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 5, 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.

On March 5, 2024, Rigel Pharmaceuticals, Inc. ("**Rigel**") announced certain financial results for its fourth quarter and year ended December 31, 2023. A copy of Rigel's press release, titled "Rigel Reports Fourth Quarter and Full Year 2023 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 5, 2024, titled "Rigel Reports Fourth Quarter and Full Year 2023 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 5, 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 Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

- *Fourth quarter 2023 Total Revenue of $35.8 million which includes TAVALISSE® net product sales of $25.7 million and REZLIDHIA® net product sales of $3.9 million*
- *Expanded product portfolio with acquisition of U.S. rights to GAVRETO®, an FDA approved targeted therapy for the treatment of RET fusion-positive metastatic non-small cell lung cancer and advanced or metastatic thyroid cancer*
- *Conference call and webcast scheduled today at 4:30 p.m. Eastern Time*

SOUTH SAN FRANCISCO, Calif., March 5, 2024 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the fourth quarter and full year ended December 31, 2023, 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 and sales of REZLIDHIA® (olutasidenib) capsules for the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

"In 2023, fueled by increased physician awareness and adoption for both TAVALISSE and REZLIDHIA, we achieved net product sales of $104.3 million, an increase of 36% compared to 2022," said Raul Rodriguez, Rigel's president and CEO. "We recently expanded our hematology and oncology portfolio with the addition of GAVRETO, a U.S. marketed product for the treatment of RET fusion-positive NSCLC. This addition is highly synergistic with our current portfolio and existing infrastructure, which we believe will further support top line growth. In 2024, we are focused on commercial expansion and execution, while advancing our pipeline with more strategic collaborations like MD Anderson and CONNECT."

Business Update

- In the fourth quarter of 2023, we achieved the highest number of TAVALISSE bottles shipped to patients and clinics in a quarter since launch. A total of 2,671 bottles were sold in the U.S., 2,463 of which were shipped directly to patients and clinics. For the full year ended December 31, 2023, 9,396 bottles of TAVALISSE were shipped directly to patients and clinics, representing an increase of 16% compared to 2022.
- During the fourth quarter of 2023, we achieved 47% growth in total REZLIDHIA bottles sold compared to the third quarter of 2023. A total of 308 bottles were sold in the U.S., 278 of which were shipped directly to patients and clinics. For the full year ended December 31, 2023, 795 bottles of REZLIDHIA were shipped directly to patients and clinics.
- In February 2024, Rigel announced the acquisition of the U.S. rights to GAVRETO® (pralsetinib). GAVRETO is a once daily, small molecule, oral, kinase inhibitor of wild-type RET (rearranged during transfection) and oncogenic RET fusions. GAVRETO is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) and advanced thyroid cancer. The acquisition of this product further expands Rigel's portfolio and leverages Rigel's existing infrastructure in both the institutional and community medical practice settings. Rigel expects to complete the transition of the asset and start recognizing product sales in the third quarter of 2024.
- In January 2024, Rigel and CONNECT announced a strategic development 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 CONNECT funding up to $3 million and study material over the four-year collaboration.

- In December 2023, Rigel and The University of Texas MD Anderson Cancer Center (MD Anderson) 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 MD Anderson $15 million in time-based milestone payments and study material over the five-year collaboration.
- In December 2023, Rigel also 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.

Financial Update

For the fourth quarter of 2023, Rigel reported a net income of $0.7 million, or $0.00 per basic and diluted share, compared to a net income of $1.4 million, or $0.01 per basic and diluted share, for the same period of 2022.

For the fourth quarter of 2023, total revenues were $35.8 million, consisting of $25.7 million in TAVALISSE net product sales, $3.9 million in REZLIDHIA net product sales, $6.2 million in contract revenue from collaborations, and $0.1 million in government contract revenue. TAVALISSE net product sales of $25.7 million represents a 17% increase compared to $21.9 million in the same period of 2022. REZLIDHIA net product sales were $3.9 million compared to $0.9 million in the same period of 2022. Contract revenue from collaborations for the fourth quarter of 2023 consisted of $3.7 million of revenue from Grifols S.A. (Grifols) and $0.3 million of revenue from Medison Pharma Trading AG (Medison) related to delivery of drug supplies and earned royalties, as well as $2.2 million of revenue from Kissei Pharmaceutical Co., Ltd. (Kissei) related to delivery of drug supplies.

For the fourth quarter of 2023, total costs and expenses were $33.8 million, compared to $49.2 million for the same period of 2022. The decrease in costs and expenses was partly due to decreased research and development costs due to the timing of trial completion activities related to the Phase 3 clinical trials of fostamatinib in patients with COVID-19 and wAIHA, as well as the timing of clinical trial activities related to the IRAK 1/4 inhibitor program. In addition, the decrease was also due to lower facility-related costs, and a milestone payment to Forma Therapeutics Inc. (Forma), now Novo Nordisk, recorded as in-process research and development (IPR&D) included within cost and expenses in the fourth quarter of 2022.

