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): **January 7, 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 January 7, 2019, Rigel Pharmaceuticals, Inc. issued a press release titled "Rigel Pharmaceuticals Provides Business Update," a copy of which 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 January 7, 2019, titled "Rigel Pharmaceuticals Provides Business 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 us, 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: January 7, 2019

RIGEL PHARMACEUTICALS, INC.

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

Exhibit 99.1

Rigel Pharmaceuticals Provides Business Update

Reports 1,794 total bottles of TAVALISSE ™ (fostamatinib disodium hexahydrate) sold in 2018

SOUTH SAN FRANCISCO, Calif., Jan. 7, 2019 /PRNewswire/ — Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today provided a business update, including the quantity of TAVALISSE™ bottles sold in 2018 and its cash position as of December 31, 2018, as well as an overview of its strategy for 2019. The company's president and CEO, Raul Rodriguez, will provide a more detailed company overview during his presentation at the 37th Annual J.P. Morgan Healthcare Conference on Wednesday, January 9 at 11:00am PT.

"2018 was a monumental year for Rigel, during which we transitioned into a commercial stage company with the successful launch of TAVALISSE. The ongoing execution of our TAVALISSE commercial strategy will be a key focus in 2019," said Mr. Rodriguez. "We will also be concentrating on the expansion of fostamatinib into Europe and further development of its utility in other indications, with the initiation of a Phase 3 trial in warm autoimmune hemolytic anemia. Our research team is making great strides identifying additional molecules that could potentially utilize the immune system to fight diseases and which we can move into clinical development or partner with leading pharmaceutical companies."

Commercial Update

TAVALISSE Early Stage of Launch

In April 2018, TAVALISSE was approved in the U.S. for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Following the product launch of TAVALISSE at the end of May 2018, the company has continued to execute on its commercial strategy.

From May 29, 2018 through December 31, 2018, Rigel sold 1,794 bottles of TAVALISSE, of which, 1,556 were shipped directly to patients and clinics. There has been encouraging early demand for TAVALISSE, including use as the first or second choice after steroids. Based on experience to date, continuity of TAVALISSE therapy has been positive as well. The company estimates that over 45% of eligible patients have continued on treatment for the fourth consecutive month.

Rigel remains on track with the execution of its global commercial strategy for fostamatinib. In early 2019, Kissei Pharmaceuticals, Rigel's partner in Asia, plans to meet with Japan's Pharmaceuticals and Medical Devices Agency. In parallel, the European Medicines Agency is progressing with its review of the marketing authorization application (MAA) for fostamatinib for the treatment of adults with chronic ITP in Europe. The company anticipates a final decision on the MAA by the end of 2019. Discussions with potential partners to commercialize the product in Europe are ongoing and an agreement is expected during 2019.

Portfolio Update

Fostamatinib in Autoimmune Hemolytic Anemia (AIHA)

In the first half of 2018, the company reported data from its Phase 2 clinical trial evaluating the use of fostamatinib to treat warm AIHA. Additional data were also presented at the 2018 American Society of Hematology annual meeting in December 2018. These data enabled meetings with the United States Food and Drug Administration (FDA) to discuss the planned Phase 3 pivotal trial, which the company hopes to launch in the first half of 2019. Clinical trial sites will be located in the U.S., Western Europe, Central Europe, Canada, and Australia.

R835[1] (IRAK 1/4 Inhibitor) Program

During 2018, Rigel initiated a Phase 1 clinical trial of R835, an investigational IRAK 1/4 inhibitor, to assess the safety, tolerability, and pharmacokinetics in healthy subjects. IRAK 1/4 plays a central role in the innate immune response to tissue damage. Therefore, it is a potential pathway to target a variety of immune-mediated diseases, allowing for a broad range of clinical opportunities. As these and other data mature, the company will pursue opportunities to optimize the strategic value of this asset across indications and geographies.

Financial Update

Based upon preliminary estimates, Rigel expects to end 2018 with approximately $128.5 million in cash, cash equivalents, and short-term investments, which it believes will be sufficient to fund its operations into 2020. These operations include continued expansion of its commercial programs for TAVALISSE in the U.S., the launch of a Phase 3 clinical trial for fostamatinib in warm AIHA, and continued support of on-going research and development programs. In 2019, the company also expects incremental contribution to its cash position from revenue generated by its commercial business.

37th Annual J.P. Morgan Webcast Presentation Details

Rigel's presentation will be webcast and is scheduled to take place Wednesday, January 9 at 11:00am PT. To access the live audio webcast or the subsequent archived recording, log on to www.rigel.com. Please connect to Rigel's website several minutes prior to the start of the live webcast to ensure adequate time for any software download that may be necessary.

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 respond to 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.

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 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 development with partners BerGenBio AS, Daiichi Sankyo, and Aclaris Therapeutics.

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[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, the commercial success of TAVALISSE in the U.S.; Rigel's ability to broaden its pipeline of assets targeting immune-mediated diseases; Rigel's efforts to expand fostamatinib in Europe; the utility of fostamatinib in other indications, including warm autoimmune hemolytic anemia and other indications; Rigel's ability to achieve development and commercial milestones; the sufficiency of Rigel's cash, cash equivalents and short-term investments and the timing of its current cash runway; 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", "expects", "anticipates", "estimates", "hopes", "believes" 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.

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