

Regulus Therapeutics Inc.  
Form 10-Q  
November 06, 2014  
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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, 2014**

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**  
**(State or Other Jurisdiction of**

**Incorporation or Organization)**

**3545 John Hopkins Ct., Suite 210**

**San Diego, CA**  
**(Address of Principal Executive Offices)**

**858-202-6300**

**26-4738379**  
**(I.R.S. Employer**

**Identification No.)**

**92121**  
**(Zip Code)**

**(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  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  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

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

As of November 3, 2014, the registrant had 48,603,831 shares of Common Stock (\$0.001 par value) outstanding.

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**REGULUS THERAPEUTICS INC.**

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(in thousands, except share and per share data)

	<b>September 30, 2014 (Unaudited)</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,958	\$ 17,807
Short-term investments	84,107	96,198
Prepaid and other current assets	3,958	3,177
Total current assets	98,023	117,182
Property and equipment, net	3,840	3,768
Intangibles, net	1,114	1,128
Other assets	1,038	987
Total assets	\$ 104,015	\$ 123,065
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,642	\$ 1,172
Accrued liabilities	3,633	3,013
Accrued compensation	1,444	1,297
Current portion of deferred revenue	4,174	4,888
Total current liabilities	11,893	10,370
Convertible note payable, at fair value	10,665	11,279
Deferred revenue, less current portion	6,235	6,500
Other long-term liabilities	1,142	1,459
Total liabilities	29,935	29,608
Stockholders equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 43,439,562 and 41,787,326 shares issued and outstanding at September 30, 2014 (unaudited) and December 31, 2013, respectively	43	42
Additional paid-in capital	187,702	172,518
Accumulated other comprehensive loss	(66)	(16)

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Accumulated deficit	(113,599)	(79,087)
Total stockholders' equity	74,080	93,457
Total liabilities and stockholders' equity	\$ 104,015	\$ 123,065

See accompanying notes to these condensed financial statements.

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
	<b>(Unaudited)</b>			
<b>Revenues:</b>				
Revenue under strategic alliances and collaborations	\$ 1,083	\$ 6,118	\$ 3,450	\$ 14,115
<b>Total revenues</b>	<b>1,083</b>	<b>6,118</b>	<b>3,450</b>	<b>14,115</b>
<b>Operating expenses:</b>				
Research and development	10,173	7,106	30,572	21,710
General and administrative	2,569	1,917	8,255	5,545
<b>Total operating expenses</b>	<b>12,742</b>	<b>9,023</b>	<b>38,827</b>	<b>27,255</b>
Loss from operations	(11,659)	(2,905)	(35,377)	(13,140)
<b>Other income (expense):</b>				
Interest and other income	86	72	283	207
Interest expense	(10)	(7)	(31)	(25)
Gain (loss) from valuation of convertible note payable	1,785	671	614	(3,787)
Loss before income taxes	(9,798)	(2,169)	(34,511)	(16,745)
Income tax (benefit) expense		(5)	1	(4)
<b>Net loss</b>	<b>\$ (9,798)</b>	<b>\$ (2,164)</b>	<b>\$ (34,512)</b>	<b>\$ (16,741)</b>
<b>Other comprehensive loss:</b>				
Unrealized (loss) gain on short-term investments, net	(24)	37	(50)	8
<b>Comprehensive loss</b>	<b>\$ (9,822)</b>	<b>\$ (2,127)</b>	<b>\$ (34,562)</b>	<b>\$ (16,733)</b>
<b>Net loss per share:</b>				
Basic	\$ (0.23)	\$ (0.05)	\$ (0.80)	\$ (0.45)
Diluted	\$ (0.26)	\$ (0.07)	\$ (0.80)	\$ (0.45)

Weighted average shares used to compute net loss per share:

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Basic	43,406,251	40,154,812	43,155,601	37,367,368
Diluted	44,855,463	41,555,660	43,155,601	37,367,368

See accompanying notes to these condensed financial statements.

