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 for myelodysplastic syndromes (MDS), chronic kidney disease, and -thalassemia and will be responsible for any Phase 3 clinical trials, as well as additional Phase 2 clinical trials, and will be responsible for overseeing the manufacture of Phase 3 and commercial supplies by third party contract manufacturing organizations.

Through September 30, 2015, the Company has received \$42.9 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.



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### 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 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, 2015, the Company has received \$56.6 million in research and development funding and milestone payments for luspatercept. The next likely clinical milestone payment would be \$15.0 million and result from Celgene's start of a Phase 3 study in MDS or  $\alpha$ -thalassemia. The Company has not yet identified additional compounds for the treatment of anemia. Accordingly, there is no assurance that the Company will generate future value from additional programs.

### 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, 2015 and 2014, the Company recognized \$0.2 million and \$0.3 million, respectively, and during the nine months ended September 30, 2015 and 2014, the Company \$1.0 million and \$1.3 million, respectively, of the total deferred revenue as license and milestone revenue in the accompanying consolidated statements of operations and comprehensive loss.

As noted above, under the terms of the 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 \$3.9 million and \$3.2 million during the three months ended September 30, 2015 and 2014, respectively, and \$13.3 million and \$9.6 million during the nine months ended September 30, 2015 and 2014, respectively.

### Other Agreements

### Other

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

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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, 2015 and 2014, the Company expensed zero and \$0.1 million, respectively, and during the nine months ended September 30, 2015 and 2014, the Company expensed \$0.1 million and \$0.1 million, respectively, of milestones and fees defined under the agreement, which is recorded as research and development expense.

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, 2015 and 2014, 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 the nine months ended September 30, 2015 and 2014, 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 and 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, 2015 and 2014 and the nine months ended September 30, 2015 and 2014, the Company expensed milestones and fees of \$0.2 million, \$0.3 million, \$1.0 million and \$0.5 million, respectively, which is recorded as research and development expense.

#### 16. Stock-Based Compensation

The Company recognized stock-based compensation expense related to stock options, restricted stock units and the 2013 Employee Stock Purchase Plan (2013 ESPP) totaling \$3.1 million, \$1.2 million, \$8.3 million and \$3.3 million during the three months ended September 30, 2015 and 2014 and the nine months ended September 30, 2015 and 2014, 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		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Research and development	\$1,201	\$486	\$3,302	\$1,339
General and administrative	1,863	708	4,993	1,988
	\$3,064	\$1,194	\$8,295	\$3,327

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## 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		Nine Months Ended		
	September 30,		September 30,		
	2015	2014	2015	2014	
Expected volatility	66.0	% 70.7	% 67.1	% 71.2	%
Expected term (in years)	6.0	6.0	6.0	6.0	
Risk-free interest rate	1.7	% 1.9	% 1.7	% 1.8	%
Expected dividend yield	—	% —	% —	% —	%

The following table summarizes the stock option activity under the Company's share-based compensation plans during the nine months ended September 30, 2015 (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, 2014	3,230	\$9.77	6.43	
Granted	861	\$40.09		
Exercised	(722)	) \$4.14		
Canceled or forfeited	(42)	) \$31.19		
Outstanding at September 30, 2015	3,327	\$18.57	6.57	\$36,624
Exercisable at September 30, 2015	1,968	\$9.69	5.10	\$32,283
Vested and expected to vest at September 30, 2015(2)	3,259	\$18.23	6.52	\$36,514

(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, 2015.

This represents the number of vested options at September 30, 2015, plus the number of unvested options expected (2) to vest at September 30, 2015, based on the unvested options outstanding at September 30, 2015, adjusted for the estimated forfeiture rate.

During the nine months ended September 30, 2015, the Company granted stock options to purchase an aggregate of 861,176 shares of its common stock, with a weighted-average grant date fair value of options granted of \$24.34.

During the nine months ended September 30, 2015, current and former employees of the Company exercised a total of 721,655 options, resulting in total proceeds of \$3.0 million.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2015 was \$22.2 million.

As of September 30, 2015, there was \$22.1 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over a weighted-average period of 2.46 years.

## Restricted Stock Units

The following table summarizes the restricted stock unit activity under the 2013 Plan during the nine months ended September 30, 2015:

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	Number of Grants	Weighted- Average Grant Date Fair Value
Unvested balance at December 31, 2014	—	\$—
Granted	526,650	\$31.67
Vested	—	\$—
Forfeited	(2,500	) \$41.20
Unvested balance at September 30, 2015	524,150	\$31.67

As of September 30, 2015, there was \$15.3 million of unrecognized compensation expense related to unvested restricted stock units that is expected to be recognized over a weighted-average period of 3.03 years.

