

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): May 5, 2020

RIGEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-29889

(Commission File No.)

94-3248524

(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))

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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 May 5, 2020, Rigel Pharmaceuticals, Inc. (“Rigel”) announced certain financial results for its first quarter ended March 31, 2020. A copy of Rigel’s press release, titled “Rigel Reports First 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 May 5, 2020, titled “Rigel Reports First Quarter 2020 Financial Results and Provides Business Update.”

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: May 5, 2020

RIGEL PHARMACEUTICALS, INC.

By: /s/ Dolly A. Vance

Dolly A. Vance

Executive Vice President, General Counsel and Corporate Secretary

**Rigel Reports First Quarter 2020 Financial Results and Provides Business Update**

First quarter net product sales of \$12.7 million and collaboration revenues of \$43.1 million

41 patients enrolled in pivotal Phase 3 clinical trial in warm AIHA

Received \$10.0 million in funding from existing credit facility

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

SOUTH SAN FRANCISCO, Calif., May 5, 2020 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the first quarter ended March 31, 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.

“During these extraordinary times, we continue to execute on our business strategy while maintaining our commitment to the well-being of our employees, patients, customers, and community. As the COVID-19 pandemic evolves, we will continue to monitor the impact this will have on our business and operations going forward,” said Raul Rodriguez, Rigel’s president and CEO. “While we began to experience the impact of COVID-19 in the latter part of the first quarter, the performance of our commercial business and progress of enrollment in our warm autoimmune hemolytic anemia clinical trial give us confidence in our ability to regain momentum as the future begins to normalize. We are also exploring opportunities for our earlier stage programs and continue to believe that we can finalize a collaboration by year end. Additionally, we added \$30 million to our financial position through a combination of a milestone payment from Grifols and non-dilutive funding from MidCap Financial.”

Business Update

In the first quarter of 2020, 1,398 bottles of TAVALISSE were shipped to patients and clinics with net product sales increasing 57% year over year to \$12.7 million. During the quarter, the company experienced typical first quarter reimbursement issues such as the resetting of co-pays and the Medicare donut hole, and was also impacted negatively by the COVID-19 pandemic in the latter part of the quarter. As of March 31, a total of 591 bottles remained in its distribution channels, a decrease of 5 bottles from the previous quarter.

Resources have been deployed to enable Rigel's field-based employees to engage remotely with health care providers and their offices. These virtual engagements have enabled its field team to support existing prescribers, as well as partner with new prescribers to identify appropriate patients for TAVALISSE.

Rigel is exploring opportunities to collaborate with research institutes to investigate the potential of TAVALISSE to treat COVID-19 pneumonia and related acute respiratory distress syndrome (ARDS). The SYK signaling pathway plays a known role in mediating the release of cytokines in response to the COVID-19 virus, providing scientific rationale for investigating the potential benefit of SYK-inhibition in these patients.

The company's FORWARD study, a pivotal Phase 3 clinical trial in warm autoimmune hemolytic anemia (AIHA) has enrolled 41 patients to date. Currently, the FORWARD study has over 80 active clinical trial sites established across 22 countries. A vast majority of these sites have temporarily postponed new patient enrollment due to the ongoing COVID-19 pandemic. As such, Rigel is no longer able to provide guidance on the timing of enrollment completion. Enrollment is expected to regain momentum as conditions permit across its over 80 globally diverse clinical sites.

Rigel currently does not anticipate disruption in supply of TAVALISSE tablets and drug substance to meet the needs of its U.S. ITP commercial business, as well as its collaborative partners and clinical trials worldwide.

In February 2020, Rigel received a \$20.0 million milestone payment from its collaborative partner Grifols, S.A. (Grifols). The payment was received upon the European Commission's (EC) approval of the marketing authorization application (MAA) for fostamatinib for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments. In addition, as a result of the EC approval, \$25.0 million of the \$30.0 million upfront fee that Rigel previously received from Grifols will no longer be repayable by Rigel to Grifols. Fostamatinib will be marketed in Europe under the brand name TAVLESSE[®] (fostamatinib).

