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 5, 2020**

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**	**94080**
(Address of principal executive offices)	(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))

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**RIGL**	**The Nasdaq Stock Market LLC**

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 5, 2020, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its third quarter ended September 30, 2020. A copy of Rigel's press release, titled "Rigel Reports Third Quarter 2020 Financial Results and Provides Business Update," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

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 or Sections 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, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated November 5, 2020, titled "Rigel Reports Third Quarter 2020 Financial Results and Provides Business Update."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 5, 2020

RIGEL PHARMACEUTICALS, INC.

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

Exhibit 99.1

Rigel Reports Third Quarter 2020 Financial Results and Provides Business Update

Third quarter total revenues of $18.4 million

Net product sales of $16.3 million, a 39% year-over-year increase

Launching Phase 3 clinical trial of fostamatinib in COVID-19 patients

Conference call and webcast today at 4:30PM Eastern Time

SOUTH SAN FRANCISCO, Calif., November 5, 2020 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the third quarter ended September 30, 2020, including sales of TAVALISSE® (fostamatinib disodium hexahydrate) tablets, for the treatment of adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

"Our team has done an excellent job advancing our key value drivers while adapting to the widespread changes in the current global environment," said Raul Rodriguez, Rigel's president and CEO. "We have continued to grow our TAVALISSE franchise with third quarter sales increasing 39% year-over-year and our global Phase 3 clinical trial for warm AIHA having enrolled over 60% of our patient goal. Additionally, exploration of fostamatinib's potential in COVID-19 is rapidly expanding with our Phase 3 clinical trial launching this quarter and enrollment ongoing in the Phase 2 trials sponsored by the NIH/NHLBI and Imperial College London."

Business Update

Rigel's FORWARD study, a Phase 3 pivotal trial of TAVALISSE in warm autoimmune hemolytic anemia (AIHA), has enrolled 57 of the 90 patients targeted for enrollment. The trial currently has over 90 clinical trial sites established across 22 countries.

Rigel plans to launch a Phase 3 clinical trial to evaluate the safety and efficacy of fostamatinib in hospitalized COVID-19 patients without respiratory failure that have certain high-risk prognostic factors. This multi-center, double-blind, placebo-controlled, adaptive design study is expected to enroll over 300 evaluable patients that will be randomly assigned to either fostamatinib plus standard of care (SOC) or matched placebo plus SOC (1:1). Treatment will be administered orally twice daily for 14 days. There will be a follow-up period to day 60. The primary endpoint of this study is the proportion of subjects who progress to severe/critical disease within 29 days.

The Phase 2 clinical trial sponsored by the NIH/NHLBI, in collaboration with Inova Health System, to evaluate the safety of fostamatinib for the treatment of hospitalized COVID-19 patients has enrolled 9 patients. This multi-center, double-blind, placebo-controlled study will randomly assign fostamatinib plus SOC or matched placebo plus SOC (1:1) to approximately 60 evaluable patients. Treatment will be administered orally twice daily for 14 days. There will be a follow-up period to day 60. The primary endpoint of this study is cumulative incidence of serious adverse events (SAE) through day 29. The trial also includes multiple secondary endpoints designed to assess the early efficacy and clinically relevant endpoints of disease course.

The Imperial College London-sponsored Phase 2 clinical trial to evaluate the efficacy of fostamatinib for the treatment of COVID-19 pneumonia has begun enrolling patients. The study is a two-stage, open label, controlled clinical trial with patients randomized (1:1:1) to fostamatinib plus SOC, ruxolitinib plus SOC, or SOC. Treatment will be administered twice daily for 14 days and patients will receive a follow-up assessment at day 14 and day 28 after the first dose. The primary endpoint of this study is progression from mild to severe COVID-19 pneumonia within 14 days in hospitalized patients.

Rigel recently launched FORTE, an observational study to further evaluate TAVALISSE as a second-line treatment for adult chronic ITP. The study goal is to generate additional data on patient quality of life and financial expenditures relative to the healthcare of ITP patients. Along with the post-hoc data analysis of its Phase 3 clinical program, Rigel plans to use this study to further increase and enhance its database of TAVALISSE in early line treatment of adult chronic ITP patients.

Financial Update

For the third quarter of 2020, Rigel reported a net loss of $14.2 million, or $0.08 per share, compared to a net loss of $11.5 million, $0.07 per share, in the same period of 2019.

