

March 7, 2017



# Rigel Announces Fourth Quarter 2016 and Year End 2016 Financial Results and Provides Company Update

## Conference Call and Webcast Today at 5:00 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., March 7, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today reported financial results for the fourth quarter and year ended December 31, 2016.

### Recent Achievements

- In August and October 2016, Rigel reported results from the three FIT Phase 3 clinical studies of fostamatinib in immune thrombocytopenia (ITP), which showed a consistent fostamatinib response rate.
- In January 2017, Rigel announced its post hoc calculations of the overall response rate for two FIT Phase 3 clinical studies (Study 047 and Study 048) by combining stable and intermediate responders. The overall response rate to fostamatinib of stable and intermediate responders is 29% (29/101) compared to 2% (1/49) for placebo ( $p < 0.0001$ ).
- In January 2017, Rigel also announced additional data for the FIT Phase 3, open-label, extension study, which further validates fostamatinib as a potential new treatment option for some patients with ITP. Rigel believes that the data from the FIT Phase 3 clinical program support its intention to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) this month.
- In February 2017, Rigel completed an underwritten public offering of 23,000,000 shares of common stock, which resulted in net proceeds to Rigel of approximately \$43.0 million, after deducting underwriting discounts and commissions and estimated offering expenses.
- In preparation for the potential launch of fostamatinib, Rigel has hired key executives, whose contributions will be instrumental in transitioning the organization into a profitable, commercial-stage biotechnology company.

"We believe that the favorable safety profile and demonstrated efficacy of fostamatinib may make it an excellent treatment option for patients with chronic ITP," said Raul Rodriguez, Rigel's president and chief executive officer. "The company expects to submit a New Drug

Application (NDA) for fostamatinib in ITP in the first quarter of 2017."

For the fourth quarter of 2016, Rigel reported a net loss of \$15.6 million, or \$0.16 per basic and diluted share, compared to a net loss of \$12.7 million, or \$0.14 per basic and diluted share, in the fourth quarter of 2015.

Contract revenues from collaborations of \$3.0 million in the fourth quarter of 2016 were related to the payment received from Bristol-Myers Squibb Company (BMS) pursuant to Rigel's collaboration and license agreement with BMS for the discovery, development and commercialization of potential immuno-oncology therapeutics. Contract revenues from collaborations of \$8.5 million in the fourth quarter of 2015 were primarily comprised of the amortization of the \$30.0 million upfront payment from BMS, as well as a license fee from a third party.

Rigel reported total costs and expenses of \$18.8 million in the fourth quarter of 2016, compared to \$21.3 million in the fourth quarter of 2015. The decrease in costs and expenses was primarily due to the reduction in workforce in September 2016, partially offset by the increase in stock-based compensation expense, mainly related to certain performance-based stock options.

For the year ended December 31, 2016, Rigel reported contract revenues from collaborations of \$20.4 million and a net loss of \$69.2 million, or \$0.73 per basic and diluted share, compared to contract revenues from collaborations of \$28.9 million and a net loss of \$51.5 million, or \$0.58 per basic and diluted share, in 2015. Contract revenues from collaborations in 2016 were mainly comprised of the \$13.4 million amortization of the upfront payment, \$3.0 million contingent payment received and \$290,000 in FTE fees we earned from BMS, as well as the \$3.7 million contingent payment received from BerGenBio AS. Contract revenues from collaborations in 2015 were mainly comprised of \$16.6 million amortization of the upfront payment from BMS and upfront payments received from other collaborators.

As of December 31, 2016, Rigel had cash, cash equivalents and short-term investments of \$74.8 million, compared to \$126.3 million as of December 31, 2015. In February 2017, Rigel completed an underwritten public offering in which it received net proceeds of approximately \$43.0 million after deducting underwriting discounts and commissions and estimated offering expenses.

Rigel expects that its cash, cash equivalents and short-term investments will be sufficient to support its current and projected funding requirements, including the preparation for the potential commercial launch of fostamatinib in ITP in the U.S., through at least the next 12 months. Rigel continues to evaluate ex-U.S. partnerships for fostamatinib and other partnering opportunities across its pipeline.

