

November 1, 2016



Rigel Announces Third Quarter 2016 Financial Results and Provides Company Update

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

SOUTH SAN FRANCISCO, Calif., Nov. 1, 2016 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today reported financial results for the third quarter and nine months ended September 30, 2016.

During the third quarter of 2016, Rigel accomplished a number of noteworthy milestones, most importantly, the announcement of topline results for its FIT Phase 3 clinical studies of fostamatinib in ITP. Additionally, the company undertook a restructuring to focus resources on building a commercial enterprise, and appointed executive-level members to the management team that will move Rigel forward toward its goals.

"We believe that the collective data from the FIT Phase 3 clinical program of fostamatinib support a clear treatment effect, a sustained clinical benefit and a positive benefit-risk profile," said Raul Rodriguez, president and chief executive officer of Rigel. "We look forward to discussing the top-line FIT program results with the FDA in the very near future, and obtaining their feed-back on our plan to submit an NDA. Assuming a successful discussion, we expect to submit the NDA in the first quarter of 2017."

For the third quarter of 2016, Rigel reported a net loss of \$22.6 million, or \$0.24 per basic and diluted share, compared to a net loss of \$6.7 million, or \$0.08 per basic and diluted share, in the same period of 2015.

Contract revenues from collaborations of \$3.8 million in the third quarter of 2016 represent the remaining amortization of the \$30.0 million upfront payment pursuant to Rigel's collaboration and license agreement with Bristol-Myers Squibb (BMS). Contract revenues from collaborations of \$13.0 million in the third quarter of 2015 were primarily comprised of an \$8.0 million upfront payment from Aclaris Therapeutics International Limited pursuant to the license agreement executed in August 2015 for the development and commercialization of certain Rigel JAK inhibitors, as well as \$4.8 million from the amortization of the upfront payment with BMS.

In September 2016, Rigel announced that it had reduced its workforce by 46 positions,

mostly in the research area. Rigel recorded restructuring charges during the third quarter of 2016 of approximately \$5.8 million, which included \$5.0 million of severance costs paid or to be paid in cash, \$319,000 impairment of certain property and equipment, and \$499,000 of non-cash stock-based compensation expense as a result of the modification of Rigel's former executive's stock options.

Rigel reported total costs and expenses of \$26.5 million in the third quarter of 2016, compared to \$19.8 million for the same period in 2015. The increase in costs and expenses was primarily due to restructuring charges incurred in the third quarter of 2016.

For the nine months ended September 30, 2016, Rigel reported a net loss of \$53.6 million, or \$0.58 per basic and diluted share, compared to a net loss of \$38.8 million, or \$0.44 per basic and diluted share, for the same period of 2015.

As of September 30, 2016, Rigel had cash, cash equivalents and short-term investments of \$85.3 million, compared to \$126.3 million as of December 31, 2015. Rigel expects this amount to be sufficient to fund its operations through the end of 2017. In this forecast, Rigel has allocated substantial funds to continue efforts in preparation of the potential commercial launch of fostamatinib in ITP in the U.S. Rigel also continues to evaluate ex-U.S. partnerships for fostamatinib and other partnering opportunities across its pipeline.

Company and Portfolio Update

Fostamatinib FIT Phase 3 Program

In August and October 2016, respectively, Rigel announced results of two identical Phase 3 clinical studies, FIT 1 (Study 047) and FIT 2 (Study 048), of fostamatinib in adult chronic/persistent immune thrombocytopenia (ITP). Study 047 met the primary endpoint in a statistically significant manner, with 18% of the patients in the fostamatinib arm achieving stable platelet response of greater than 50,000 platelets per μL of blood on at least four of the last scheduled visits between weeks 14 and 24 of treatment and no patients on placebo meeting the stable platelet response criteria ($p=0.0261$). Study 048, which also had an 18% responder rate for the fostamatinib subjects, did not achieve a statistically significant distinction between the treatment and placebo cohorts ($p=0.15$) because a single placebo patient met the stable platelet response criteria. When the data from the two studies are combined ($n=150$), the difference between the fostamatinib and placebo groups would be statistically significant ($p=0.007$).

Rigel also announced in October 2016 that as of June 2016, the open-label long-term extension study (Study 049), was tracking the experience of 118 patients who opted to receive treatment with fostamatinib after completing either Study 047 or Study 048. Patients who responded to fostamatinib in the parent studies had achieved a median platelet count of 96,000/ μL in Study 049. In addition, there were 36 patients out of 43 who were placebo non-responders in the parent studies who had a minimum of 12 weeks of follow-up in the extension study. Of those, 6 patients (17%) have achieved a prospectively defined stable platelet response, which is statistically significant and similar to the response rate fostamatinib achieved in the parent studies.

