ACCELERON PHARMA INC
Form 10-Q
August 04, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-36065

ACCELERON PHARMA INC.
(Exact name of registrant as specified in its charter)

Delaware	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 x No o

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

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

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

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

As of July 31, 2016, there were 37,596,691 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)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$36,995	$27,783
Collaboration receivables (all amounts are with related party)	3,239	3,628
Prepaid expenses and other current assets	3,081	2,458
Short-term investments	83,724	77,064
Total current assets	127,039	110,933
Property and equipment, net	4,190	3,106
Restricted cash	996	796
Other assets	8	368
Long-term investments	141,997	31,134
Total assets	$274,230	$146,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$566	$875
Accrued expenses	11,824	12,400
Deferred revenue	541	555
Deferred rent	762	661
Total current liabilities	13,693	14,491
Deferred revenue, net of current portion	3,973	4,239
Deferred rent, net of current portion	1,340	1,157
Warrants to purchase common stock	11,368	17,187
Total liabilities	30,374	37,074
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Undesignated preferred stock, $0.001 par value: 25,000,000 shares authorized and no shares issued or outstanding	—	—
Common stock, $0.001 par value: 175,000,000 shares authorized; 37,328,903 and 33,313,355 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	38	34
Additional paid-in capital	567,999	416,926
Accumulated deficit	(324,433)	(307,477)
Accumulated other comprehensive income (loss)	252	(220)
Total stockholders' equity	243,856	109,263
Total liabilities and stockholders' equity	$274,230	$146,337

See accompanying notes to these condensed consolidated financial statements.

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Acceleron Pharma Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(amounts in thousands except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue:				
License and milestone	$135	$431	$15,279	$803
Cost-sharing, net	3,060	5,286	6,117	9,336
Total revenue (all amounts are with related party)	3,195	5,717	21,396	10,139
Costs and expenses:				
Research and development	16,138	14,150	32,390	28,930
General and administrative	6,712	4,661	12,618	9,360
Total costs and expenses	22,850	18,811	45,008	38,290
Loss from operations	(19,655)	(13,094)	(23,612)	(28,151)
Other (expense) income, net:				
Other (expense) income, net	(2,864)	2,557	5,819	2,979
Interest income	503	154	837	217
Total other (expense) income, net	(2,361)	2,711	6,656	3,196
Net loss applicable to common stockholders	$(22,016)	$(10,383)	$(16,956)	$(24,955)
Net loss per share applicable to common stockholders-basic and diluted (Note 9)	$(0.59)	$(0.32)	$(0.46)	$(0.76)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders-basic and diluted	37,272	32,870	37,092	32,754
Other comprehensive loss:				
Net loss	$(22,016)	$(10,383)	$(16,956)	$(24,955)
Net unrealized holding gains (losses) on short-term and long-term investments during the period	227	(19)	472	(62)
Comprehensive loss	$(21,789)	$(10,402)	$(16,484)	$(25,017)

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)

	Six Months Ended June 30,	
	2016	2015
Operating Activities		
Net loss	$(16,956)	$(24,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	715	574
Loss on disposition of fixed assets	19	12
Stock-based compensation	8,800	5,231
Change in fair value of warrants	(5,819)	(2,979)
Net amortization of premium on investments	(432)	(777)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(619)	648
Collaboration receivables	389	(1,919)
Accounts payable	(309)	1,066
Accrued expenses	(525)	1,373
Restricted cash	(200)	—
Deferred revenue	(280)	(803)
Deferred rent	284	(244)
Net cash used in operating activities	(14,933)	(22,773)
Investing Activities		
Purchase of investments	(160,798)	(132,709)
Proceeds from maturities of investments	44,178	14,985
Purchases of property and equipment	(1,560)	(244)
Net cash used in investing activities	(118,180)	(117,968)
Financing Activities		
Proceeds from issuance of common stock from public offering, net issuance costs	140,391	—
Proceeds from exercise of stock options and warrants to purchase common stock	1,550	2,130
Proceeds from issuances of common stock related to employee stock purchase plan	384	307
Net cash provided by financing activities	142,325	2,437
Net increase (decrease) in cash and cash equivalents	9,212	(138,304)
Cash and cash equivalents at beginning of period	27,783	176,460
Cash and cash equivalents at end of period	$36,995	$38,156
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Reclassification of warrant liability to additional paid-in capital	$—	$465
Purchase of property and equipment included in accounts payable and accrued expenses	$258	$157

See accompanying notes to these condensed consolidated financial statements.

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Acceleron Pharma Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

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

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

2. Basis of Presentation

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

The accompanying interim condensed consolidated financial statements are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2015, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2016, and the results of its operations and its cash flows for the three and six months ended June 30, 2016 and 2015.

The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, together with Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

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

The accompanying interim condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the financial statements. As of June 30, 2016, the Company's significant accounting policies and estimates, which are detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, have not changed.

3. Use of Estimates

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

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used

in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of

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reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the consolidated financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: revenue recognition, stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of liability-classified warrants, accrued expenses, and the recoverability of the Company's net deferred tax assets and related valuation allowance.

4. Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment, which is the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. The Company does use contract research organizations and research institutions located outside the United States. Some of these expenses are subject to collaboration reimbursement which is presented as a component of cost sharing, net in the consolidated statements of operations and comprehensive loss.

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

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

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

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

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

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

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

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	$36,995	$ —	$ —	$ 36,995
Available-for-sale securities:				
Corporate obligations due in one year or less	45,836	10	(10)	45,836
Corporate obligations due in more than one year	53,187	155	(9)	53,333
U.S. Treasury securities due in one year or less	7,497	7	—	7,504
U.S. Treasury securities due in more than one year	26,535	86	—	26,621
Certificates of deposit due in one year or less	19,116	—	—	19,116
Certificates of deposit due in more than one year	11,746	—	—	11,746
Mortgage and other asset backed securities due in one year or less				