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 13, 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 8.01. Other Events.

On August 13, 2021, Rigel Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has informed the Company that clinical data submitted in late-May 2021 from a 59-patient National Institute of Health/National Heart, Lung, and Blood Institute-sponsored Phase 2 trial of fostamatinib to treat hospitalized patients suffering from COVID-19 are insufficient for an emergency use authorization at this time. The FDA noted in their response that they remain committed to working with the Company in the development of fostamatinib for COVID-19, as the Company is currently conducting a larger Phase 3 clinical trial evaluating fostamatinib in hospitalized patients with COVID-19. A copy of the Company's press release, titled "Rigel Pharmaceuticals Provides Update on COVID-19 Program," is attached as Exhibit 99.1 to this Current Report and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated August 13, 2021, titled "Rigel Pharmaceuticals Provides Update on COVID-19 Program."
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 13, 2021

RIGEL PHARMACEUTICALS, INC.

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

Rigel Pharmaceuticals Provides Update on COVID-19 Program

-- FDA declines to issue emergency use authorization for fostamatinib for the treatment of COVID-19 in hospitalized adults --

-- Rigel's COVID-19 program continues to actively enroll patients and will provide a robust data set to support the potential benefits of fostamatinib in COVID-19 --

SOUTH SAN FRANCISCO, Calif., August 13, 2021 – Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), today announced that the U.S. Food and Drug Administration (FDA) has informed the Company that clinical data submitted in late-May from a 59-patient NIH/NHLBI-sponsored Phase 2 trial of fostamatinib to treat hospitalized patients suffering from COVID-19 are insufficient for an emergency use authorization (EUA) at this time. The FDA noted in their response that they remain committed to working with Rigel in the development of fostamatinib for COVID-19 as the Company is currently conducting a larger Phase 3 clinical trial evaluating fostamatinib in hospitalized patients with COVID-19.

"With new virus variants spreading and vaccination rates plateauing, there remains a need for therapies that can improve outcomes for hospitalized patients, particularly patients suffering from hyperinflammatory COVID-19-related complications," said Raul Rodriguez, president and CEO of Rigel. "The Rigel team continues to focus on enrolling our Phase 3 clinical trial, which we anticipate completing later this year, and we look forward to providing further safety and efficacy data from this larger, 308-patient trial of fostamatinib in COVID-19 patients. If this trial meets its endpoints, we plan to resubmit our EUA application with this additional data."

Fostamatinib Clinical Development Program in COVID-19

The broader clinical development program for fostamatinib is comprised of three ongoing studies and a recently completed Phase 2 study. These studies are evaluating a wide range of hospitalized patients, including those not on oxygen therapy, who are experiencing mild to severe COVID-19-related complications:

- **Rigel-led Phase 3 Trial.** This ongoing Phase 3 clinical trial will 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 study will enroll ~308 evaluable patients to either fostamatinib plus SOC or matched placebo plus SOC (1:1). The primary endpoint of this study is the proportion of patients who progress to severe/critical disease within 29 days. The study has enrolled ~176 patients as of August 12, 2021, and enrollment is expected to be complete by year-end. More detail on the study can be found on clinicaltrials.gov: NCT04629703.

- **ACTIV-4 Host Tissue Phase 3 Trial.** The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) study, initiated and funded by the National Heart Lung and Blood Institute (NHLBI), part of the National Institutes of Health, is a multi-site, randomized, placebo-controlled trial of therapies, including fostamatinib, targeting the host response to COVID-19 in hospitalized patients. The Master Protocol is designed to be flexible in the number of study arms, the use of a single placebo group, and the stopping and adding of new therapies. Each active arm will include approximately 300 patients. Eligible participants will include patients hospitalized for COVID-19 with laboratory-confirmed SARS-CoV-2 infection on oxygen therapy. The primary outcome is oxygen-free days through day 28. Secondary outcomes include hospital mortality, use of mechanical ventilation, and WHO scale scores. The study enrolled its first patient on July 22, 2021. More detail on the study can be found on clinicaltrials.gov: NCT04924660.

- **Imperial College of London IST.** The Imperial College London Investigator-Sponsored Trial (IST) is a two-stage, open-label, controlled clinical trial of patients randomized (1:1:1) to fostamatinib, ruxolitinib, or SOC. The primary objective will be to determine the efficacy of fostamatinib and the efficacy of ruxolitinib compared to SOC to reduce the proportion of hospitalized patients progressing from mild or moderate to severe COVID-19 pneumonia. Rigel is providing support for this trial along with Novartis. More detail on the study can be found on clinicaltrials.gov: NCT04581954.

- **NIH/NHLBI-sponsored Phase 2 Trial.** This randomized, double-blind, placebo-controlled study, which has been completed, evaluated the safety of fostamatinib plus SOC and matched placebo plus SOC (1:1) in hospitalized patients with COVID-19 requiring supplemental oxygen. The primary endpoint was the cumulative incidence of serious adverse events (SAEs) by Day 29. As previously announced, the study met its primary endpoint of safety and provided evidence of broad and consistent improvement in numerous secondary endpoints including mortality, time to sustained recovery, change in ordinal scale assessment, number of days on oxygen, and number of days in the ICU. Results from this study have been submitted for publication in a peer-reviewed medical journal. More details on the study can be found on clinicaltrials.gov: NCT04579393.

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]

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 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 thromboinflammation, 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 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 (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 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.

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.

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

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. 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
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. *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, Rigel's COVID-19 clinical program, including its use of fostamatinib to treat hospitalized patients suffering from COVID-19; the clinical development program for fostamatinib, including the Rigel-led Phase 3 Trial, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) study and the Imperial College of London Investigator-Sponsored Trial; and Rigel's recently completed Phase 2 study on fostamatinib. 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 June 30, 2021. 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.

Contact for Investors & Media

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