In May 2020, Rigel accessed the second \$10.0 million tranche from its \$60.0 million term loan credit facility with MidCap Financial. The facility provides the company with access to an additional \$40.0 million which is subject to the achievement of certain conditions.

Financial Update

For the first quarter of 2020, Rigel reported net income of \$21.2 million, or \$0.13 per share, compared to a net loss of \$17.6 million, \$0.11 per share, in the same period of 2019.

In the first quarter of 2020, total revenues were \$55.8 million, consisting of \$12.7 million in net product sales and \$43.1 million in contract revenues from collaborations. Net product sales increased by 57% compared to \$8.1 million in the first quarter of 2019.

Contract revenues from collaborations of \$43.1 million in the first quarter of 2020 relate to revenue from the upfront fee Rigel previously received from Grifols in the first quarter of 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. The Company will recognize the remaining \$2.2 million deferred portion of the above payments upon performance of certain research and development services under the collaboration agreement with Grifols.

Rigel reported total costs and expenses of \$34.7 million in the first quarter of 2020, compared to \$31.0 million for the same period in 2019. The increase in total costs and expenses was primarily due to the increase in third-party costs related to Rigel's ongoing pivotal Phase 3 study in warm AIHA, research and development costs related to other clinical programs, and personnel-related costs, partially offset by stock-based compensation expense.

Rigel will continue to undertake efforts to prevent or minimize disruptions to its business and operations while monitoring for new developments related to the evolving COVID-19 pandemic. Rigel does not yet know the full impact of such disruptions on its business, operations or financial condition.

As of March 31, 2020, Rigel had cash, cash equivalents and short-term investments of \$95.9 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 (877) 407-3088 (domestic) or (201) 389-0927 (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 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 (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. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients. 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.

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.
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- 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 (\geq 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 (\geq 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) 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 will be marketed in Europe under the name TAVLESSE[®] (fostamatinib).

Rigel's clinical programs include a Phase 3 study of fostamatinib in warm autoimmune hemolytic anemia (AIHA); a completed Phase 1 study of R835¹, a proprietary molecule from its interleukin receptor associated kinase (IRAK) inhibitor program; and an ongoing Phase 1 study of R552¹, a proprietary molecule from its receptor-interacting protein kinase (RIP) inhibitor program. In addition, Rigel has product candidates in clinical development with partners Aclaris Therapeutics, AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

¹The 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 the timing thereof; 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; 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 March 31, 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 March 31,	
	2020	2019
	(unaudited)	
Revenues:		
Product sales, net	\$ 12,680	\$ 8,054
Contract revenues from collaborations	43,081	4,570
Total revenues	55,761	12,624
Costs and expenses:		
Cost of product sales	155	107
Research and development (see Note A)	16,149	10,949
Selling, general and administrative (see Note A)	18,430	19,946
Total costs and expenses	34,734	31,002
Loss from operations	21,027	(18,378)
Interest income	358	780
Interest expense	(142)	—
Net income (loss)	\$ 21,243	\$ (17,598)
Net income (loss) per share		
Basic	\$ 0.13	\$ (0.11)
Diluted	\$ 0.13	\$ (0.11)
Weighted-average shares used in computing net income (loss) per share		
Basic	168,469	167,173
Diluted	168,568	167,173

Note A

Stock-based compensation expense included in:		
Selling, general and administrative	\$ 1,330	\$ 2,166
Research and development	694	787
	\$ 2,024	\$ 2,953

SUMMARY BALANCE SHEET DATA
(in thousands)

	March 31,	December 31,
	2020	2019 ⁽¹⁾
	(unaudited)	
Cash, cash equivalents and short-term investments	\$ 95,926	\$ 98,078
Total assets	143,363	147,569
Stockholders' equity	78,499	53,815

(1) Derived from audited financial statements