In the third quarter of 2020, total revenues were $18.4 million, consisting of $16.3 million in net product sales and $2.1 million in contract revenues from collaborations for the achievement of a milestone in accordance with the amended license and collaboration agreement with Daiichi-Sankyo. Net product sales increased by 39% from $11.7 million in the third quarter of 2019. The decrease in contract revenues from collaborations in the third quarter of 2020 from $9.1 million in the same period of 2019 was due to developmental and commercial milestones from our various collaborative partners in 2019, partially offset by the milestone in the third quarter of 2020 from Daiichi-Sankyo as noted above.

Rigel reported total costs and expenses of $32.2 million in the third quarter of 2020, compared to $32.9 million in the same period of 2019.The decrease in total costs and expenses was primarily due to decreases to the timing of certain commercial-related activities due to the COVID-19 pandemic, partially offset by the increases in personnel-related costs and increased use of consultants.

For the nine months ended September 30, 2020, Rigel reported a net loss of $10.5 million, or $0.06 per share, compared to a net loss of $49.7 million, or $0.30 per share, in the same period of 2019.

Rigel reported total revenues of $90.2 million for the nine months ended September 30, 2020, compared to $43.9 million in the same period of 2019. Total revenues for the nine months ended September 30, 2020 consisted of $43.9 million in net product sales and $46.2 million in contract revenues from collaborations. The increase in contract revenues from collaborations related to revenue from the upfront fee previously received in 2019, as well as the milestone payment received from Grifols in the first quarter of 2020 upon EC approval of the MAA for fostamatinib in Europe and the $2.1 million in contract revenues for achievement of a milestone in accordance with the amended license and collaboration agreement with Daiichi-Sankyo, partially offset by the developmental and commercial milestones from our various collaborative partners in 2019.

Total costs and expenses for the nine months ended September 30, 2020 were $100.3 million, compared to $95.6 million in the same period of 2019. The increase in total costs and expenses was primarily related to increases in research and development cost for the on-going Phase 3 trial in warm AIHA, Phase 1 trial in RIP 1 inhibitor program and Phase 1 trial in IRAK 1/4 inhibitor program, partially offset by decreases in stock-based compensation expense and various third-party costs.

As of September 30, 2020, Rigel had cash, cash equivalents and short-term investments of $72.8 million, compared to $98.1 million as of December 31, 2019.

Conference Call and Webcast with Slides Today at 4:30pm Eastern Time

Rigel will hold a live conference call and webcast today at 4:30pm Eastern Time (1:30pm Pacific Time).

Participants can access the live conference call by dialing 1-800-954-0603 (domestic) or 1-415-226-5355 (international). The conference call and accompanying slides will also be webcast live and can be accessed from the Investor Relations section of the company's website at www.rigel.com. The webcast will be archived and available for replay after the call via the Rigel website.

About ITP

In patients with ITP (immune thrombocytopenia), 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 include fatigue, 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. In addition to fostamatinib, current therapies for ITP include steroids, blood platelet production boosters (TPO-RAs) 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

Autoimmune hemolytic anemia (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 45,000 adult patients in the U.S. and can be a severe, debilitating disease. Warm AIHA (wAIHA), the most common form of AIHA, is characterized by the presence of antibodies that react with the red blood cell surface at body temperature. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients.

About Coronavirus Disease 2019 (COVID-19) & SYK-Signaling

COVID-19 is the infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). SARS-CoV-2 primarily infects the upper and lower respiratory tract and can lead to acute respiratory distress syndrome (ARDS). Additionally, some patients develop other organ dysfunction including myocardial injury, acute kidney injury, shock resulting in endothelial dysfunction and subsequently micro and macrovascular thrombosis.[1] Much of the underlying pathology of SARS-CoV-2 is thought to be secondary to a hyperinflammatory immune response associated with increased risk of thrombosis.[2]

Spleen tyrosine kinase (SYK) is involved in the intracellular signaling pathways of many different immune cells. Therefore, SYK inhibition may improve outcomes in patients with COVID-19 via inhibition of key Fc gamma receptor (FcγR) and c-type lectin receptor (CLR) mediated drivers of pathology, such as inflammatory cytokine release by monocytes and macrophages, production of neutrophil extracellular traps (NETs) by neutrophils, and platelet aggregation.[3,4,5] Furthermore, SYK inhibition in neutrophils and platelets may lead to decreased thromboinflammation, alleviating organ dysfunction in critically ill patients with COVID-19.

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) tablets, the only 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. The product has been approved by the European Commission for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments and is marketed in Europe under the name TAVLESSE® (fostamatinib).

