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): **August 3, 2021**

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 August 3, 2021, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its second quarter ended June 30, 2021. A copy of Rigel's press release, titled "Rigel Reports Second Quarter 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 August 3, 2021, titled "Rigel Reports Second Quarter 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: August 3, 2021

RIGEL PHARMACEUTICALS, INC.

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

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Exhibit 99.1

Rigel Reports Second Quarter 2021 Financial Results and Provides Business Update

- *Net product sales of $17.1 million and total revenues of $26.3 million*
- *Rigel's Phase 3 trial in patients with wAIHA has enrolled 80 patients*
- *Rigel's Phase 3 trial in high-risk hospitalized patients with COVID-19 has enrolled ~150 patients*
- *Fostamatinib selected for NIH ACTIV-4 trial in hospitalized patients with COVID-19*
- *Rigel enters into new research collaboration with MD Anderson to evaluate Rigel's IRAK1/4 inhibitor in preclinical models of MDS and CMML*
- *Conference call and webcast today at 4:30PM Eastern Time*

SOUTH SAN FRANCISCO, Calif., August 3, 2021 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the second quarter ended June 30, 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.

"As we begin the second half of 2021, Rigel is well-positioned to execute on several key milestones that have the potential to be important inflection points for the company," said Raul Rodriguez, Rigel's president and CEO. "TAVALISSE sales are growing as we are able to access more clinicians in-person, and we are expanding our commercial team to allow us to have a greater impact as physicians and patients continue to return to the clinic. Our pipeline programs continue to advance as we wait for a decision on our EUA, with our own Phase 3 clinical trial of fostamatinib in hospitalized COVID-19 patients rapidly enrolling and our Phase 3 clinical trial of fostamatinib in wAIHA nearing its enrollment goal," continued Mr. Rodriguez.

Business Update

In July, Rigel initiated expansion of its sales force from 39 to 55 territories. Recruiting is underway and it is expected that the team will be fully trained and in the field by the end of September.

In June, Rigel announced that fostamatinib had been selected as part of the National Institutes of Health (NIH) sponsored ACTIV-4 Host Tissue trial. Recruiting is underway and the first patient has been enrolled in the multi-site, randomized, placebo-controlled trial of therapies, including fostamatinib, targeting the host response to COVID-19 in hospitalized patients.

In late-May, Rigel submitted a request to the U.S. Food and Drug Administration (FDA) for an emergency use authorization (EUA) for fostamatinib in hospitalized patients diagnosed with COVID-19. The request included data from a NHLBI/NIH-sponsored Phase 2 study, which reported positive topline results in April.

Rigel's Phase 3 clinical trial evaluating fostamatinib in high-risk patients hospitalized with COVID-19 has enrolled ~150 of the targeted 308 patients, and expects to complete enrollment by year-end 2021.

Rigel's FORWARD study, a Phase 3 pivotal trial of TAVALISSE in patients with warm autoimmune hemolytic anemia (wAIHA), has enrolled80 of the targeted 90 patients. If approved, TAVALISSE has the potential to be the first to market therapy for patients with wAIHA.

During the quarter, Rigel received feedback from the FDA supporting its proposed clinical program to evaluate R289, a pro-drug formulation of R835, in low-risk myelodysplastic syndromes (MDS). Planning is now underway on the Phase 1/2 clinical trial.

In June, Rigel entered into a research collaboration with MD Anderson Cancer Center to evaluate Rigel's novel IRAK 1/4 inhibitors in a series of preclinical studies of MDS and chronic myelomonocytic leukemia (CMML). The translational research generated from these studies will add to the body of data generated to date on R835 and R289 and further elucidate the therapeutic potential of targeting deregulated innate immune signaling in MDS and CMML.

Financial Update

For the second quarter of 2021, Rigel reported net loss of $13.8 million, or $0.08 per basic and diluted share, compared to a net loss of $17.6 million, or $0.10 per basic and diluted share, for the same period of 2020.

In the second quarter of 2021, total revenues were $26.3 million, consisting of $17.1 million in TAVALISSE net product sales, $3.7 million in contract revenues from collaborations, and $5.5 million in government contract revenue. TAVALISSE net product sales of $17.1 million in the second quarter of 2021 increased by 14% from $15.0 million for the same period of 2020.

Contract revenues from collaborations of $3.7 million for the second quarter of 2021 consisted of $3.3 million in revenue related to Rigel's license agreement with Lilly, and $0.4 million in revenue related to the performance of certain research and development services pursuant to its collaboration agreement with Grifols. Government contract revenue was related to the income recognized pursuant to the agreement Rigel entered in January 2021 with the U.S. Department of Defense (DOD) to support Rigel's ongoing Phase 3 clinical trial of fostamatinib in hospitalized patients with COVID-19.

Rigel reported total costs and expenses of $39.3 million in the second quarter of 2021, compared to $33.4 million for the same period in 2020. The increase in costs and expenses was primarily due to increases in personnel-related costs, stock-based compensation expense, and research and development costs related to Rigel's various on-going clinical studies.

For the six months ended June 30, 2021, Rigel reported net income of $25.7 million, or $0.15 per basic and diluted share, compared to a net income of $3.7 million, or $0.02 per basic and diluted share, for the same period of 2020.

