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): **January 8, 2024**

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.)
611 Gateway Boulevard **Suite 900** **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.

In connection with the press release described in Item 8.01 below, on January 8, 2024, Rigel Pharmaceuticals, Inc. ("Rigel") provided, on a preliminary and unaudited basis, certain estimated financial results for its fourth quarter and fiscal year ended December 31, 2023. The preliminary estimates are based on currently available information and do not present all necessary information for a complete understanding of Rigel's financial condition as of December 31, 2023 or Rigel's results of operations for the fourth quarter or year ended December 31, 2023.

Item 8.01. Other Events.

On January 8, 2024, Rigel issued a press release titled "Rigel Pharmaceuticals Provides Business Update." A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	**Description**
99.1	Press Release, dated January 8, 2024, titled "Rigel Pharmaceuticals 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: January 8, 2024

RIGEL PHARMACEUTICALS, INC.

By: /s/ Ray Furey, J.D.
Ray Furey, J.D.
Executive Vice President, General Counsel and Corporate Secretary

Exhibit 99.1

Rigel Pharmaceuticals Provides Business Update

- *Preliminary fourth quarter 2023 total revenue of approximately $35.7 million which includes record TAVALISSE® net product sales of $25.7 million and REZLIDHIA® net product sales of $3.9 million*
- *Strategic alliance with MD Anderson to advance REZLIDHIA in AML and other cancers*
- *Collaboration with CONNECT to evaluate REZLIDHIA in a Phase 2 clinical trial in glioma*

SOUTH SAN FRANCISCO, Calif., January 8, 2024 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today provided a business update including preliminary total revenue for the fourth quarter of 2023, ongoing activity from the commercial portfolio, including TAVALISSE ® (fostamatinib disodium hexahydrate) tablets and REZLIDHIA® (olutasidenib) capsules, and upcoming catalysts for 2024.

"2023 was a year of significant growth across our commercial hematology-oncology portfolio. We grew TAVALISSE net product sales nearly 24% over 2022 and successfully achieved more than $10 million of REZLIDHIA revenue during its first full year of launch. This enabled us to generate more than $104 million of total net product sales this year," said Raul Rodriguez, Rigel's president and CEO. "Also, our recent collaborations with MD Anderson and CONNECT will allow us to evaluate the potential of REZLIDHIA as a possible therapy in a broad range of IDH1-mutant cancers. As we head into the future, we are focused on commercial execution, the advancement of our hematology-oncology pipeline, and our plan to reach financial breakeven."

Commercial and Preliminary Financial Update

In the fourth quarter of 2023, a total of 2,671 bottles of TAVALISSE were sold in the U.S., of which, 2,463 bottles were shipped directly to patients and clinics, representing the highest daily bottles shipped to patients and clinics in a quarter since launch. While Rigel is still determining final results for the fourth quarter of 2023, it expects to report net product sales of TAVALISSE of $25.7 million for the fourth quarter compared to $21.9 million for the same period of 2022.

In the fourth quarter of 2023, a total of 308 bottles of REZLIDHIA were sold in the U.S., of which, 278 bottles were shipped directly to patients and clinics. While Rigel is still determining final results for the fourth quarter of 2023, it expects to report net product sales of REZLIDHIA of $3.9 million for the fourth quarter compared to $0.9 million for the same period of 2022.

Overall, Rigel expects to report net product sales of $104.3 million in 2023, representing 36% growth over 2022.

Contract revenues for the fourth quarter of 2023 are expected to be approximately $6.1 million, consisting of $6.0 million in contract revenue from collaborations and $0.1 million in government contract revenue. Contract revenue from collaborations is expected to include $3.7 million of revenue from Grifols S.A., related to delivery of drug supplies and earned royalties, as well as $2.2 million of revenue from Kissei Pharmaceutical Co., Ltd. and $0.1 million of revenue from Medison Pharma Trading AG, related to delivery of drug supplies.

For the fourth quarter of 2023, Rigel expects to report total revenue of approximately $35.7 million.

Rigel expects to report cash, cash equivalents, and short-term investments of approximately $56.9 million as of December 31, 2023, compared to $58.2 million as of December 31, 2022.

The above information is preliminary, has not been audited, and is subject to change upon the audit of Rigel's financial statements for the year ended December 31, 2023. Rigel expects to provide complete fourth quarter and full year 2023 financial results in March 2024.

Q4 Business Update

- Rigel and The University of Texas MD Anderson Cancer Center (MD Anderson) recently announced a multi-year strategic development collaboration to expand the evaluation of REZLIDHIA (olutasidenib) in acute myeloid leukemia (AML) and other hematologic cancers. Under the strategic collaboration, Rigel and MD Anderson will evaluate the potential of olutasidenib to treat newly diagnosed and relapsed or refractory (R/R) patients with AML, higher-risk myelodysplastic syndromes (MDS), and advanced myeloproliferative neoplasms (MPN), in combination with other agents. The collaboration will also support the evaluation of olutasidenib as monotherapy in lower-risk MDS and maintenance therapy in post-hematopoietic stem cell transplant (HSCT) patients. Rigel will provide $15 million in time-based milestone payments and study material over the five-year collaboration.