Fostamatinib[6] is currently being studied in a Phase 3 trial for the treatment of warm autoimmune hemolytic anemia (AIHA); a NIH/NHLBI-Sponsored Phase 2 trial for the treatment of hospitalized COVID-19 patients, in collaboration with Inova® Health System; and a Phase 2 trial for the treatment of COVID-19 pneumonia being conducted by Imperial College London.

Rigel's other clinical programs include an ongoing Phase 1 study of R835[6], a proprietary molecule from its interleukin receptor associated kinase (IRAK) inhibitor program, and an ongoing Phase 1 study of R552[6], a proprietary molecule from its receptor-interacting protein kinase (RIP) inhibitor program. In addition, Rigel has product candidates in clinical development with partners AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

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

1. Berlin DA, Gulick RM, Martinez FJ. Severe Covid-19. N Engl J Med 2020

2. Becker RC. COVID-19 Update: COVID-19 associated coagulopathy. Journal of Thrombosis and Thrombolysis May 15, 2020. DOI: https://doi.org/10.1007/s11239-020-02134-3

3. Hoepel W. et al. Anti-SARS-CoV-2 IgG from severely ill COVID-19 patients promotes macrophage hyper-inflammatory responses. bioRxiv July 13, 2020. DOI: https://doi.org/10.1101/2020.07.13.190140

4. Sung P-S and Hsieh S-L (2019) CLEC2 and CLEC5A: Pathogenic Host Factors in Acute Viral Infections. Front. Immunol. 10:2867. DOI: https://doi.org/10.3389/fimmu.2019.02867

5. Behnen M. Immobilized Immune Complexes Induce Neutrophil Extracellular Trap Release by Human Neutrophil Granulocytes via Fcγ RIIIB and Mac-1. The Journal of Immunology July 2014. DOI: https://doi.org/10.4049/jimmunol.1400478

6. 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.; the sufficiency of Rigel's supplies of TAVALISSE; the commercialization of TAVLESSE in Europe and the timing thereof; the utility of fostamatinib in warm autoimmune hemolytic anemia (AIHA); the impact of the COVID-19 pandemic on Rigel's results and operations; Rigel's ability to complete enrollment in its phase 3 clinical trial for AIHA and as a treatment for COVID-19 related conditions and the timing thereof; the trial design, the potential clinical benefit of fostamatinib for the treatment of hospitalized COVID-19 patients and the role of SYK inhibition in potentially improving outcomes of critically ill COVID-19 patients, including by alleviating organ dysfunction in critically ill patients with COVID-19; Rigel's ability to further develop its clinical stage products; the scientific rationale for exploring use of fostamatinib to treat COVID-19 and related conditions; Rigel's plans to support Imperial College London's IST; the potential clinical benefit of fostamatinib in COVID-19 patients and the prevention of ARDS; role of SYK inhibition in potentially improving outcomes in COVID-19 patients; and Rigel's partnering efforts. 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 "potential," "may," "expects" 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 Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. In addition, the COVID-19 pandemic may result in further delays in Rigel's studies, trials and sales, or impact Rigel's ability to obtain supply of TAVALISSE. 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Revenues:				
Product sales, net	$ 16,289	$ 11,716	$ 43,943	$ 29,943
Contract revenues from collaborations	2,100	9,141	46,228	13,945
Total revenues	18,389	20,857	90,171	43,888
Costs and expenses:				
Cost of product sales	140	310	574	728
Research and development (see Note A)	14,600	14,463	44,963	38,638
Selling, general and administrative (see Note A)	17,430	18,121	54,780	56,276
Total costs and expenses	32,170	32,894	100,317	95,642
Loss from operations	(13,781)	(12,037)	(10,146)	(51,754)
Interest income	36	555	563	2,068
Interest expense	(429)	(8)	(924)	(8)
Net loss	$ (14,174)	$ (11,490)	$ (10,507)	$ (49,694)
Net loss per share, basic and diluted	$ (0.08)	$ (0.07)	$ (0.06)	$ (0.30)
Weighted average shares used in computing net loss per share, basic and diluted	168,932	167,609	168,658	167,326

Note A

Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,352	$ 1,611	$ 3,981	$ 5,519
Research and development	532	487	1,684	2,185
	$ 1,884	$ 2,098	$ 5,665	$ 7,704

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30, 2020	December 31, 2019 [1]
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 72,812	$ 98,078
Total assets	123,058	147,569
Stockholders' equity	50,955	53,815

(1) Derived from audited financial statements