Regulus Therapeutics Inc.
Form 10-Q
November 02, 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 SEPTEMBER 30, 2016
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO
Commission file number: 001-35670
Regulus Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	26-4738379
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
10614 Science Center Drive San Diego, CA	92121
(Address of Principal Executive Offices)	(Zip Code)

858-202-6300
(Registrant's Telephone Number, Including Area Code)

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 ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
As of October 28, 2016, the registrant had 52,923,305 shares of Common Stock ($0.001 par value) outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Regulus Therapeutics Inc.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 14,706	$ 15,960
Short-term investments	76,877	98,103
Restricted cash	80	1,256
Prepaid expenses	10,614	8,159
Contract and other receivables	286	10,021
Other current assets	267	759
Total current assets	102,830	134,258
Property and equipment, net	12,042	5,400
Intangibles, net	1,051	1,081
Other assets	343	344
Total assets	$ 116,266	$ 141,083
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,724	$ 2,717
Accrued liabilities	5,066	6,329
Accrued compensation	2,290	2,392
Current portion of deferred revenue	72	1,194
Total current liabilities	13,152	12,632
Term loan, less debt issuance costs	19,787	—
Deferred revenue, less current portion	2,011	2,065
Other long-term liabilities	8,631	2,308
Total liabilities	43,581	17,005
Commitments and Contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized, 52,923,305 and 52,669,266 shares issued and outstanding at September 30, 2016 (unaudited) and December 31, 2015, respectively	53	53
Additional paid-in capital	326,076	315,673
Accumulated other comprehensive loss	(113)	(133)
Accumulated deficit	(253,331)	(191,515)
Total stockholders' equity	72,685	124,078
Total liabilities and stockholders' equity	$ 116,266	$ 141,083

See accompanying notes to these condensed financial statements.

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Regulus Therapeutics Inc.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
	(Unaudited)			
Revenues:				
Revenue under strategic alliances and collaborations	$204	$1,865	$1,176	$9,899
Total revenues	204	1,865	1,176	9,899
Operating expenses:				
Research and development	14,554	10,965	49,326	43,593
General and administrative	4,842	4,245	13,609	13,703
Total operating expenses	19,396	15,210	62,935	57,296
Loss from operations	(19,192)	(13,345)	(61,759)	(47,397)
Other income (expense):				
Interest and other income	237	335	608	686
Interest and other expense	(560)	(6)	(674)	(22)
Loss from valuation of convertible note payable	—	—	—	(1,811)
Loss before income taxes	(19,515)	(13,016)	(61,825)	(48,544)
Income tax (expense) benefit	(4)	16	9	22
Net loss	$(19,519)	$(13,000)	$(61,816)	$(48,522)
Other comprehensive loss:				
Unrealized (loss) gain on short-term investments, net	(30)	40	20	96
Comprehensive loss	$(19,549)	$(12,960)	$(61,796)	$(48,426)
Net loss per share, basic and diluted	$(0.37)	$(0.25)	$(1.17)	$(0.95)
Weighted average shares used to compute basic and diluted net loss per share	52,835,414	51,990,460	52,776,459	51,052,068

See accompanying notes to these condensed financial statements.

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Regulus Therapeutics Inc.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)

