August 1, 2017

Rigel Announces Second Quarter 2017 Financial Results and Provides Company Update

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

SOUTH SAN FRANCISCO, Calif., Aug. 1, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today reported financial results for the second quarter and six months ended June 30, 2017.

Recent Achievements

- On June 19, 2017, Rigel announced the U.S Food & Drug Administration (FDA) had accepted for filing its New Drug Application (NDA) for the use of TAVALISSE™ (fostamatinib disodium) in patients with chronic or persistent immune thrombocytopenia (ITP).
- The FDA has set the date of April 17, 2018 to complete its review of fostamatinib in ITP under the Prescription Drug User Fee Act (PDUFA).
- Strengthened leadership team with three key hires to support its commercial and regulatory efforts.

"The FDA acceptance of our NDA for our lead product candidate, TAVALISSE™, in ITP is a significant milestone for us," said Raul Rodriguez, Rigel's president and chief executive officer. "Over the next nine months, we will work collaboratively with the FDA as they review our application. In addition, we will continue to prepare for the commercial launch of fostamatinib as well as explore its potential across other indications."

For the second quarter of 2017, Rigel reported a net loss of $19.1 million, or $0.16 per basic and diluted share, compared to a net loss of $13.5 million, or $0.15 per basic and diluted share, in the same period of 2016.

There were no contract revenues from collaborations in the second quarter of 2017. Contract revenues from collaborations of $8.6 million in the second quarter of 2016 were comprised of $4.8 million from the amortization of the $30.0 million upfront payment, which was fully amortized in September 2016, and $95,000 in FTE fees earned pursuant to Rigel's collaboration and license agreement with Bristol-Myers Squibb, as well as payments of $3.7 million that Rigel received pursuant to its license agreement with BerGenBio AS.

Rigel reported total costs and expenses of $19.3 million in the second quarter of 2017, compared to $22.2 million for the same period in 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 increase in costs related to the preparation for the potential commercial launch of fostamatinib in ITP.

For the six months ended June 30, 2017, Rigel reported a net loss of $34.5 million, or $0.29 per basic and diluted share, compared to a net loss of $31.0 million, or $0.34 per basic and diluted share, for the same period of 2016.

As of June 30, 2017, Rigel had cash, cash equivalents and short-term investments of $82.3 million, compared to $74.8 million as of December 31, 2016. Rigel expects that its cash, cash equivalents and short-term investments as of June 30, 2017 will be sufficient to support its current and projected funding requirements, including the preparation for the potential U.S. commercial launch, through at least the next 12 months. Rigel continues to evaluate ex-U.S. partnerships for fostamatinib and other partnering opportunities across its pipeline.

Corporate Update

In support of its regulatory process and commercial launch efforts, Rigel recently made three key hires. Dana Pizzuti, who was Vice President of Regulatory Affairs at Gilead Sciences since 2007 and facilitated the approval of 14 new medicines during her tenure there, joins as Senior Vice President of Regulatory Affairs and Clinical Quality Assurance; Giovanna Matthews joins as Executive Director, Market Access, bringing with her many years of great experience in Market Access and reimbursement; and, later this month Sandra Tong, M.D., most recently Vice President of Clinical Research at Plexxikon Inc. will join Rigel as Vice President, Clinical Science & Drug Safety.

Portfolio Update

TAVALISSE™ (fostamatinib disodium) in ITP

On June 19, 2017, Rigel announced that the FDA had accepted for filing its NDA for fostamatinib 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). Together with an initial proof of concept study, the NDA included 163 ITP patients. Across all indications, fostamatinib has been evaluated in over 4,600 patients. Data from all studies, including preclinical evaluation and drug manufacturing data, were included in the NDA submission.

Fostamatinib in autoimmune hemolytic anemia (AIHA)

Enrollment remains on track for Stage 1 (n=17) of Rigel's Phase 2, open-label, multi-center, two-stage study of fostamatinib for the treatment of warm antibody autoimmune hemolytic anemia (AIHA). Also known as the SOAR study, it will evaluate the safety and efficacy of fostamatinib (150mg BID, twice a day for 12 weeks) in patients with warm AIHA who have previously received at least one treatment for this disease, but have not benefited from it and are still anemic. Rigel expects to report preliminary results for Stage 1 of the study, which is over 70% enrolled, by the end of 2017. Rigel will evaluate the results from Stage 1 before proceeding to Stage 2 of the study, which would enroll another 20 patients using the same protocol.

Fostamatinib in IgA nephropathy (IgAN)
Enrollment continues in Rigel's second cohort in its Phase 2 study of fostamatinib (150mg BID) in IgAN. Similar to the first cohort, which reported results in January 2017, the study will evaluate the efficacy, safety, and tolerability of fostamatinib as measured by change in proteinuria, renal function, and histology (comparing the pre- and post-study renal biopsies). However, the second cohort evaluates a higher dose of fostamatinib, 150mg BID, whereas the first cohort evaluated 100mg BID. The primary efficacy endpoint is the mean change of proteinuria from baseline at 24 weeks. Rigel expects the second cohort will finish enrollment in 2017 with results in 2018.

Additional Product Development
During the second quarter, Rigel selected a molecule from its IRAK program for preclinical development. The molecule is differentiated in that it inhibits both the IRAK 1 and IRAK 4 signaling pathways, with potential to treat autoimmune and inflammatory diseases such as lupus, gout, psoriatic arthritis and multiple sclerosis. Rigel expects to initiate clinical trials in the first half of 2018.

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 complication, or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPOs) and splenectomy. However, not all patients are adequately treated with 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 55352069. 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 biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with immune and hematological disorders, cancer and rare diseases. 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. Rigel has submitted and the FDA has accepted for review, an NDA for fostamatinib in patients with chronic or persistent immune thrombocytopenia (ITP). 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 enrollment and results of on-going clinical trials; the results of the FDA's review of Rigel's NDA for fostamatinib in patients with chronic and persistent ITP; the sufficiency of Rigel's cash, cash equivalents and short-term investments to support its funding requirements through at least the next 12 months; and Rigel's evaluation of ex-US partnerships for fostamatinib and other partnering opportunities. 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 Rigel's findings differently, which could result in the FDA not approving the 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; market competition; 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 Quarterly Report on Form 10-Q for the period ended March 31, 2017. 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)			
Revenues:				
Contract revenues from collaborations	$ -	$ 8,594	$ 3,584	$ 13,623
Costs and expenses:				
Research and development (see Note A)	11,524	17,468	23,900	35,641
General and administrative (see Note A)	7,820	4,774	15,230	9,197
Total costs and expenses	19,344	22,242	39,130	44,838
Loss from operations	(19,344)	(13,648)	(35,546)	(31,215)
Gain on disposal of assets	—	—	732	—
Interest income	197	115	353	218
Net loss	$ (19,147)	$ (13,533)	$ (34,461)	$ (30,997)
Net loss per share, basic and diluted	$ (0.16)	$ (0.15)	$ (0.29)	$ (0.34)
Weighted-average shares used in computing net loss per share, basic and diluted	122,500	92,495	118,074	91,525

Note A

Stock-based compensation expense included in:				
General and administrative	$ 764	$ 604	$ 1,359	$ 1,349
Research and development	336	1,410	696	2,103
	$ 1,100	$ 2,014	$ 2,055	$ 3,452

SUMMARY BALANCE SHEET DATA
(in thousands)

	June 30, 2017	December 31, 2016 (1)
	(unaudited)	
	$	$
Cash, cash equivalents and short-term investments	82,302	74,766
Total assets	85,478	78,134
Stockholders' equity	69,605	55,027

(1) Derived from audited financial statements

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