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): **February 28, 2019**

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 February 28, 2019, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its fourth quarter and year ended December 31, 2018. A copy of Rigel's press release, titled "Rigel Reports Fourth Quarter and Full Year 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 February 28, 2019, titled "Rigel Reports Fourth Quarter and Full Year 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: February 28, 2019

RIGEL PHARMACEUTICALS, INC.

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

Exhibit 99.1

Rigel Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Company Update

Fourth quarter total revenues of $37.9 million; full year total revenues of $44.5 million

Fourth quarter net product sales of $7.3 million; full year net product sales of $13.9 million

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

SOUTH SAN FRANCISCO, Calif., February 28, 2019 /PRNewswire/— Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL), today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided a business update.

Recent Highlights

- Fourth quarter 2018 total revenues were $37.9 million; including $30.6 million in collaboration revenues and $7.3 million in net product sales of TAVALISSE® (fostamatinib disodium hexahydrate) for the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment
- Full year 2018 total revenues were $44.5 million, including $13.9 million in net product sales of TAVALISSE®
- As of December 31, 2018, cash, cash equivalents, and short-term investments were $128.5 million
- On January 23, 2019, Rigel entered into an exclusive license and supply agreement with Grifols, S.A. (Grifols) to commercialize fostamatinib in Europe and Turkey

“Since the successful U.S. launch of TAVALISSE in May of 2018, our momentum has continued to build with a growing number of physicians utilizing our product as an early treatment option,” stated Raul Rodriguez, president and CEO. “Our recent commercial collaborations with European and Japanese partners, Grifols and Kissei, lay the groundwork for us to advance fostamatinib globally and to access the worldwide ITP market which is estimated to be $1.8 billion annually. These recent collaborations, along with growing TAVALISSE sales, have also provided additional funds to strengthen our balance sheet. While we remain focused on building our commercial business, we will continue the expansion of our pipeline with the upcoming initiation of our Phase 3 trial in warm autoimmune hemolytic anemia.”

Financial Update

For the fourth quarter of 2018, Rigel reported net income of $3.2 million, or $0.02 basic and diluted net income per share, compared to a net loss of $25.9 million, or $0.18 basic and diluted net loss per share, in the same period of 2017.

For the fourth quarter of 2018, Rigel reported total revenues of $37.9 million, consisting of $30.6 million in collaboration revenues and $7.3 million in net product sales of TAVALISSE. There were no net product sales nor contract revenues from collaborations in the fourth quarter of 2017.

Contract revenue from collaborations of $30.6 million in the fourth quarter of 2018 were related to the portion of the $33.0 million upfront fee recognized as revenue upon delivery of license rights to Kissei Pharmaceutical Co., Ltd. (Kissei) for the development and commercialization of fostamatinib in all current and potential indications in Japan, China, Taiwan and the Republic of Korea.

Rigel reported total costs and expenses of $35.3 million in the fourth quarter of 2018, compared to $26.2 million for the same period in 2017. The increase in costs and expenses was primarily due to the increase in personnel costs as Rigel expanded its customer-facing and medical affairs teams, third party costs to support Rigel's ongoing commercial efforts for TAVALISSE, as well as research and development cost for its warm autoimmune hemolytic anemia (AIHA) and other preclinical studies.

For the year ended December 31, 2018, Rigel reported a net loss of $70.5 million, or $0.44 per share, compared to a net loss of $78.0 million, or $0.62 per share, for the same period of 2017.

Rigel reported total revenues of $44.5 million for the year ended December 31, 2018, compared to $4.5 million in 2017. Total revenues in 2018 consisted of $30.6 million in collaboration revenue related to Rigel's collaboration agreement with Kissei and $13.9 million in net product sales of TAVALISSE. Contract revenues from collaborations in 2017 consisted of a $3.3 million payment Rigel received from BerGenBio ASA as a result of advancing BGB324, an investigational and orally available small molecule AXL kinase inhibitor, to a Phase 2 clinical study, and a $1.2 million payment Rigel earned pursuant to its license agreement with a third party. There were no product sales for the year ended December 31, 2017.

Total costs and expenses for the year ended December 31, 2018 were $117.2 million, versus $84.1 million for the full year 2017, primarily related to an increase in personnel and third-party costs associated with the launch of TAVALISSE.

As of December 31, 2018, Rigel had cash, cash equivalents and short-term investments of $128.5 million, compared to $115.8 million as of December 31, 2017.

Business Update

Revenue from sales of TAVALISSE grew approximately 50% in the fourth quarter of 2018 compared to the third quarter of 2018, driven in part by continued use of the product as an early treatment option in steroid refractory patients and strong continuation of therapy among patients.