**Employee Stock Purchase Plan**

The Company recorded \$0.1 million and \$0.0 million during the three months ended September 30, 2015 and 2014, respectively, and \$0.2 million and \$0.0 million during the nine months ended September 30, 2015 and 2014, respectively.

**17. Income Taxes**

For the three and nine months ended September 30, 2015 and 2014, the Company did not record a current or deferred income tax expense or benefit.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of September 30, 2015 and December 31, 2014.

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, 2014. 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.

**18. Related Party Transactions****Celgene Corporation (Celgene)**

In connection with prior transactions, Celgene owned 12.3% and 12.8% of the Company's fully diluted equity as of September 30, 2015 and December 31, 2014, respectively. Refer to Note 15 for additional information regarding this collaboration agreement.

During the three and nine months ended September 30, 2015 and 2014, all revenue recognized by the Company was recognized under the Celgene collaboration arrangement and, as of September 30, 2015, the Company had \$5.0 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 information and the notes thereto included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014.

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", "contemplate", "continue", "could", "estimate", "expect", "forecast", "goal", "intend", "may", "plan", "potential", "predict", "project", "should", "strategy", "target", "will", "would", "vision", 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, 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 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 change 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 statement, 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 risk factors described in the section "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014 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 Information" and our financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutic candidates that are based on the mechanisms that the human body uses to regulate the growth and repair of its



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cells and tissues. Our research focuses on key natural regulators of cellular growth and repair, particularly the Transforming Growth Factor-Beta (TGF- $\beta$ ) protein superfamily. We are leaders 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. Our lead programs, luspatercept and sotatercept, are partnered with Celgene Corporation (Celgene). We and Celgene plan to initiate a Phase 3 program with luspatercept in myelodysplastic syndromes (MDS) and  $\beta$ -thalassemia by year-end 2015.

Luspatercept and sotatercept are designed to promote red blood cell production through a novel mechanism, and we are developing luspatercept to treat anemia and associated complications in patients with  $\beta$ -thalassemia and MDS. The red blood cell complications of  $\beta$ -thalassemia are generally unresponsive to currently approved drugs, and MDS is a heterogeneous disease for which certain subgroups of patients have no approved drug therapy. Sotatercept is also designed to promote increases in bone mineral density. We and Celgene are developing sotatercept for the treatment of chronic kidney disease, a disorder characterized by anemia and a mineral and bone disorder that leads to bone loss and heart disease. The mineral and bone disorder in these patients is not well-managed with current therapies. Our third clinical stage therapeutic candidate, dalantercept, is designed to treat cancers by inhibiting blood vessel formation through a mechanism that is distinct from, and potentially synergistic with, the dominant class of cancer drugs that inhibit blood vessel formation, the vascular endothelial growth factor, or VEGF, pathway inhibitors. We are developing dalantercept primarily for use in combination with VEGF pathway inhibitors to produce better outcomes for cancer patients. Our fourth therapeutic candidate, ACE-083, is designed to promote muscle growth and function in specific, treated muscle groups. In 2014, we initiated a Phase 1 clinical trial with ACE-083 in healthy volunteers. We have completed enrollment and treatment for the ACE-083 Phase 1 clinical trial, and we expect to initiate one or more Phase 2 clinical trials with ACE-083 in 2016.

We are developing sotatercept and luspatercept through our exclusive worldwide collaborations with Celgene. As of January 1, 2013, Celgene became responsible for paying 100% of worldwide development costs for both programs. We may receive up to an additional \$560.0 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 sotatercept and luspatercept, if approved, in North America for which our commercialization costs will be entirely funded by Celgene.

We have not entered into partnerships for dalantercept or ACE-083 and we retain worldwide rights to these programs. As of September 30, 2015, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$219.3 million from public investors, \$64.2 million in equity investments from our collaboration partners and \$229.5 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 equity, debt financings or other sources, including potential additional collaborations. However, we may be unable to raise

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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.

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
- the timing and receipt of any regulatory approvals.

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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 FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of 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, 2015, we have incurred \$380.4 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. Of the Phase 2 clinical trials that are underway for sotatercept, luspatercept and dalantercept, we are expensing the costs of clinical trials of luspatercept and dalantercept, of which the luspatercept clinical trials are reimbursed by Celgene. We are also expensing the costs of a Phase 1 clinical trial for ACE-083.

