



May 4, 2017

## **Regulus Reports First Quarter 2017 Financial Results and Corporate Restructuring**

**Company to Restructure Operations Accompanied by a Workforce Reduction  
Dr. Paul Grint, President and CEO, to Resign; Jay Hagan to Succeed Him  
Conference Call Today at 5:00 p.m. ET**

LA JOLLA, Calif., May 4, 2017 /PRNewswire/ -- [Regulus Therapeutics Inc.](#) (Nasdaq: RGLS), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, today reported financial results for the three months ended March 31, 2017. The Company also announced a corporate restructuring plan to streamline its operations as it focuses on its most promising discovery and development programs.



The restructuring includes an immediate workforce reduction of approximately 30%, which is expected to result in approximately \$6.0 million in annual savings after one-time restructuring costs. Also in line with the restructuring, the Board of Directors has accepted the resignation of Dr. Paul C. Grint, President and Chief Executive Officer and director, effective immediately, and appointed Joseph P. "Jay" Hagan, the Company's Chief Operating Officer, to the position of President and Chief Executive Officer and director, also effective immediately. The Company also promoted Daniel R. Chevallard, its Vice President, Finance and Accounting, to the position of Chief Financial Officer, effective immediately.

"We are very grateful for the leadership of Dr. Grint and the many contributions of our other impacted employees who have dedicated themselves to Regulus' efforts in advancing the science of microRNAs," said Stelios Papadopoulos, Chairman of the Board of Directors. "We are confident that Regulus is well positioned for success under Jay's guidance."

"Our priorities remain on our most promising programs allowing us to achieve anticipated milestones," said Jay Hagan, President and Chief Executive Officer of Regulus. "We continue to advance our clinical and pre-clinical pipeline, and importantly, are on track to commence the Phase II HERA and renal biopsy studies for RG-012 as planned."

### **Pipeline Update**

**RG-012 for the treatment of Alport Syndrome:** The Company has completed dosing of RG-012 in its Phase I multiple ascending dose (MAD) study and has selected the dose for the upcoming Phase II HERA and renal biopsy studies, which is expected to commence mid-2017. Preliminary data from the MAD study indicated that RG-012 was well tolerated with no serious adverse events (SAEs) reported in any subjects. The plasma PK profile of RG-012 was in-line with expectations, with a dose dependent increase in plasma exposure seen across the three dose groups. Data from the renal biopsy study is anticipated by year-end 2017, and interim data from the Phase II HERA study is anticipated in mid-2018.

### **Q1 Financial Results**

**Cash Position:** Cash, cash equivalents and short-term investments were \$57.5 million at March 31, 2017, compared with \$76.1 million at December 31, 2016.

**Research and Development (R&D) Expenses:** R&D expenses were \$15.8 million for the quarter ended March 31, 2017, compared to \$16.8 million for the quarter ended March 31, 2016. The decrease in R&D expenses was primarily driven by a decrease in spend on the RG-101 program due to the FDA clinical hold, partially offset by an increase in internal costs attributable to our preclinical pipeline.

**General and Administrative (G&A) Expenses:** G&A expenses were \$4.0 million for the quarter ended March 31, 2017, compared to \$5.1 million for the quarter ended March 31, 2016.

**Revenue:** Revenue was less than \$0.1 million for the quarter ended March 31, 2017, compared to \$0.5 million for the quarter ended March 31, 2016.

**Net Loss:** Net loss was \$20.0 million, or \$0.38 per share (basic and diluted), for the quarter ended March 31, 2017, compared to a net loss of \$21.2 million, or \$0.40 per share (basic and diluted), for the quarter ended March 31, 2016.

## Conference Call Details

Regulus will host a conference call and webcast at 5:00 p.m. Eastern Time today to discuss first quarter financial results and provide a general business update. A live webcast of the call will be available online at [www.regulusrx.com](http://www.regulusrx.com). To access the call, please dial (877) 257-8599 (domestic) or (970) 315-0459 (international) and refer to conference ID12962939. To access the replay of the call, dial (855) 859-2056 (domestic) or (404) 537-3406 (international), passcode 12962939. The webcast and telephone replay will be archived on the company's website following the call.

## About Regulus

Regulus Therapeutics Inc. (Nasdaq: RGLS) is a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs. Regulus has leveraged its oligonucleotide drug discovery and development expertise to develop a well-balanced microRNA therapeutics pipeline complemented by a rich intellectual property estate to retain its leadership in the microRNA field. Regulus is advancing several programs in renal, hepatic and central nervous systems diseases, both independently and with our strategic alliance partners, Sanofi and AstraZeneca. Regulus maintains its corporate headquarters in La Jolla, CA. For more information, please visit <http://www.regulusrx.com>.

## Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Regulus to undertake certain activities and accomplish certain goals (including with respect to development and other activities related to RG-101 or RG-012), the projected timeline of clinical development activities, and expectations regarding future therapeutic and commercial potential of Regulus' business plans, technologies and intellectual property related to microRNA therapeutics and biomarkers being discovered and developed by Regulus. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Regulus' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Regulus' financial position and programs are described in additional detail in Regulus filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Regulus undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**Regulus Therapeutics Inc.**  
**Selected Financial Information**  
**Condensed Statement of Operations**  
(In thousands, except share and per share data)

Three months ended	
March 31,	
2017	2016
_____	_____

Revenues:		
Revenue under strategic alliances	\$ 18	\$ 489
Operating expenses:		
Research and development	15,752	16,764
General and administrative	3,959	5,103
Total operating expenses	19,711	21,867
Loss from operations	(19,693)	(21,378)
Other (expense) income, net	(332)	166
Loss before income taxes	(20,025)	(21,212)
Income tax benefit	4	5
Net loss	\$ (20,021)	\$ (21,207)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.40)
Weighted average shares used to compute basic and diluted net loss per share:	52,990,383	52,710,672

**Regulus Therapeutics Inc.**  
**Condensed Balance Sheets**  
(In thousands)

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Cash, cash equivalents and short-term investments	\$ 57,464	\$ 76,111
Total assets	80,174	100,661
Term loan, less debt issuance costs	19,816	19,802
Stockholders' equity	\$ 38,728	\$ 56,075

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/regulus-reports-first-quarter-2017-financial-results-and-corporate-restructuring-300451797.html>

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