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): **March 1, 2022**

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 March 1, 2022, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its fourth quarter and year ended December 31, 2021. A copy of Rigel's press release, titled "Rigel Reports Fourth Quarter and Full Year 2021 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 March 1, 2022, titled "Rigel Reports Fourth Quarter and Full Year 2021 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: March 1, 2022

RIGEL PHARMACEUTICALS, INC.

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

Rigel Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- *Fourth quarter total revenues of $20.4 million; full year total revenues of $149.2 million*
- *On track to report topline data from Phase 3 pivotal trials of fostamatinib in warm autoimmune hemolytic anemia (wAIHA) and COVID-19 in mid-2022*
- *Rigel Phase 3 trial in high-risk patients with COVID-19 has enrolled 265 patients*
- *Phase 1b trial of R289, a potent and selective IRAK1/4 inhibitor, in lower-risk myeloid dysplastic syndrome (LR-MDS) is being initiated*
- *Conference call and webcast today at 4:30 p.m. Eastern Time*

SOUTH SAN FRANCISCO, Calif., March 1, 2022 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the fourth quarter and full year ended December 31, 2021, 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.

“In 2021 we implemented several key activities to drive success in 2022, including expanding our hematology/oncology commercial capabilities, completing enrollment of our pivotal Phase 3 wAIHA trial, and our continued pipeline advancement,” said Raul Rodriguez, Rigel’s president and CEO. “In 2022 we look forward to reporting Phase 3 fostamatinib results from both our wAIHA and COVID-19 trials in mid-2022. With respect to wAIHA, this new indication fits well within our existing commercial infrastructure and would be the first approved treatment for these patients. For COVID-19, we believe that if the data is positive, fostamatinib could be an important new treatment for physicians treating high-risk patients hospitalized with COVID-19.”

Business Update

- In the fourth quarter of 2021, 1,785 bottles of TAVALISSE were shipped directly to patients and clinics, representing the highest daily bottles shipped to patients and clinics in a quarter since launch. For the full year ended December 31, 2021, 6,787 bottles of TAVALISSE were shipped directly to patients and clinics, representing an increase of 8% compared to 2020.

- Rigel is on track to report topline data from its FORWARD trial, a pivotal Phase 3 clinical trial of TAVALISSE, an oral SYK inhibitor, in patients with wAIHA, in mid-2022. Rigel previously announced it completed enrollment in the 24-week Phase 3 trial in November of 2021. If the data is positive, Rigel expects to proceed with regulatory filings and if approved, TAVALISSE has the potential to be the first-to-market therapy for patients with wAIHA in 2023.

- Rigel's pivotal Phase 3 clinical trial evaluating fostamatinib in high-risk patients hospitalized with COVID-19 has enrolled 265 of the targeted 308 patients as of February 28, 2022. Rigel expects to complete enrollment and report topline data in mid-2022.

- Rigel’s open-label, Phase 1b clinical trial of R289, a potent and selective IRAK1/4 inhibitor, in patients with low-risk myeloid dysplastic syndrome (LR-MDS) who are refractory/resistant to prior therapies is being initiated. R289 blocks inflammatory cytokine production in response to toll-like receptor (TLR) and interleukin-1 receptor family (IL-1R) signaling. Chronic stimulation of both of these receptor systems is thought to cause the pro-inflammatory environment in the bone marrow responsible for persistent cytopenias in LR-MDS patients. The primary endpoint for this trial is safety with key secondary endpoints including preliminary efficacy and evaluation of pharmacokinetic properties. Rigel will also collect key biomarker data to further characterize R289’s mechanism of action in LR-MDS.

- R552, a potent and selective RIPK1 inhibitor, is on track to advance into Phase 2 development in psoriasis in the first half of 2022 with partner Eli Lilly (Lilly). RIPK1 is implicated in a broad range of key inflammatory cellular processes and plays a key role in tumor necrosis factor (TNF) signaling, especially in the induction of pro-inflammatory necroptosis.

- During the fourth quarter of 2021, Rigel and its partners continued to execute on the global expansion of TAVALISSE in ITP. In December 2021, partner Kissei Pharmaceutical Co., Ltd. (Kissei) reported positive topline results for a Phase 3 clinical trial in ITP in Japan and is preparing a new drug application (NDA) for submission to Japan's Pharmaceuticals and Medical Devices Agency (PMDA). Rigel has an exclusive license and supply agreement with Kissei to develop and commercialize fostamatinib in all current and potential indications in Japan, China, Taiwan and the Republic of Korea.