Rigel believes that the data from the FIT Phase 3 clinical program (comprised of Study 047, 048 and 049) demonstrate that fostamatinib works effectively for some ITP patients, providing a substantial and enduring clinical benefit in a disease that has proven difficult to manage for many physicians and patients. This benefit was consistent across all sub-groups

analyzed including TPO (blood platelet production booster) experienced patients who have limited treatment options remaining.

Rigel is continuing its work on compiling the NDA, which it plans to file in the first quarter of 2017, pending positive feedback from discussions of the data with the FDA.

Restructuring to Focus on Commercialization

Following the release of the results for Study 047, Rigel announced a restructuring and plans to build a commercial organization to support the potential launch of fostamatinib. The restructuring reduced the size of the research department while maintaining Rigel's most advanced and promising projects. The savings from the restructuring will be devoted to support the commercialization of the company's first potential drug product as well as extending the company's financial runway.

As part of the restructuring announcement in September, the first of Rigel's new management team members was introduced; Eldon Mayer joined the company as its first chief commercial officer. Mr. Mayer will be responsible for establishing and managing a commercial organization that will lead the launch of fostamatinib. He brings pharmaceutical marketing and sales management experience to Rigel, having most recently led Questcor Pharmaceuticals' commercial strategy and operations.

This quarter Rigel made additional key senior management appointments to drive the organization forward. Esteban Masuda, Ph.D. was appointed senior vice president research and will lead Rigel's refocused research efforts. Joe Lasaga was appointed vice president business development and alliance management and will lead Rigel's effort to partner certain assets including ex-U.S. partnerships for fostamatinib.

Clinical Portfolio Update

Fostamatinib Phase 2 Study in IgA Nephropathy (IgAN)

Rigel is conducting a global Phase 2, double blind, placebo-controlled study of fostamatinib in IgAN consisting of two sequential dose cohorts (100mg BID, followed by 150 mg BID). Enrollment for the first cohort has been completed and the company expects to report those results by the end of 2016. The second cohort is currently enrolling patients.

Fostamatinib Phase 2 Study in Autoimmune Hemolytic Anemia (AIHA)

Rigel is conducting a Phase 2, open-label, multi-center, two-stage study that will evaluate the safety and efficacy of fostamatinib in patients with warm antibody AIHA who have previously received treatment for the disorder, but have relapsed. Results of the Stage 1 segment of the trial are expected in 2017.

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 5733500. The conference call and accompanying slide presentation will also be webcast live and can be accessed from Rigel's website at www.rigel.com. The webcast will be archived and available for replay after the call via the Rigel website.

About Rigel (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 trials of fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor, in a number of indications. The company completed and reported results from two Phase 3 clinical studies of fostamatinib in chronic immune thrombocytopenia (ITP) in August and October 2016. Rigel is also conducting a Phase 2 clinical trial with fostamatinib in autoimmune hemolytic anemia (AIHA) and a Phase 2 clinical trial for IgA nephropathy (IgAN). In addition, Rigel has two oncology product candidates in Phase 1 development with partners BerGenBio AS and Daiichi Sankyo.

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 availability of resources to develop Rigel's product candidates, Rigel's need for additional capital in the future to sufficiently fund Rigel's operations and research, the uncertain timing of completion of and the success of clinical trials, 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 June 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

Media Contact: Susan C. Rogers, Rivily, Inc.

Phone: 650.430.3777

Email: susan@rivily.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(unaudited)			
Revenues:				
Contract revenues from collaborations	\$ 3,760	\$ 12,996	\$ 17,383	\$ 20,358
Costs and expenses:				
Research and development (see Note A)	16,171	15,501	51,812	46,262
General and administrative (see Note A)	4,558	4,276	13,755	13,092
Restructuring charges (see Note A)	5,770	-	5,770	-
Total costs and expenses	26,499	19,777	71,337	59,354
Loss from operations	(22,739)	(6,781)	(53,954)	(38,996)
Interest income, net	110	54	328	162
Gain on disposal of assets	-	55	-	57
Net loss	\$ (22,629)	\$ (6,672)	\$ (53,626)	\$ (38,777)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.08)	\$ (0.58)	\$ (0.44)
Weighted-average shares used in computing net loss per share, basic and diluted	95,454	88,506	92,844	88,231

Note A

Stock-based compensation expense included in:				
Research and development	\$ 643	\$ 966	\$ 2,746	\$ 3,182
General and administrative	572	849	1,921	2,596
Restructuring charges	499	-	499	-
	\$ 1,714	\$ 1,815	\$ 5,166	\$ 5,778

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30, 2016	December 31, 2015 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	\$ 85,255	\$ 126,276
Total assets	88,641	131,747
Stockholders' equity	65,943	91,381

(1) Derived from audited financial statements

Logo - <https://photos.prnewswire.com/prnh/20030226/RIGLLOGO>

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/rigel-announces-third-quarter-2016-financial-results-and-provides-company-update-300355221.html>

SOURCE Rigel Pharmaceuticals, Inc.