In January 2019, Rigel announced that it had entered into an exclusive license and supply agreement with Grifols to commercialize fostamatinib disodium hexahydrate in all potential indications in Europe and Turkey.

With this agreement, Rigel is positioned to access the three largest markets for ITP (U.S., EU, and Japan), an indication with a global market that is estimated to be over $1.8 billion annually. This collaboration partners fostamatinib with one of the largest intravenous immunoglobulin (IVIG) manufacturers globally that has established relationships with European hematologists and hematologist/oncologists, as well as a distribution infrastructure across the EU. Fostamatinib is on track for potential EMA approval by the end of 2019, which could enable a product launch in initial European markets as early as 2020.

Under terms of the commercial license agreement, Rigel received a $30.0 million upfront cash payment, with the potential for $297.5 million in payments related to regulatory and commercial milestones, which includes a $20.0 million payment upon EMA approval of fostamatinib for the treatment of chronic ITP. Rigel will also receive stepped double-digit royalty payments based on tiered net sales which may reach 30% of net sales of fostamatinib. In return, Grifols receives exclusive rights to fostamatinib in human diseases in Europe and Turkey, including chronic ITP, autoimmune hemolytic anemia (AIHA), and IgA nephropathy (IgAN). In the event that, in 2021, after the second anniversary of the agreement, fostamatinib has not been approved by the EMA for the treatment of ITP in Europe, Grifols will have the option during a six-month time-frame to terminate the entire agreement which would terminate all their rights to ITP, AIHA, and all other indications. In this limited circumstance, Rigel will pay Grifols $25.0 million and regain all rights to fostamatinib in the Grifols territories. Rigel retains the global rights to fostamatinib outside the Grifols and Kissei territories.

In addition to growing its commercial business, Rigel has been working to broaden its pipeline by expanding the potential use of fostamatinib in other indications and developing new molecules. Rigel is on track to initiate a pivotal Phase 3 trial of fostamatinib in warm AIHA in the first half of 2019. Additionally, the Phase 1 trial of R835[1], Rigel's investigational IRAK 1/4 inhibitor, is expected to report initial data in the second 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. The safety and efficacy of R835 has not been established by the FDA or any healthcare authority.

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 2257425. 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).

TAVALISSE is a registered trademark of Rigel Pharmaceuticals, Inc.

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 in autoimmune hemolytic anemia and an ongoing Phase 1 study of R835, a proprietary molecule from its interleukin receptor associated kinase (IRAK) program. In addition, Rigel has product candidates in clinical development with partners BerGenBio ASA, Daiichi Sankyo, Aclaris Therapeutics, and AstraZeneca.

[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 Grifols, Kissei and other partnering opportunities across its pipeline; Rigel's ability to achieve regulatory and commercial milestone payments under its agreement with Grifols; expectations related to the market opportunity for ITP; Rigel's ability to broaden its pipeline; the potential opportunity for fostamatinib to obtain approval in the EU by the end of 2019 and obtain product launch in initial European markets in 2020. 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," "anticipate," 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 September 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.

# # #

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
Revenues:				
Product sales, net	$ 7,295	$ —	$ 13,947	$ —
Contract revenues from collaborations	30,562	—	30,562	4,484
Total revenues	37,857	—	44,509	4,484
Costs and expenses:				
Cost of product sales	188	—	287	—
Research and development (see Note A)	13,767	11,561	46,903	46,269
Selling, general and administrative (see Note A)	21,370	14,654	70,002	37,831
Total costs and expenses	35,325	26,215	117,192	84,100
Income (loss) from operations	2,532	(26,215)	(72,683)	(79,616)
Interest income	696	344	2,203	892
Gain on disposal of assets	—	—	—	732
Net income (loss)	$ 3,228	$ (25,871)	$ (70,480)	$ (77,992)
Net income (loss) per share, basic and diluted	$ 0.02	$ (0.18)	$ (0.44)	$ (0.62)
Weighted-average shares used in computing net income (loss) per share				
Basic	166,680	144,252	160,529	126,324
Diluted	167,617	144,252	160,529	126,324
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,470	$ 2,540	$ 5,383	$ 4,490
Research and development	587	519	2,321	1,497
	$ 2,057	$ 3,059	$ 7,704	$ 5,987

SUMMARY BALANCE SHEET DATA
(in thousands)

	December 31,	
	2018	2017
Cash, cash equivalents and short-term investments	$ 128,537	$ 115,751
Total assets	139,109	119,111
Stockholders' equity	109,877	100,646