## **Portfolio Update**

### **Fostamatinib in Immune Thrombocytopenia (ITP)**

During the fourth quarter of 2016, Rigel continued to report topline results for its FIT Phase 3 clinical studies of fostamatinib in ITP. Results from the FIT Phase 3 clinical studies demonstrated that patients who responded to fostamatinib have a timely, robust, and sustained response to treatment. Seventeen patients who achieved a stable response to

fostamatinib in the parent studies (047, 048) enrolled in the open-label, long-term extension study (049). As of September 2016, these responders had been on fostamatinib treatment for a median of 16 months and maintained a median platelet count over 100,000/ $\mu$ L.

Rigel also recently announced its calculations of an overall response rate for Study 047 and Study 048 by combining stable and intermediate responders. The overall response rate to fostamatinib of stable and intermediate responders is 29% (29/101) compared to 2% (1/49) for placebo ( $p < 0.0001$ ). In this post-study analysis performed by Rigel, an intermediate response was defined to include patients achieving at least 2 consecutive median platelet counts over 50,000/ $\mu$ L during study without rescue, but who did not otherwise meet the stable response criteria. Also notable:

- Data from the FIT Phase 3 clinical program (comprised of Study 047, 048 and 049) demonstrate that fostamatinib works effectively for certain ITP patients and that the benefit was consistent across all sub-groups analyzed including TPO (blood platelet production booster) experienced patients who have limited treatment options remaining.
- Adverse events (AEs) in the fostamatinib group in Study 047 and 048 were generally mild or moderate, with gastrointestinal-related AEs reported most frequently, and were reversible over time.
- In Study 049, 41 former placebo patients newly exposed to fostamatinib for a minimum of 12 weeks achieved a prospectively defined stable platelet response of 22% (9/41,  $p = 0.0078$ ). Rigel believes this further validates fostamatinib as a potential new treatment option for some patients with this serious disease.

### **Fostamatinib in IgA nephropathy (IgAN)**

In January 2017, Rigel reported results from the first cohort in the Phase 2 clinical study of fostamatinib in IgAN, which evaluated the efficacy, safety, and tolerability of a low dose of fostamatinib (100mg BID,  $n = 26$ ; placebo  $n = 12$ ) as measured by change in proteinuria, renal function, and histology (comparing the pre- and post-study renal biopsies). The primary efficacy endpoint was the mean change of proteinuria from baseline at 24 weeks. The study found that at 24 weeks fostamatinib was well tolerated with a good safety profile and data suggest a trend towards a greater reduction in proteinuria in fostamatinib treated patients relative to placebo. Rigel expects that the second cohort, evaluating a higher dose of fostamatinib (150mg BID) for IgAN, will finish enrollment in 2017 with results in 2018.

### **Additional Product Development**

- Rigel expects to complete enrollment and have results from its proof-of-concept study of fostamatinib in patients with autoimmune hemolytic anemia (AIHA) in 2017.
- Pursuant to Rigel's license agreement with BerGenBio AS, Rigel received a milestone payment of \$3.3 million in the first quarter of 2017. This is the result of BerGenBio AS advancing BGB324, its selective, potent and orally available small molecule AXL kinase inhibitor, to a Phase 2 clinical study. BGB324 is the most advanced, selective AXL kinase inhibitor and was discovered by Rigel and licensed to BerGenBio AS.
- Rigel plans on selecting a molecule from its IRAK program for preclinical development in 2017. It is expected that the program will include clinical evaluation in immunology areas, such as for lupus, gout and/or psoriasis.

### **Conference Call and Webcast Today at 5:00PM Eastern Time**

Rigel will hold a live conference call and webcast today at 5:00pm Eastern Time (2:00pm Pacific Time).

Participants can access the live conference call by dialing 855-892-1489 (domestic) or 720-634-2939 (international) and using the Conference ID number 75337580. The conference call and accompanying slide presentation will also be webcast live and can be accessed from Rigel's website at [www.rigel.com](http://www.rigel.com). The webcast will be archived and available for replay after the call via the Rigel website.

