UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 6, 2018**

RIGEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-29889	**94-3248524**
(Commission File No.)	(IRS Employer Identification No.)

1180 Veterans Boulevard
South San Francisco, CA
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code: **(650) 624-1100**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2018, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its third quarter ended September 30, 2018. A copy of Rigel's press release, titled "Rigel Announces Third Quarter 2018 Financial Results and Provides Company Update," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated November 6, 2018, titled "Rigel Announces Third Quarter 2018 Financial Results and Provides Company Update."

The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Rigel Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 6, 2018

RIGEL PHARMACEUTICALS, INC.

By: /s/ Dolly A. Vance
Dolly A. Vance
Executive Vice President, General Counsel and Corporate Secretary

Exhibit 99.1

Rigel Announces Third Quarter 2018 Financial Results and Provides Company Update

Reports TAVALISSE™ (fostamatinib disodium hexahydrate) net product sales of $4.9 million

Conference call and webcast today at 5:00PM Eastern Time

SOUTH SAN FRANCISCO, Calif., November 6, 2018 /PRNewswire/— Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL), today reported financial results for the third quarter ended September 30, 2018, and also provided an update on the commercial launch of TAVALISSE™ for treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment and its clinical development pipeline.

Recent Highlights

- Net product sales of $4.9 million for TAVALISSE during the third quarter
- On October 29, entered into an exclusive license and supply agreement with Kissei Pharmaceutical Co., Ltd. (Kissei) for development and marketing rights to fostamatinib in Asia; Rigel to receive upfront cash payment of $33 million, with the potential for up to an additional $147 million in milestone payments and product transfer price payments based on tiered net sales
- On October 4, the European Medicines Agency (EMA) validated the company's Marketing Authorization Application (MAA) for fostamatinib in adult chronic ITP, initiating the review process
- Phase 3 trial design for fostamatinib investigational candidate in autoimmune hemolytic anemia (AIHA) to be submitted to U.S. Food and Drug Administration (FDA) in early November

"We continue to advance our corporate strategy with solid execution across all business areas. The success of our TAVALISSE commercial launch in the United States, our collaboration with Kissei in Asia, and our MAA validation highlight the expanding capabilities of our organization," said Raul Rodriguez, president and CEO of Rigel. "In parallel, our clinical development plans continue to increase the potential of our pipeline. For our investigational agents, we plan to initiate our Phase 3 study for fostamatinib in autoimmune hemolytic anemia in the first half of 2019 and we continue to explore potential drug development opportunities including for our IRAK1/4 inhibitor, R835."

Financial Update

For the third quarter of 2018, Rigel reported a net loss of $23.8 million, or $0.14 per share, compared to a net loss of $17.7 million, or $0.14 per share, in the same period of 2017.

For the third quarter of 2018, Rigel reported net product sales from TAVALISSE of $4.9 million. Rigel recognizes revenue using the sell-in methodology when products are delivered to its distributors. There were no product sales in the third quarter of 2017.

There were no contract revenues from collaborations in the third quarter of 2018. Contract revenues from collaborations of $900,000 in the third quarter of 2017 were related to a payment received from a license agreement with a third party.

Rigel reported total costs and expenses of $29.2 million in the third quarter of 2018, compared to $18.8 million for the same period in 2017. The increase in costs and expenses was primarily due to the increases in personnel costs as Rigel expanded its customer-facing team, third party costs to support Rigel's ongoing commercial efforts for TAVALISSE in chronic ITP, as well as stock-based compensation expense related to certain performance-based stock options.

For the nine months ended September 30, 2018, Rigel reported net product sales from TAVALISSE of $6.7 million. There were no product sales for the nine months ended September 30, 2017. For the nine months ended September 30, 2018, Rigel reported a net loss of $73.7 million, or $0.47 per share, compared to a net loss of $52.1 million, or $0.43 per share, for the same period of 2017.