	Nine months ended September 30,	
	2016	2015
	(Unaudited)	
Operating activities		
Net loss	$(61,816)	$(48,522)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	1,589	1,177
Loss from valuation of convertible note payable	—	1,811
Stock-based compensation	9,453	11,607
Amortization of premium on investments, net	525	1,130
Other	338	73
Change in operating assets and liabilities:		
Contracts and other receivables	9,735	(50)
Prepaid expenses	(2,455)	(116)
Other assets	492	25
Accounts payable	3,007	1,024
Accrued liabilities	(1,187)	1,649
Accrued compensation	(102)	(109)
Deferred revenue	(1,176)	(2,257)
Deferred rent and other liabilities	(178)	(257)
Net cash used in operating activities	(41,775)	(32,815)
Investing activities		
Purchases of short-term investments	(60,716)	(67,064)
Sales and maturities of short-term investments	81,437	76,411
Purchases of property and equipment	(746)	(873)
Acquisition of intangibles	(48)	(40)
Net cash provided by investing activities	19,927	8,434
Financing activities		
Proceeds from borrowing under term loan, net	19,768	—
Proceeds from issuance of common stock, net	641	492
Proceeds from exercise of common stock options	309	5,001
Principal payments on other long-term obligations	(124)	(115)
Net cash provided by financing activities	20,594	5,378
Net decrease in cash and cash equivalents	(1,254)	(19,003)
Cash and cash equivalents at beginning of period	15,960	37,327
Cash and cash equivalents at end of period	$14,706	$18,324
Supplemental disclosure of cash flow information		
Net changes in restricted cash	$(1,176)	$1,400
Interest paid	$(518)	$(22)
Income taxes paid	$(1)	$(1)
Supplemental disclosure of non-cash investing and financing activities		
Allowance for tenant improvements	$6,653	$—
Amounts accrued for property and equipment	$14	$179
Amounts accrued for patent expenditures	$5	$—

See accompanying notes to these condensed financial statements.

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Regulus Therapeutics Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management's opinion, the accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results for the interim periods presented.

Interim financial results are not necessarily indicative of results anticipated for the full year. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2015, from which the balance sheet information herein was derived.

Use of Estimates

Our condensed financial statements are prepared in accordance with GAAP, which requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. An estimated loss contingency is accrued in our financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Although these estimates are based on our knowledge of current events and actions we may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

Revenue Recognition

Our revenues generally consist of upfront payments for licenses or options to obtain licenses in the future, milestone payments and payments for other research services under strategic alliance and collaboration agreements. We recognize revenues when all four of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

Multiple element arrangements, such as our strategic alliance agreements with Sanofi and AstraZeneca AB ("AstraZeneca"), are analyzed to determine whether the deliverables within the agreement can be separated or whether they must be accounted for as a single unit of accounting. Deliverables under the agreement will be accounted for as separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis; and (ii) if the agreement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The allocation of consideration amongst the deliverables under the agreement is derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence of fair value is not available. If the delivered element does not have stand-alone value, the arrangement is then accounted for as a single unit of accounting, and we recognize the consideration received under the arrangement as revenue on a straight-line basis, which approximates effort over our estimated period of performance, which for us is typically the expected term of the research and development plan.

Milestones

We apply the milestone method of accounting to recognize revenue from milestone payments when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance; (ii) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (iii) that would result in additional payments being due to us. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty's performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (i) the consideration is commensurate with either our performance to achieve the

milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone; (ii) the consideration relates solely to past performance; and (iii) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

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We assess whether a milestone is substantive at the inception of each arrangement. If a milestone is deemed non-substantive, we will account for that milestone payment using a method consistent with the related units of accounting for the arrangement over the estimated performance period.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized within the next 12 months are classified as non-current deferred revenue.

Stock-Based Compensation

We account for stock-based compensation expense related to stock options granted to employees and members of our board of directors by estimating the fair value of each stock option on the date of grant using the Black-Scholes option pricing model. We recognize stock-based compensation expense using the accelerated multiple-option approach. Under the accelerated multiple-option approach (also known as the graded-vesting method), we recognize compensation expense over the requisite service period for each separately vesting tranche of the award as though the award was in substance multiple awards, resulting in accelerated expense recognition over the vesting period. For performance-based awards granted to employees (i) the fair value of the award is determined on the grant date, (ii) we assess the probability of the individual milestones under the award being achieved and (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met.