Rigel reported total revenues of $107.3 million for the six months ended June 30, 2021, consisting of $29.4 million in TAVALISSE net product sales, $69.4 million in contract revenues from collaborations, and $8.5 million in government contract revenues. TAVALISSE net product sales of $29.4 million increased by 6% from $27.7 million for the same period of 2020. Contract revenues from collaborations of $69.4 million for the six months ended June 30, 2021, consisted of $63.9 million in revenue related to Rigel's license agreement with Lilly, $4.0 million in revenue related to the grant of a non-exclusive license of a certain patent to an unrelated third-party company, and $1.4 million in revenue for the delivery of drug supply, as well as performance of certain research and development services pursuant to its collaboration agreement with Grifols. Government contract revenue of $8.5 million for the six months ended June 30, 2021, was related to the income recognized pursuant to the agreement Rigel entered in January 2021 with the DOD to support Rigel's ongoing Phase 3 clinical trial of fostamatinib in hospitalized patients with COVID-19.

Total costs and expenses for the six months ended June 30, 2021, were $78.6 million, compared to $68.1 million for the same period in 2020. The increase in costs and expenses was primarily due to increases in personnel-related costs, stock-based compensation expense, and research and development costs related to Rigel's various on-going clinical studies.

As of June 30, 2021, Rigel had cash, cash equivalents, and short-term investments of $153.4 million, compared to $57.3 million as of December 31, 2020.

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 destroy 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 antibody 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 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.[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]

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.[3,4,5,6] 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 RIP1 Inhibitor, R552
Investigational candidate, R552, is an orally available, potent and selective inhibitor of receptor-interacting serine/threonine-protein kinase 1 (RIP1). RIP1 is believed to play a critical role in necroptosis. Necroptosis is a form of regulated cell death where the rupturing of cells leads to the dispersion of their inner contents, which induces immune responses and enhances inflammation. In preclinical studies, R552 prevented joint and skin inflammation in a RIP1-mediated murine model of inflammation and tissue damage. The safety and efficacy of R552 has not been established by the FDA or any healthcare authority.

About IRAK1/4 Inhibitor R835/R289
Investigational candidates, R835 and its pro-drug, R289 are orally available, potent and selective inhibitors of both IRAK1 and IRAK4. In clinical and preclinical studies, R835 has been shown to block inflammatory cytokine production in response to toll-like receptor (TLR) and the interleukin-1 receptor (IL-1R) family 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 treatment demonstrates amelioration of clinical symptoms in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout. The safety and efficacy of R835 or its pro-drug, R289, have 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.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 (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 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 (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)[7]; a Phase 3 clinical trial (NCT04629703) for the treatment of hospitalized high-risk patients with COVID-19[7]; an NIH/NHLBI-sponsored Phase 3 clinical trial (ACTIV-4 Host Tissue Trial) for the treatment of COVID-19 in hospitalized patients, and a Phase 2 clinical trial for the treatment of COVID-19 being conducted by Imperial College London. An NIH/NHLBI-sponsored Phase 2 clinical trial for the treatment of hospitalized patients with COVID-19, in collaboration with Inova Health System, was recently completed.

Rigel's other clinical programs include its interleukin receptor-associated kinase (IRAK) inhibitor program, and a receptor-interacting serine/threonine-protein kinase (RIP1) inhibitor program in clinical development with partner Eli Lilly and Company. In addition, Rigel has product candidates in development with partners AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

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

1. Berlin DA, Gulick RM, and Martinez FJ. *Severe Covid-19*. N Engl J Med 2020. DOI: https://doi.org/10.1056/NEJMcp2009575
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. *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
4. 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
5. 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
6. 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

7. *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 its ability to expand its sales force; expectations related to the potential and market opportunity for fostamatinib as a COVID-19 therapeutic; Rigel's ability to further develop its clinical stage and early-stage product candidates and programs; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021. 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 for Investors & Media:
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RIGEL PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)			
Revenues:				
Product sales, net	$ 17,053	$ 14,974	$ 29,429	$ 27,654
Contract revenues from collaborations	3,713	1,047	69,355	44,128
Government contract	5,500	-	8,500	-
Total revenues	26,266	16,021	107,284	71,782
Costs and expenses:				
Cost of product sales	129	279	445	434
Research and development (see Note A)	16,807	14,214	33,633	30,363
Selling, general and administrative (see Note A)	22,378	18,920	44,499	37,350
Total costs and expenses	39,314	33,413	78,577	68,147
Income from operations	(13,048)	(17,392)	28,707	3,635
Interest income	16	169	17	527
Interest expense	(1,759)	(353)	(2,244)	(495)
Income before income taxes	(14,791)	(17,576)	26,480	3,667
Provision for (Benefit from) income taxes	(970)	-	801	-
Net income	$ (13,821)	$ (17,576)	$ 25,679	$ 3,667
Net loss per share, basic and diluted				
Basic	$ (0.08)	$ (0.10)	$ 0.15	$ 0.02
Diluted	$ (0.08)	$ (0.10)	$ 0.15	$ 0.02
Weighted average shares used in computing net loss per share, basic and diluted				
Basic	170,192	168,570	169,997	168,519
Diluted	170,192	168,570	175,912	168,525
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,772	$ 1,299	$ 3,825	$ 2,629
Research and development	534	458	1,120	1,152
	$ 2,306	$ 1,757	$ 4,945	$ 3,781

SUMMARY BALANCE SHEET DATA
(in thousands)

	June 30, 2021	December 31, 2020 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 153,387	$ 57,327
Total assets	201,598	110,378
Stockholders' equity	68,110	34,026

(1) Derived from audited financial statements