As of September 30, 2018, Rigel had cash, cash equivalents and short-term investments of $115.6 million, compared to $115.8 million as of December 31, 2017. With the $33.0 million upfront payment Rigel will receive under its collaboration agreement with Kissei, as discussed below, Rigel expects that its cash, cash equivalents and short-term investments will be sufficient to support its current and projected funding requirements, including the on-going commercial launch of TAVALISSE for chronic ITP in the U.S., into the first quarter of 2020.

Business Update

Since commercial launch in May 2018, demand for TAVALISSE in adult patients with previous treatment failure in cITP continues to grow, with broad usage seen in steroid refractory patients. TAVALISSE has been utilized by a broad base of prescribers and community physicians, and the payor response has been positive with an approval rate of 85-90%.

Outside of the U.S., the company continues to further its global commercialization strategy. Rigel has entered an exclusive license and supply agreement with Kissei for the development and commercialization of fostamatinib in all indications in Japan. The agreement also provides Kissei with rights to fostamatinib in China, Taiwan, and the Republic of Korea. In exchange, Rigel will receive an upfront cash payment of $33 million with the potential for up to an additional $147 million in development and commercial milestone payments. The company will also receive product transfer price payments in the mid to upper twenty percent range based on tiered net sales for exclusive supply of fostamatinib.

In the EU, which is the second largest market for adult chronic ITP, the EMA validated the MAA for fostamatinib[1] in the indication. The review process was initiated in October and the company anticipates an opinion from the Committee on Human Medicinal Products (CHMP) of the EMA by the fourth quarter of 2019.

Rigel continues to progress with its expansion plans for fostamatinib in other indications[1] and will submit its Phase 3 trial design for the treatment of warm AIHA (wAIHA) to the FDA in early November. The trial, designed in consultation with the FDA, is a placebo-controlled study of approximately 80 patients with primary or secondary wAIHA who have failed at least one prior treatment. The primary endpoint will be a durable hemoglobin response by week 24, defined as Hgb > 10 g/dL and > 2 g/dL

greater than baseline and durability of response, with the response not being attributed to rescue therapy. Enrollment is expected to begin in the first half of 2019.

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 an 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, 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 in which 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 U.S. and can be a severe, debilitating disease. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients.

About R835[1]

The investigational candidate, R835, is an orally available, potent and selective inhibitor of IRAK1 and IRAK4 that has been shown preclinically to block inflammatory cytokine production in response to toll-like receptor (TLR) and the interleukin-1 (IL-1R) family receptor signaling. TLRs and IL-1Rs play a critical role in the innate immune response and dysregulation of these pathways can lead to a variety of inflammatory conditions. R835 is active in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout.

Conference Call and Webcast with Slides 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 1398326. The webcast, with slide presentation, 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 TAVALISSE

Indication

TAVALISSE™ (fostamatinib disodium hexahydrate) tablets is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Important Safety Information

Warnings and Precautions

- Hypertension can occur with TAVALISSE treatment. Patients with pre-existing hypertension may be more susceptible to the hypertensive effects. Monitor blood pressure every 2 weeks until stable, then monthly, and adjust or initiate antihypertensive therapy for blood pressure control maintenance during therapy. If increased blood pressure persists, TAVALISSE interruption, reduction, or discontinuation may be required.

- Elevated liver function tests (LFTs), mainly ALT and AST, can occur with TAVALISSE. Monitor LFTs monthly during treatment. If ALT or AST increase to >3 x upper limit of normal, manage hepatotoxicity using TAVALISSE interruption, reduction, or discontinuation.

- Diarrhea occurred in 31% of patients and severe diarrhea occurred in 1% of patients treated with TAVALISSE. Monitor patients for the development of diarrhea and manage using supportive care measures early after the onset of symptoms. If diarrhea becomes severe (≥Grade 3), interrupt, reduce dose or discontinue TAVALISSE.