- Rigel and CONNECT recently announced a collaboration to evaluate REZLIDHIA (olutasidenib) in combination with temozolomide as maintenance therapy in patients with high-grade glioma (HGG) harboring an isocitrate dehydrogenase-1 (IDH1) mutation. Under the collaboration, CONNECT will include olutasidenib in CONNECT's TarGeT-D, a molecularly guided Phase 2 umbrella clinical trial for HGG. The Rigel-sponsored arm will study post-radiotherapy administration of olutasidenib in combination with temozolomide followed by olutasidenib monotherapy as maintenance treatment in newly diagnosed pediatric and young adult patients (<39 years old) with IDH1 mutation positive HGG, including diffuse intrinsic pontine glioma (DIPG), an aggressive brain tumor with limited treatment options. Rigel will provide funding up to $3 million and study material over the four-year collaboration.

- In December 2023, Rigel presented four posters highlighting data from the Company's commercial and clinical-stage hematology-oncology portfolio at the 65th American Society of Hematology Annual Meeting and Exposition. Included was a poster, Abstract #2888, reporting post hoc analyses in a subset of patients with *m*IDH1 R/R AML or MDS that were R/R to HSCT, ivosidenib, or venetoclax. The analyses suggest that olutasidenib alone or in combination with azacitidine may induce complete remissions in these patients.

- Rigel continues to advance its open-label, Phase 1b clinical trial of R289[1], an investigational, potent, and selective IRAK1/4 inhibitor, in patients with lower-risk myeloid dysplastic syndrome (LR-MDS) who are refractory/resistant to prior therapies. The primary endpoint for this trial is safety with key secondary endpoints including preliminary efficacy and evaluation of pharmacokinetic properties. Rigel is currently enrolling patients in the third cohort.

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 AML

Acute myeloid leukemia (AML) is a rapidly progressing cancer of the blood and bone marrow that affects myeloid cells, which normally develop into various types of mature blood cells. AML occurs primarily in adults and accounts for about 1 percent of all adult cancers. The American Cancer Society estimates that in the United States alone, there were about 20,380 new cases, most in adults, in 2023.[2]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[3] Refractory AML, which affects between 10 and 40 percent of newly diagnosed patients, occurs when a patient fails to achieve remission even after intensive treatment.[4] Quality of life declines for patients with each successive line of treatment for AML, and well-tolerated treatments in relapsed or refractory disease remain an unmet need.

About R289

R289 is a prodrug of R835, an IRAK1/4 dual inhibitor, which has been shown in preclinical studies to block inflammatory cytokine production in response to toll-like receptor (TLR) and 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 various inflammatory conditions. Chronic stimulation of both these receptor systems is thought to cause the pro-inflammatory environment in the bone marrow responsible for persistent cytopenias in lower-risk MDS patients.[5]

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 is a registered trademark of Rigel Pharmaceuticals, Inc.

About REZLIDHIA®

INDICATION

REZLIDHIA is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME

Differentiation syndrome, which can be fatal, can occur with REZLIDHIA treatment. Symptoms may include dyspnea, pulmonary infiltrates/pleuropericardial effusion, kidney injury, hypotension, fever, and weight gain. If differentiation syndrome is suspected, withhold REZLIDHIA and initiate treatment with corticosteroids and hemodynamic monitoring until symptom resolution.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome

REZLIDHIA can cause differentiation syndrome. In the clinical trial of REZLIDHIA in patients with relapsed or refractory AML, differentiation syndrome occurred in 16% of patients, with grade 3 or 4 differentiation syndrome occurring in 8% of patients treated, and fatalities in 1% of patients. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal. Symptoms of differentiation syndrome in patients treated with REZLIDHIA included leukocytosis, dyspnea, pulmonary infiltrates/pleuropericardial effusion, kidney injury, fever, edema, pyrexia, and weight gain. Of the 25 patients who experienced differentiation syndrome, 19 (76%) recovered after treatment or after dose interruption of REZLIDHIA. Differentiation syndrome occurred as early as 1 day and up to 18 months after REZLIDHIA initiation and has been observed with or without concomitant leukocytosis.

If differentiation syndrome is suspected, temporarily withhold REZLIDHIA and initiate systemic corticosteroids (e.g., dexamethasone 10 mg IV every 12 hours) for a minimum of 3 days and until resolution of signs and symptoms. If concomitant leukocytosis is observed, initiate treatment with hydroxyurea, as clinically indicated. Taper corticosteroids and hydroxyurea after resolution of symptoms. Differentiation syndrome may recur with premature discontinuation of corticosteroids and/or hydroxyurea treatment. Institute supportive measures and hemodynamic monitoring until improvement; withhold dose of REZLIDHIA and consider dose reduction based on recurrence.

