May 2, 2017

Rigel Announces First Quarter 2017 Financial Results and Provides Company Update

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

SOUTH SAN FRANCISCO, Calif., May 2, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today reported financial results for the first quarter ended March 31, 2017.

Recent Achievements

- On April 27, 2017, Rigel announced the conditional acceptance by the U.S Food & Drug Administration (FDA) of the proprietary name Tavalisse™ for fostamatinib disodium, its lead investigational product candidate.
- On April 17, 2017, Rigel announced it submitted a New Drug Application (NDA) to the FDA for Tavalisse for the treatment of chronic and persistent immune thrombocytopenia (ITP). The FDA previously granted Orphan Drug designation to Tavalisse for the treatment of patients with ITP.
- 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 offering expenses paid by Rigel.

"The first quarter was an exciting time at Rigel as we achieved significant milestones related to our lead product candidate, Tavalisse, in ITP," said Raul Rodriguez, Rigel's president and chief executive officer. "Looking ahead, we hope to report on FDA acceptance of our submitted NDA for review by the end of the second quarter. In addition, we will continue to advance fostamatinib across other indications."

For the first quarter of 2017, Rigel reported a net loss of $15.3 million, or $0.13 per share, compared to a net loss of $17.5 million, or $0.19 per share, in the first quarter of 2016.

Contract revenues from collaborations of $3.6 million in the first quarter of 2017 is comprised primarily of the $3.3 million payment from BerGenBio AS as a result of advancing BGB324, its selective, potent and orally available small molecule AXL kinase inhibitor, to a Phase 2 clinical study. Contract revenues from collaborations of $5.0 million during the first quarter of 2016 were comprised of the $4.8 million amortization of the $30.0 million upfront payment,

which was fully amortized in September 2016, and $195,000 in FTE fees earned pursuant to Rigel's collaboration and license agreement with Bristol-Myers Squibb, for the discovery, development and commercialization of potential immuno-oncology therapeutics.

Rigel reported total costs and expenses of $19.8 million in the first quarter of 2017, compared to $22.6 million in the first quarter of 2016. The decrease in costs and expenses was primarily due to the decreases in personnel costs and research-related costs as a result of the reduction in workforce in September 2016, partially offset by the increases in costs related to NDA preparation, as well as preparation for the potential commercial launch of Tavalisse (fostamatinib disodium) in ITP.

As of March 31, 2017, Rigel had cash, cash equivalents and short-term investments of $98.1 million, compared to $74.8 million as of December 31, 2016. Rigel expects this amount will be sufficient to support its current and projected funding requirements, including the preparation for the potential commercial launch of Tavalisse in ITP in the U.S., through at least the next 12 months. Rigel continues to evaluate ex-U.S. partnerships for Tavalisse and other partnering opportunities across its pipeline.

Portfolio Update

Tavalisse (fostamatinib disodium) in ITP

On April 17, 2017, Rigel submitted an NDA to the FDA for Tavalisse for the treatment of patients with chronic and persistent ITP. The NDA is supported by data from the Phase 3 clinical program, which was comprised of three studies, two randomized placebo-controlled studies (Studies 047 and 048) and an open-label extension study (Study 049).

Fostamatinib in autoimmune hemolytic anemia (AIHA)

Enrollment remains on track for stage 1 of Rigel's Phase 2, open-label, multi-center, two-stage study of fostamatinib for the treatment of warm antibody autoimmune hemolytic anemia (AIHA). The SOAR study will evaluate the safety and efficacy of fostamatinib at 150 mg (oral, twice daily for 12 weeks) in approximately 17 patients with AIHA who have previously received treatment for the disorder, but have relapsed. Rigel expects to have results of the Stage 1 segment of the trial in 2017.

Fostamatinibin 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 the lower 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 the second cohort, evaluating a higher dose of fostamatinib (150mg BID) will finish enrollment in 2017 with results in 2018.

Additional Product Development

Rigel is selecting a molecule from its IRAK program for preclinical development. It is expected that the program will include clinical evaluation in immunology areas, such as for lupus, gout and/or psoriasis.

About ITP

In patients with ITP, the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. Common symptoms of ITP are excessive bruising and bleeding. People suffering with chronic ITP may live with increased risk of severe bleeding events that can result in serious medical complications, or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPOs) and splenectomy. However, a portion of patients do not derive a benefit from existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About AIHA

AIHA is a rare, serious blood disorder where the immune system produces antibodies that result in the destruction of the body's own red blood cells. AIHA affects approximately 40,000 adult patients in the US and can be a severe, debilitating anemia. To date, there are no FDA approved disease-targeted therapies for AIHA, despite the tremendous medical need that exists for these patients as disease relapse is common. Instead, physicians generally treat acute and chronic cases of the disorder with corticosteroids, IV immunoglobulin infusion, other immuno-suppressants, or splenectomy (the surgical removal of the spleen).

About IgAN

IgAN (also known as Berger's disease) is a chronic autoimmune disease associated with inflammation in the kidneys that diminishes their ability to filter blood. It is the most common primary glomerular disease affecting an estimated 82,500 to 165,000 cases in the US, with a higher prevalence in Asia. For as many as 25 percent of those living with IgAN, the disease results in end-stage renal failure requiring dialysis or kidney transplantation. Other than angiotensin blockade (primarily for blood-pressure control), there are no disease-targeted therapies for IgAN.

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 11028280. The conference call 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 submitted a NDA to the FDA for fostamatinib in patients with chronic and persistent immune thrombocytopenia (ITP) in April 2017. Rigel is also conducting Phase 2 clinical studies with fostamatinib in IgA nephropathy (IgAN) and autoimmune hemolytic anemia (AIHA). In addition, Rigel has product candidates in development with partners BerGenBio AS, Daiichi Sankyo and Aclaris Therapeutics.

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, the timing of a response from the FDA to our NDA submission and Rigel's belief that fostamatinib may be an attractive alternative for patients with ITP. 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," "conditional" 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 not accept our NDA submission; the FDA may interpret Rigel's findings differently, which could result in the FDA not approving any submitted NDA; 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 enrollment and completion of and the results of clinical studies; market competition, risks associated with and Rigel's dependence on Rigel's corporate partnerships; risks related to changes in estimated cash position based on the completion of financial closing procedures and the audit of Rigel's financial statements; as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 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.

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

	Three Months Ended March 31,	
	2017	2016
	(unaudited)	
Revenues:		
Contract revenues from collaborations	$ 3,584	$ 5,029
Costs and expenses:		
Research and development (see Note A)	12,376	18,173
General and administrative (see Note A)	7,410	4,423
Total costs and expenses	19,786	22,596
Loss from operations	(16,202)	(17,567)
Gain on disposal of assets	732	—
Interest income	156	103
Net loss	$ (15,314)	$ (17,464)
Net loss per share, basic and diluted	$ (0.13)	$ (0.19)
Weighted-average shares used in computing net loss per share, basic and diluted	113,598	90,555

Note A

Stock-based compensation expense included in:		
General and administrative	$ 595	$ 745
Research and development	360	693
	$ 955	$ 1,438

SUMMARY BALANCE SHEET DATA
(in thousands)

	March 31, 2017	December 31, 2016 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 98,141	$ 74,766
Total assets	101,326	78,134
Stockholders' equity	84,081	55,027

(1) Derived from audited financial statements

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/rigel-announces-first-quarter-2017-financial-results-and-provides-company-update-300449943.html

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