### **About Rigel ([www.rigel.com](http://www.rigel.com))**

Rigel Pharmaceuticals, Inc. is a clinical-stage biotechnology company dedicated to the discovery and development of novel, targeted drugs in the therapeutic areas of immunology, oncology and immuno-oncology. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's current clinical programs include clinical studies of fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor in a number of indications. The company completed and reported results from the FIT Phase 3 clinical program of fostamatinib in chronic immune thrombocytopenia (ITP). Rigel is also conducting a Phase 2 clinical study with fostamatinib in autoimmune hemolytic anemia (AIHA) and a Phase 2 clinical study for IgA nephropathy (IgAN). In addition, Rigel has two oncology product candidates in development with partners BerGenBio AS (Phase 2) and Daiichi Sankyo (Phase 1).

*This press release contains "forward-looking" statements relating to, among other things, the timing of a potential New Drug Application submission to the Food and Drug Administration for fostamatinib in ITP; the management and advancement of Rigel's clinical programs; Rigel's belief that fostamatinib may be an attractive alternative for patients with ITP; Rigel's ability to successfully prepare for potential commercial launch of its product candidates; the sufficiency of Rigel's cash, cash equivalents, and short-term investments; Rigel's ability to extend the value of Rigel's pipeline into fields that are beyond its therapeutic focus; the evaluation of fostamatinib and Rigel's other product candidates for new treatment indications; and Rigel's product pipeline and development programs. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "planned," "will," "may," "expect," and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Rigel's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, the FDA may interpret our findings differently, which could result in the FDA not approving any submitted NDA, the availability of resources to develop Rigel's product candidates, the uncertain timing of completion of and the success of clinical studies, Rigel's need for additional capital in the future to sufficiently fund Rigel's operations and research, risks associated with and Rigel's dependence on Rigel's corporate partnerships, as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the period ended September 30, 2016. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.*

Contact: Ryan D. Maynard  
Phone: 650.624.1284  
Email: [invrel@rigel.com](mailto:invrel@rigel.com)

Media Contact: Jessica Daitch, Inventiv Health PR Group  
Phone: 917-816-6712  
Email: [jessica.daitch@inventivhealth.com](mailto:jessica.daitch@inventivhealth.com)



**RIGEL PHARMACEUTICALS, INC**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
	(unaudited)			
Revenues:				
Contract revenues from collaborations	\$ 3,000	\$ 8,537	\$ 20,383	\$ 28,895
Costs and expenses:				
Research and development (see Note A)	11,634	16,563	63,446	62,825
General and administrative (see Note A)	7,153	4,721	20,908	17,813
Restructuring charges (see Note A)	-	-	5,770	-
Total costs and expenses	<u>18,787</u>	<u>21,284</u>	<u>90,124</u>	<u>80,638</u>
Loss from operations	(15,787)	(12,747)	(69,741)	(51,743)
Interest income	109	60	437	222
Gain on disposal of assets	88	-	88	57
Net loss	<u>\$ (15,590)</u>	<u>\$ (12,687)</u>	<u>\$ (69,216)</u>	<u>\$ (51,464)</u>
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.14)</u>	<u>\$ (0.73)</u>	<u>\$ (0.58)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>98,981</u>	<u>89,038</u>	<u>94,387</u>	<u>88,434</u>

**Note A**

Stock-based compensation expense included in:				
General and administrative	\$ 2,309	\$ 707	\$ 4,230	\$ 3,303
Research and development	357	918	3,103	4,100
Restructuring charges	-	-	499	-
	<u>\$ 2,666</u>	<u>\$ 1,625</u>	<u>\$ 7,832</u>	<u>\$ 7,403</u>

**SUMMARY BALANCE SHEET DATA**  
(in thousands)

	December 31,	
	2016	2015
Cash, cash equivalents and short-term investments	\$ 74,766	\$ 126,276
Total assets	78,134	131,747
Stockholders' equity	55,027	91,381

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/rigel-announces-fourth-quarter-2016-and-year-end-2016-financial-results-and-provides-company-update-300419641.html>

SOURCE Rigel Pharmaceuticals, Inc.