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 for luspatercept, dalantercept and ACE-083 (for which development commenced in the fourth quarter of 2013) during the three months ended September 30, 2015 and 2014 and the nine months ended September 30, 2015 and 2014 are as follows:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Luspatercept(1)	\$2,418	\$1,877	7,647	6,025
Dalantercept	2,463	1,226	6,555	4,211
ACE-083	291	982	2,058	3,533
Total direct research and development expenses	5,172	4,085	16,260	13,769
Other expenses(2)	8,163	7,791	26,001	22,549
Total research and development expenses	\$13,335	\$11,876	\$42,261	\$36,318

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

#### General and Administrative Expenses

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

Since the completion of our initial public offering in September 2013, we have experienced increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, director and officer insurance premiums, and investor relations costs associated with being a public company. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential

commercialization of our 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 Income, Net

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

To estimate the fair value of our liability classified warrants, we use either the Black-Scholes option pricing model, due to the warrants being deeply in the money, or the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock. 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 Monte Carlo simulation framework was used at September 30, 2015.

## 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, 2014. 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, 2014.

## Results of Operations

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

(in thousands)	Three Months Ended September 30,		Increase (Decrease)
	2015	2014	
Revenue:			
Collaboration revenue:			
License and milestone	\$205	\$280	\$(75 )
Cost-sharing, net	3,950	3,228	722
Total revenue	4,155	3,508	647
Costs and expenses:			
Research and development	13,335	11,876	1,459
General and administrative	5,433	3,023	2,410
Total costs and expenses	18,768	14,899	3,869
Loss from operations	(14,613 )	(11,391 )	(3,222 )
Other income, net	2,755	3,419	(664 )
Net loss	\$(11,858 )	\$(7,972 )	\$(3,886 )

Revenue. We recognized revenue of \$4.2 million in the three months ended September 30, 2015, compared to \$3.5 million in the same period in 2014. All of the revenue in both periods was derived from the Celgene agreements. This \$0.6 million increase was primarily due to higher cost sharing revenue of \$0.7 million caused by higher expenses for luspatercept clinical trials and manufacturing bulk drug substance during 2015.

Research and Development Expenses. Research and development expenses were \$13.3 million in the three months ended September 30, 2015, compared to \$11.9 million in the same period in 2014. This \$1.5 million increase was primarily due to an increase in clinical and toxicology expenses totaling \$1.0 million and increases in personnel expenses of \$0.6 million.

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**General and Administrative Expenses.** General and administrative expenses were \$5.4 million in the three months ended September 30, 2015, compared to \$3.0 million for the same period in 2014. This \$2.4 million increase was primarily due to an increase in personnel expenses totaling \$2.3 million.

**Other Income, Net.** Other income, net was \$2.8 million in the three months ended September 30, 2015, compared to \$3.4 million for the same period in 2014. This \$0.7 million decrease was due to a \$0.8 million difference in the effect of marking the common warrant liability to market in each period offset by an increase in interest income of \$0.1 million.

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

(in thousands)	Nine Months Ended September 30,		Increase
	2015	2014	(Decrease)
Revenue:			
Collaboration revenue:			
License and milestone	\$ 1,008	\$ 1,302	\$(294 )
Cost-sharing, net	13,286	9,592	3,694
Total revenue	14,294	10,894	3,400
Costs and operating expenses:			
Research and development	42,261	36,318	5,943
Litigation settlement	—	5,000	(5,000 )
General and administrative	14,796	10,485	4,311
Total costs and expenses	57,057	51,803	5,254
Income (loss) from operations	(42,763 )	(40,909 )	(1,854 )
Other expense, net	5,951	7,267	(1,316 )
Net loss	\$(36,812 )	\$(33,642 )	\$(3,170 )

**Revenue.** We recognized revenue of \$14.3 million in the nine months ended September 30, 2015, compared to \$10.9 million in the same period in 2014. All of the revenue in both periods was derived from the Celgene agreement. This \$3.4 million increase was primarily due to higher cost sharing revenue of \$3.7 million caused by higher expenses for luspatercept clinical trials and manufacturing bulk drug substance during 2015.

**Research and Development Expenses.** Research and development expenses were \$42.3 million in the nine months ended September 30, 2015, compared to \$36.3 million in the same period in 2014. This \$5.9 million increase was primarily due to an increase in clinical and toxicology expenses totaling \$3.1 million and increases in personnel expenses of \$2.5 million.

**Litigation settlement.** Legal settlements in the nine months ended September 30, 2015 were zero compared to \$5.0 million in the same period in 2014. The settlement to end ongoing litigation was accrued as of June 30, 2014.