- Neutropenia occurred in 6% of patients treated with TAVALISSE; febrile neutropenia occurred in 1% of patients. Monitor the ANC monthly and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction, or discontinuation.

- TAVALISSE can cause fetal harm when administered to pregnant women. Advise pregnant women the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Verify pregnancy status prior to initiating TAVALISSE. It is unknown if TAVALISSE or its metabolite is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during TAVALISSE treatment and for at least 1 month after the last dose.

Drug Interactions

- Concomitant use of TAVALISSE with strong CYP3A4 inhibitors increases exposure to the major active metabolite of TAVALISSE (R406), which may increase the risk of adverse reactions. Monitor for toxicities that may require a reduction in TAVALISSE dose.

- It is not recommended to use TAVALISSE with strong CYP3A4 inducers, as concomitant use reduces exposure to R406.

- Concomitant use of TAVALISSE may increase concentrations of some CYP3A4 substrate drugs and may require a dose reduction of the CYP3A4 substrate drug.

- Concomitant use of TAVALISSE may increase concentrations of BCRP substrate drugs (eg, rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (eg, digoxin), which may require a dose reduction of the BCRP and P-gp substrate drug.

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).

- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Please see www.TAVALISSE.com for full Prescribing Information.

To report side effects of prescription drugs to the FDA, visit www.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

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 hematologic disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's first FDA approved product is TAVALISSE™ (fostamatinib disodium hexahydrate), an oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Rigel's current clinical programs include an upcoming Phase 3 study of fostamatinib[1] in autoimmune hemolytic anemia and an ongoing Phase 1 study of R835[1], a proprietary molecule from its interleukin receptor associated kinase (IRAK) program. In addition, Rigel has product candidates in development with partners BerGenBio AS, Daiichi Sankyo, and Aclaris Therapeutics.

[1] The product for this use or indication is investigational and has not been proven safe or effective by any regulatory authority.

Forward Looking Statements
This release contains forward-looking statements relating to, among other things, Rigel's partnership with Kissei; Rigel's ability to achieve development and commercial milestone payments; the sufficiency of Rigel's cash, cash equivalents and short-term investments and the timing of its current cash runway; Rigel's interactions with the FDA and EMA; the timing of the EMA's MAA review process and when Rigel expects a decision; and the design, timing and results of Rigel's clinical trials. 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, risks and uncertainties associated with the commercialization and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; 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, 2018. 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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Contact: David Burke
Phone: 650.624.1232
Email: dburke@rigel.com

Media Contact: Jessica Daitch
Phone: 917.816.6712
Email: jessica.daitch@syneoshealth.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)			
Revenues:				
Product sales, net	$ 4,865	$ —	$ 6,652	$ —
Contract revenues from collaborations	—	900	—	4,484
Total revenues	4,865	900	6,652	4,484
Costs and expenses:				
Cost of product sales	69	—	99	—
Research and development (see Note A)	11,097	10,808	33,136	34,708
Selling, general and administrative (see Note A)	18,069	7,947	48,632	23,177
Total costs and expenses	29,235	18,755	81,867	57,885
Loss from operations	(24,370)	(17,855)	(75,215)	(53,401)
Interest income	604	195	1,507	548
Gain on disposal of assets	—	—	—	732
Net loss	$ (23,766)	$ (17,660)	$ (73,708)	$ (52,121)
Net loss per share, basic and diluted	$ (0.14)	$ (0.14)	$ (0.47)	$ (0.43)
Weighted-average shares used in computing net loss per share, basic and diluted	166,464	124,628	158,456	120,282
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 2,194	$ 591	$ 3,913	$ 1,950
Research and development	801	282	1,734	978
	$ 2,995	$ 873	$ 5,647	$ 2,928

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30, 2018	December 31, 2017 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 115,637	$ 115,751
Total assets	123,169	119,111
Stockholders' equity	103,473	100,646

(1) Derived from audited financial statements