Hepatotoxicity

REZLIDHIA can cause hepatotoxicity, presenting as increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased blood alkaline phosphatase, and/or elevated bilirubin. Of 153 patients with relapsed or refractory AML who received REZLIDHIA, hepatotoxicity occurred in 23% of patients; 13% experienced grade 3 or 4 hepatotoxicity. One patient treated with REZLIDHIA in combination with azacitidine in the clinical trial, a combination for which REZLIDHIA is not indicated, died from complications of drug-induced liver injury. The median time to onset of hepatotoxicity in patients with relapsed or refractory AML treated with REZLIDHIA was 1.2 months (range: 1 day to 17.5 months) after REZLIDHIA initiation, and the median time to resolution was 12 days (range: 1 day to 17 months). The most common hepatotoxicities were elevations of ALT, AST, blood alkaline phosphatase, and blood bilirubin.

Monitor patients frequently for clinical symptoms of hepatic dysfunction such as fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. Obtain baseline liver function tests prior to initiation of REZLIDHIA, at least once weekly for the first two months, once every other week for the third month, once in the fourth month, and once every other month for the duration of therapy. If hepatic dysfunction occurs, withhold, reduce, or permanently discontinue REZLIDHIA based on recurrence/severity.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions, including laboratory abnormalities, were aspartate aminotransferase increased, alanine aminotransferase increased, potassium decreased, sodium decreased, alkaline phosphatase increased, nausea, creatinine increased, fatigue/malaise, arthralgia, constipation, lymphocytes increased, bilirubin increased, leukocytosis, uric acid increased, dyspnea, pyrexia, rash, lipase increased, mucositis, diarrhea and transaminitis.

DRUG INTERACTIONS

- Avoid concomitant use of REZLIDHIA with strong or moderate CYP3A inducers.
- Avoid concomitant use of REZLIDHIA with sensitive CYP3A substrates unless otherwise instructed in the substrates prescribing information. If concomitant use is unavoidable, monitor patients for loss of therapeutic effect of these drugs.

LACTATION

Advise women not to breastfeed during treatment with REZLIDHIA and for 2 weeks after the last dose.

GERIATRIC USE

No overall differences in effectiveness were observed between patients 65 years and older and younger patients. Compared to patients younger than 65 years of age, an increase in incidence of hepatotoxicity and hypertension was observed in patients ≥65 years of age.

HEPATIC IMPAIRMENT

In patients with mild or moderate hepatic impairment, closely monitor for increased probability of differentiation syndrome.

Click here for Full Prescribing Information, including Boxed WARNING.

To report side effects of prescription drugs to the FDA, visitwww.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

REZLIDHIA is a registered trademark of Rigel Pharmaceuticals, Inc.

About Rigel

Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) is a biotechnology company dedicated to discovering, developing and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. Founded in 1996, Rigel is based in South San Francisco, California. For more information on Rigel, the Company's marketed products and pipeline of potential products, visit www.rigel.com.

1. R289 is an investigational compound not approved by the FDA.
2. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised January 12, 2023. Accessed Feb. 15, 2023: https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html
3. Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3. Reviewed October 2021. Accessed Feb 15, 2023: https://media.leukaemiacare.org.uk/wp-content/uploads/Relapse-in-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf
4. Thol F, Schlenk RF, Heuser M, Ganser A. *H o w I treat refractory and early relapsed acute myeloid leukemia*. Blood (2015) 126 (3): 319-27. doi: https://doi.org/10.1182/blood-2014-10-551911
5. Sallman DA et al. *Unraveling the Pathogenesis of MDS: The NLRP3 Inflammasome and Pyroptosis Drive the MDS Phenotype*. Front Oncol. June 16, 2016. DOI: https://doi.org/10.3389/fonc.2016.0015

Forward Looking Statements

This press release contains forward-looking statements relating to, among other things,expected commercial and financial results for the fourth quarter and fiscal year ended December 31, 2023, expectations related to the potential and market opportunity of olutasidenib as therapeutics for R/R AML and other conditions, the commercialization of fostamatinib or olutasidenib in the U.S. and international markets, and Rigel's ability to further develop its clinical stage product candidates and Rigel's partnering and collaboration efforts, including the progress of Phase 1b clinical trial of R289 for the treatment of lower-risk myeloid dysplastic syndrome, olutasidenib's evaluation in acute myeloid leukemia (AML) and other hematologic cancers, and in newly diagnosed pediatric and young adult patients with high-grade glioma (HGG) harboring an isocitrate dehydrogenase-1 (IDH1) mutation. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements can be identified by words such as "plan", "potential", "may", "expects", "will" and similar expressions in reference to future periods. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Rigel's current beliefs, expectations, and assumptions and hence they inherently involve significant risks, uncertainties and changes in circumstances that are difficult to predict and many of which are outside of our control Therefore, you should not rely on any of these forward-looking statements. 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 fostamatinib or olutasidenib; risks that the FDA, European Medicines Agency, PMDA or other regulatory authorities may make adverse decisions regarding fostamatinib or olutasidenib; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that fostamatinib or olutasidenib 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, 2023 and subsequent filings. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. Rigel does not undertake any obligation to update forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise, 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.

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