**General and Administrative Expenses.** General and administrative expenses were \$14.8 million in the nine months ended September 30, 2015, compared to \$10.5 million for the same period in 2014. This \$4.3 million increase was primarily due to an increase in personnel expenses totaling \$4.9 million, offset by a decrease in fees primarily associated with debt prepayment of \$0.7 million for the nine months ended September 30, 2014.

**Other Income, Net.** Other income, net was \$6.0 million in the nine months ended September 30, 2015, compared to \$7.3 million for the same period in 2014. This \$1.3 million decrease was primarily due a \$2.5 million difference in the effect of marking the common warrant liability to market in each period offset by a decrease of \$0.9 million in interest expense because our outstanding long term debt was retired during March 2014. In addition, interest income in the nine months ended September 30, 2015 increased by \$0.3 million.

#### 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, 2015, we had an accumulated deficit of \$280.4 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of equity, debt financings or other sources, including potential additional

collaborations.

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As of September 30, 2015, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$219.3 million from public investors, \$64.2 million in equity investments from our collaboration partners and \$229.5 million in upfront payments, milestones, and net research and development payments from our collaboration partners.

As of September 30, 2015, we had \$148.1 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 2017.

**Cash Flows**

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

(in thousands)	Nine Months Ended	
	September 30, 2015	2014
Net cash (used in) provided by:		
Operating activities	\$(31,750 )	\$(39,601 )
Investing activities	(104,849 )	(498 )
Financing activities	3,577	116,192
Net (decrease) increase in cash and cash equivalents	\$(133,022 )	\$76,093

**Operating Activities**

Net cash used in operating activities was \$31.8 million for the nine months ended September 30, 2015 compared to \$39.6 million in the same period in 2014. The decrease was primarily due to a decrease in operating assets and liabilities of \$3.5 million, primarily due to changes in accrued expenses, offset by an increase in net loss of \$3.2 million and a non-cash expense increase of \$7.5 million including stock-based compensation expense and the effect of marking the common warrant liability to market.

**Investing Activities**

Net cash used in investing activities was \$104.8 million for the nine months ended September 30, 2015 and \$0.5 million for the nine months ended September 30, 2014. The significant increase in 2015 was due to the purchase of investments. During the nine months ended September 30, 2014 the Company only had cash and cash equivalents.

**Financing Activities**

Net cash provided by financing activities was \$3.6 million for the nine months ended September 30, 2015 compared to \$116.2 million during the nine months ended September 30, 2014. The decrease is primarily because of \$129.2 million in net proceeds received from our public offering in January 2014, offset by \$16.3 million of principal repayments to pay off our venture debt line in March 2014.

**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 incident 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 2017. 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 \$89.8 million as of December 31, 2014, 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, 2014, we had federal NOL carryforwards of approximately \$211.2 million and state NOL carryforwards of \$165.0 million available to reduce future taxable income, if any. These federal NOL carryforwards expire at various times through 2034 and the state NOL carryforwards expire at various times through 2034. 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 12 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2014.



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Contractual Obligations and Commitments

During the three months ended September 30, 2015, 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, 2014.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, see Recently Adopted Accounting Pronouncements 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, 2015 and December 31, 2014, we had cash, cash equivalents and investments of \$148.1 million and \$176.5 million, respectively. Our cash equivalents are invested primarily in money market 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. 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 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, 2015, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2015, 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.

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, 2014.

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

(a) Unregistered Sales of Equity Securities

We issued the following unregistered securities during the three months ended September 30, 2015:

In August 2015, we issued 2,075 shares of Common Stock upon the cashless exercise of warrants to purchase 2,399 shares of Common Stock.

These issuances of shares of our Common Stock were exempt from registration under the Securities Act pursuant to Rule 506 of Regulation D of the Securities Act and Section 4(a)(2) of the Securities Act.

Item 6. Exhibits

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

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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 4, 2015

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

Date: November 4, 2015

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
10.1*	First Amendment to Amended and Restated Employment Agreement, by and between Steven D. Ertel and Acceleron Pharma Inc., dated as of September 9, 2015 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed September 11, 2015)
10.2*	First Amendment to Amended and Restated Employment Agreement, by and between Kevin F. McLaughlin and Acceleron Pharma Inc., dated as of September 9, 2015 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed September 11, 2015)
10.3*	Form of Restricted Stock Unit Award Agreement under the 2013 Equity Incentive Plan (Executives) (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed September 11, 2015)
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

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\*Management contract or compensatory plan or arrangement.