We account for stock options granted to non-employees using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

Fair Value Option

Applicable accounting policies permit entities to choose, at specified election dates, to measure specified items at fair value if the decision about the election is: (1) applied instrument by instrument, (2) irrevocable, and (3) applied to an entire instrument. The balance of our convertible note payable, which was valued under the fair value option, was converted into shares of common stock in January 2015 (see Note 4).

Clinical Trial and Preclinical Study Accruals

We make estimates of our accrued expenses for clinical trial and preclinical study activities as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. These accruals are based upon estimates of costs incurred and fees that may be associated with services provided by clinical trial investigational sites, clinical research organizations (“CROs”) and for other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Restricted Cash

Restricted cash consists of amounts received for a specific and limited purpose, and therefore not available for general operating activities. In August 2015, we received $1.4 million in connection with our facility lease agreement with Walton Torrey Owner B, L.L.C, entered into in July 2015. The use of these funds are restricted to costs associated with the relocation of our corporate headquarters. As of September 30, 2016, our restricted cash balance was $0.1 million.

Prepaid Materials

We capitalize the purchase of certain raw materials and related supplies for use in the manufacturing of drug product in our clinical development programs, as we have determined that these materials have alternative future use. We can use these raw materials and related supplies in multiple clinical drug products, and therefore have future use

independent of the development status of any particular drug program until it is utilized in the manufacturing process. We periodically review these capitalized materials for indicators of impairment, including shelf life, continued alternative future use and obsolescence.

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We have not recorded any adjustments to the carrying value of these materials to date. As of September 30, 2016 and December 31, 2015, our prepaid materials balance was $6.9 million and $5.5 million, respectively, which amounts are included in prepaid expenses in our consolidated balance sheets.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers. Adoption of ASU No. 2014-09 requires that an entity recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This update is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein and requires expanded disclosures. We are currently evaluating the impact of adoption on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements Going Concern, which requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances. This standard is effective for annual reporting periods ending after December 15, 2016 and interim periods thereafter. Early application is permitted. The adoption of this guidance will have no impact on our financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Interest- Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs were not affected by the amendments in ASU No. 2015-03. In June 2016, upon entering into a loan and security agreement, we adopted ASU No. 2015-03, which resulted in the classification of $0.2 million of debt issuance costs against the principal balance of our outstanding term loan of $20.0 million.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which eliminates the requirement for public companies to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. Additionally, the standard requires public companies to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes. Furthermore, the standard requires presentation of financial assets and liabilities by measurement category and form of financial asset on the balance sheet or accompanying notes to the financial statements. The standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which increases transparency and comparability among organizations by requiring recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. The standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting, which is intended to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual reporting periods. Early application is permitted. We are currently evaluating the impact of adoption on our financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments, which addresses the presentation and classification of certain cash receipts and cash payments in the statement of cash flows under Accounting Standards Codification 230. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those fiscal years. Early application is permitted. The adoption of this guidance will have no impact on our financial statements.

2. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing net loss

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by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of options outstanding under our stock option plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted net loss per share.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive consisted of 3,131,911 and 3,762,952 shares attributable to common stock options for the three and nine months ended September 30, 2016, respectively, compared to 2,269,605 and 2,499,389 shares attributable to common stock options for the same periods in 2015.

3. Investments

We invest our excess cash in commercial paper and debt instruments of financial institutions and corporations. As of September 30, 2016, our short-term investments had a weighted average maturity of less than two years.

The following tables summarize our short-term investments (in thousands):

	Maturity (in years)	Amortized cost	Unrealized Gains	Losses	Estimated fair value
As of September 30, 2016					
Corporate debt securities	2 or less	$ 66,294	$ 14	$ (63)	$ 66,245
Certificates of deposit	2 or less	7,640	—	—	7,640
Commercial paper	1 or less	2,993	—	(1)	2,992
Total		$ 76,927	$ 14	$ (64)	$ 76,877

	Maturity (in years)	Amortized cost	Unrealized Gains	Losses	Estimated fair value
As of December 31, 2015					