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**Regulus Therapeutics Inc.**  
**Condensed Statements of Cash Flows**

(In thousands)

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(Unaudited)</b>	
<b>Operating activities</b>		
Net loss	\$ (34,512)	\$ (16,741)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	1,098	996
(Gain) loss from valuation of convertible note payable	(614)	3,787
Stock-based compensation	4,710	2,524
Amortization of premium on investments, net	1,235	1,012
Loss on disposal of long-term assets	18	
Change in operating assets and liabilities:		
Contracts and other receivables	50	(95)
Prepaid and other assets	(882)	(512)
Accounts payable	1,470	829
Accrued liabilities	610	851
Accrued compensation	147	(120)
Deferred revenue	(980)	(11,615)
Deferred rent and other liabilities	(203)	68
Net cash used in operating activities	(27,853)	(19,016)
<b>Investing activities</b>		
Purchases of short-term investments	(52,268)	(50,390)
Maturities and sales of short-term investments	63,074	16,520
Purchases of property and equipment	(1,120)	(608)
Acquisition of intangibles	(53)	(46)
Net cash provided by (used in) investing activities	9,633	(34,524)
<b>Financing activities</b>		
Proceeds from issuance of common stock, net	9,853	46,562
Proceeds from exercise of common stock options	624	
Principal payments on other long-term obligations	(106)	(84)
Net cash provided by financing activities	10,371	46,478
Net decrease in cash and cash equivalents	(7,849)	(7,062)
Cash and cash equivalents at beginning of period	17,807	40,552



Cash and cash equivalents at end of period	\$ 9,958	\$ 33,490
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	\$ 30	\$
Income taxes paid	\$ 1	\$ 1
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Amounts accrued for property and equipment, net	\$	\$ 57
Allowance for tenant improvements	\$	\$ 947

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 Company s audited financial statements and footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2013, 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. 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, research and development funding and milestone payments under strategic alliance agreements, as well as funding received under government grants. We recognize revenues when all four of the following criteria are met: (1) persuasive evidence that 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, AstraZeneca AB ( AstraZeneca ), Glaxo Group Limited ( GSK ), an affiliate of GlaxoSmithKline plc, and our collaboration agreement with Biogen Idec MA Inc. ( Biogen Idec ), 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 units of accounting 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 over our estimated period of performance, which for us is often 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 acknowledgement 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.

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 in accordance with the multiple element arrangements guidance and recognize revenue consistent with the related units of accounting for the arrangement over the related performance period.

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### *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 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, which primarily consist of members of our scientific advisory board, 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.

In July 2012, we amended and restated the \$5.0 million convertible promissory note originally issued in February 2010 to GSK (the 2010 GSK Note ), which resulted in a debt extinguishment for accounting purposes. Concurrently with the debt extinguishment, we elected the fair value option for the 2010 GSK Note. The difference between the carrying value of the 2010 GSK Note and the fair value of the amended and restated 2010 GSK Note was recorded as a loss on extinguishment of debt to non-operating earnings. Thereafter, any change to the fair value of the amended note is recorded as gain (loss) from valuation of convertible note payable to non-operating earnings.

### **Clinical Trial and Pre-Clinical Study Accruals**

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our accrued expenses for pre-clinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by clinical trial investigational sites, clinical research organizations ( CROs ) and other clinical trial-related vendors. 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 service fees, 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 activity 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.

### **Recent Accounting Pronouncements**

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* ( ASU 2013-11 ). This update provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. We adopted this guidance in 2014 and it did not have a material impact on our financial condition, results of operations or related financial statement disclosures.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ( ASU 2014-19 ). 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, 2016 and interim periods therein and requires expanded disclosures. We are currently evaluating the impact of adoption on our financial position, results of operations and cash flows.

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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 position, results of operations or cash flows.

**2. Net Loss Per Share**

Basic net loss per share is calculated by dividing the 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 the net loss 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 plan and convertible note payable.

As of September 30, 2014, we had a convertible note payable outstanding with a principal balance of \$5.4 million that was convertible into shares of our common stock at a conversion price of \$4.00 per share, at the option of the note holder.

Applicable accounting standards provide that a contract convertible into common stock that is reported as an asset or liability for accounting purposes may require an adjustment to the numerator of the diluted earnings per share calculation for any changes in income or loss that would result if the contract had been reported as an equity instrument during the period. Securities are assumed to be converted at the beginning of the period, and the resulting shares of common stock are included in the denominator of the diluted earnings per share calculation for the entire period presented, if the effect is dilutive. Adding back the gain from the change in valuation of the convertible note payable for the three months ended September 30, 2014 and 2013 to the numerator and adding the number of shares to be issued upon conversion of the convertible note payable into the denominator of the diluted earnings per share calculation resulted in an increase to the net loss per share for the period. The impact of the conversion to the numerator and denominator for the nine months ended September 30, 2014 and 2013 was anti-dilutive, and therefore was excluded.

The following table summarizes the adjustment to net loss for the diluted net loss per share calculation for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (9,798)	\$ (2,164)	\$ (34,512)	\$ (16,741)
Less: gain from change in valuation of note payable	1,785	671		