- In the fourth quarter of 2021, Rigel announced a sharpened focus on its advanced portfolio opportunities, exiting its early-stage research programs and prioritizing its mid to late-stage development programs and commercial efforts. This strategic initiative strengthens Rigel's ability to build value for shareholders by executing on the company's near-term value drivers: growing ITP sales, expanding the addressable market for TAVALISSE with wAIHA and COVID-19, advancing its wholly owned IRAK1/4 program in hematology and immunology.

Financial Update

For the fourth quarter of 2021, Rigel reported a net loss of $22.6 million, or $0.13 per basic and diluted share, compared to a net loss of $19.2 million, or $0.11 per basic and diluted share, in the same period of 2020.

In the fourth quarter of 2021, total revenues were $20.4 million, consisting of $17.6 million in TAVALISSE net product sales and $2.8 million in contract revenues from collaborations and a government contract. TAVALISSE net product sales of $17.6 million decreased by 1% from $17.8 million in the fourth quarter of 2020. Contract revenues of $2.8 million for the fourth quarter of 2021 consisted of $1.8 million in revenue from collaborative partners and $1.0 million in revenue from a government contract with the U.S. Department of Defense (DOD).

Rigel reported total costs and expenses of $41.8 million in the fourth quarter of 2021, compared to $37.3 million for the same period in 2020.The increase in costs and expenses was primarily due to the research and development costs for various ongoing clinical studies, including Rigel’s Phase 3 clinical trial of fostamatinib for the treatment of hospitalized patients with COVID-19, increased commercial activities, including the recent sales force expansion, and the restructuring charges due to the exit from early-stage

research and development.

For the full year 2021, Rigel reported a net loss of $17.9 million, or $0.11 per basic and diluted share, compared to a net loss of $29.7 million, or $0.18 per basic and diluted share, for the same period of 2020.

Rigel reported total revenues of $149.2 million for the full year 2021, consisting of $63.0 million in TAVALISSE net product sales and $86.2 million in contract revenues from collaborations and the government contract. TAVALISSE net product sales of $63.0 million for the full year 2021 increased by 2% from $61.7 million for the same period of 2020. Contract revenues of $86.2 million for the full year 2021, consisted of $66.6 million in revenue related to Rigel's license agreement with Lilly, $9.1 million revenue from other collaborative partners, and $10.5 million revenue from the government contract with the DOD.

Total costs and expenses for the full year 2021 were $161.7 million, compared to $137.6 million for the same period in 2020. The increase in costs and expenses was primarily due to increases in research and development costs related to Rigel's various ongoing clinical studies, including its Phase 3 clinical trial of fostamatinib for the treatment of hospitalized patients with COVID-19, increased commercial activities, including the recent sales force expansion, personnel-related costs, stock-based compensation expense, and the restructuring charges due to the exit from early-stage research and development.

As of December 31, 2021, Rigel had cash, cash equivalents, and short-term investments of $125.0 million, compared to $57.3 million as of December 31, 2020. In February 2022, Rigel accessed an additional $10.0 million term loan through its credit facility with MidCap Financial Trust and amended the terms of the agreement to extend our option to access the remaining $30 million of principal available on this credit facility through March 31, 2023.

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 lead to the destruction of the body's own red blood cells. Warm antibody AIHA (wAIHA), which is the most common form of AIHA, is characterized by the presence of antibodies that react with the red blood cell surface at body temperature. wAIHA affects approximately 36,000 adult patients in the U.S.[1] and can be a severe, debilitating disease. To date, there are no disease-targeted therapies approved for wAIHA, despite the unmet medical need that exists for these patients.

About COVID-19 & SYK Inhibition

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.[2] 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.[3]

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 pro-inflammatory cytokine release by monocytes and macrophages, production of neutrophil extracellular traps (NETs) by neutrophils, and platelet aggregation. [4,5,6,7] Furthermore, SYK inhibition in neutrophils and platelets may lead to decreased thrombo-inflammation, alleviating organ dysfunction in critically ill patients with COVID-19.

For more information on Rigel's comprehensive clinical program in COVID-19, go to:https://www.rigel.com/pipeline/proprietary-programs/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.TAVALISSEUSPI.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 and TAVLESSE are registered trademarks of Rigel Pharmaceuticals, Inc.

About Rigel

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 hematologic disorders, cancer and rare immune 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 is also commercially available in Europe, the United Kingdom (TAVLESSE) and Canada (TAVALISSE) for the treatment of chronic immune thrombocytopenia in adult patients.

Fostamatinib is currently being studied in a Phase 3 clinical trial (NCT03764618) for the treatment of warm autoimmune hemolytic anemia (wAIHA)[8]; a Phase 3 clinical trial (NCT04629703) for the treatment of hospitalized high-risk patients with COVID-19[8]; an NIH/NHLBI-sponsored Phase 3 clinical trial (ACTIV-4 Host Tissue Trial, NCT04924660) for the treatment of COVID-19 in hospitalized patients, and a Phase 2 clinical trial NCT04581954) for the treatment of COVID-19 being conducted by Imperial College London.

Rigel's other clinical programs include its interleukin receptor-associated kinase (IRAK) inhibitor program, and a receptor-interacting serine/threonine-protein kinase (RIPK) inhibitor program in clinical development with partner Eli Lilly and Company. In addition, Rigel has product candidates in development with partners BerGenBio ASA and Daiichi Sankyo.

For further information, visit www.rigel.com or follow us on Twitter or LinkedIn.

1. Prevalence: A. Zanella, et al, *haematologica* 2014; 99(10); % Warm AIHA: T. Kalfa; Hematology Am Soc Hematol Educ Program. 2016 Dec 2; 2016(1): 690–697
2. Berlin DA, Gulick RM, and Martinez FJ.*Severe Covid-19*. N Engl J Med 2020. DOI: https://doi.org/10.1056/NEJMcp2009575
3. 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
4. Hoepel W et al. *High titers and low fucosylation of early human anti–SARS-CoV-2 IgG promote inflammation by alveolar macrophages* Science Translational Medicine 02 Jun 2021. DOI: https://www.doi.org/10.1126/scitranslmed.abf8654
5. Sung P-S and Hsieh S-L. *CLEC2 and CLEC5A: Pathogenic Host Factors in Acute Viral Infections*. Frontiers in Immunology December 6, 2019. DOI: https://doi.org/10.3389/fimmu.2019.02867
6. Strich J et al. *Fostamatinib Inhibits Neutrophils Extracellular Traps Induced by COVID-19 Patient Plasma: A Potential Therapeutic*. Journal of Infectious Disease March 15, 2021. DOI: https://doi.org/10.1093/infdis/jiaa789
7. Bye AP et al. *Aberrant glycosylation of anti-SARS-CoV-2 IgG is a pro-thrombotic stimulus for platelets*. BioRxiv March 26, 2021. DOI: https://doi.org/10.1101/2021.03.26.437014
8. *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. and TAVLESSE in Europe; including expectations related to the potential and market opportunity for fostamatinib as therapeutic for, among other things, wAIHA and COVID-19; the commercialization of fostamatinib in international markets; Rigel's ability to further develop its clinical stage and early-stage product candidates and programs including its IRAK1/4 inhibitor program; and Rigel's partnering effort. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and subsequent filings. 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, except as required by law.

Contact for Investors & Media:
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RIGEL PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Revenues:				
Product sales, net	$ 17,569	$ 17,753	$ 63,010	$ 61,696
Contract revenues from collaborations	1,840	697	75,726	46,925
Government contract	1,000	-	10,500	-
Total revenues	20,409	18,450	149,236	108,621
Costs and expenses:				
Cost of product sales	487	321	1,083	895
Research and development (see Note A)	13,304	15,138	65,237	60,101
Selling, general and administrative (see Note A)	24,515	21,818	91,891	76,598
Restructuring charges (see Note A)	3,521	-	3,521	-
Total costs and expenses	41,827	37,277	161,732	137,594
Income from operations	(21,418)	(18,827)	(12,496)	(28,973)
Interest income	16	19	47	582
Interest expense	(1,299)	(429)	(4,860)	(1,353)
Loss before income taxes	(22,701)	(19,237)	(17,309)	(29,744)
(Benefit from) Provision for income taxes	(60)	-	605	-
Net loss	$ (22,641)	$ (19,237)	$ (17,914)	$ (29,744)
Net loss per share, basic and diluted	$ (0.13)	$ (0.11)	$ (0.11)	$ (0.18)
Weighted average shares used in computing net loss per share, basic and diluted	171,071	169,039	170,492	168,754
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,712	$ 1,242	$ 7,337	$ 5,223
Research and development	178	388	1,700	2,072
Restructuring charges	449	-	449	-
	$ 2,339	$ 1,630	$ 9,486	$ 7,295

SUMMARY BALANCE SHEET DATA
(in thousands)

	December 31,	
	2021	2020
Cash, cash equivalents and short-term investments	$ 124,967	$ 57,327
Total assets	167,328	110,378
Stockholders' equity	30,374	34,026