For the full year 2023, Rigel reported a net loss of $25.1 million, or $0.14 per basic and diluted share, compared to a net loss of $58.6 million, or $0.34 per basic and diluted share, for the full year 2022.

For the full year 2023, total revenues were $116.9 million, consisting of $93.7 million in TAVALISSE net product sales, $10.6 million in REZLIDHIA net product sales, $11.5 million in contract revenue from collaborations, and $1.1 million in government contract revenue. TAVALISSE net product sales of $93.7 million represents a 24% increase compared to $75.8 million in full year 2022. REZLIDHIA net product sales of $10.6 million increased by $9.7 million compared to $0.9 million in the full year 2022. Contract revenue from collaborations for the full year 2023, consisted of $8.8 million of revenue from Grifols related to the delivery of drug supplies and earned royalties, $2.2 million of revenue from Kissei related to the delivery of drug supplies, and $0.5 million of revenue from Medison related to delivery of drug supplies, earned royalties, and a milestone payment. Government contract revenue for the full year 2023 was primarily related to income recognized in the second quarter of 2023 pursuant to the agreement with the U.S. Department of Defense to support Rigel's Phase 3 clinical trial of fostamatinib in high-risk hospitalized patients with COVID-19.

For the full year 2023, total costs and expenses were $137.4 million, compared to $175.8 million for the full year 2022. The decrease in costs and expenses was partly due to decreased research and development costs due to the completion of trial activities related to the Phase 3 clinical trials of fostamatinib in patients with COVID-19 and wAIHA, as well as timing of clinical trial activities related to the IRAK 1/4 inhibitor program. In addition, the decrease was also due to lower facility-related costs, and an upfront and a milestone payment to Forma recorded as IPR&D included within cost and expenses in the full year 2022.

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

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 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 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 there will be about 20,800 new cases in the United States, most in adults, in 2024.[1]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[2] 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.[3] 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 NSCLC

It is estimated that over 230,000 adults in the U.S. will be diagnosed with lung cancer in 2024. Lung cancer is the leading cause of cancer death in the U.S, with NSCLC being the most common type accounting for 80-85% of all lung cancer diagnoses.[4] RET fusions are implicated in approximately 1-2% of patients with NSCLC.[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, visitwww.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 GAVRETO® (pralsetinib)

INDICATIONS

GAVRETO (pralsetinib) is indicated for the treatment of:

- Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)*

*This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

- **Interstitial Lung Disease (ILD)/Pneumonitis:** Severe, life-threatening, and fatal ILD/pneumonitis can occur in patients treated with GAVRETO. Pneumonitis occurred in 12% of patients who received GAVRETO, including 3.3% with Grade 3-4, and 0.2% with fatal reactions. Monitor for pulmonary symptoms indicative of ILD/pneumonitis. Withhold GAVRETO and promptly investigate for ILD in any patient who presents with acute or worsening of respiratory symptoms (e.g., dyspnea, cough, and fever). Withhold, reduce dose or permanently discontinue GAVRETO based on severity of confirmed ILD.
- **Hypertension:** Occurred in 35% of patients, including Grade 3 hypertension in 18% of patients. Overall, 8% had their dose interrupted and 4.8% had their dose reduced for hypertension. Treatment-emergent hypertension was most commonly managed with anti-hypertension medications. Do not initiate GAVRETO in patients with uncontrolled hypertension. Optimize blood pressure prior to initiating GAVRETO. Monitor blood pressure after 1 week, at least monthly thereafter and as clinically indicated. Initiate or adjust anti-hypertensive therapy as appropriate. Withhold, reduce dose, or permanently discontinue GAVRETO based on the severity.
- **Hepatotoxicity:** Serious hepatic adverse reactions occurred in 1.5% of patients treated with GAVRETO. Increased aspartate aminotransferase (AST) occurred in 49% of patients, including Grade 3 or 4 in 7% and increased alanine aminotransferase (ALT) occurred in 37% of patients, including Grade 3 or 4 in 4.8%. The median time to first onset for increased AST was 15 days (range: 5 days to 2.5 years) and increased ALT was 24 days (range: 7 days to 3.7 years). Monitor AST and ALT prior to initiating GAVRETO, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose or permanently discontinue GAVRETO based on severity.
- **Hemorrhagic Events:** Serious, including fatal, hemorrhagic events can occur with GAVRETO. Grade ≥3 events occurred in 4.1% of patients treated with GAVRETO including one patient with a fatal hemorrhagic event. Permanently discontinue GAVRETO in patients with severe or life-threatening hemorrhage.
- **Tumor Lysis Syndrome (TLS):** Cases of TLS have been reported in patients with medullary thyroid carcinoma receiving GAVRETO. Patients may be at risk of TLS if they have rapidly growing tumors, a high tumor burden, renal dysfunction, or dehydration. Closely monitor patients at risk, consider appropriate prophylaxis including hydration, and treat as clinically indicated.

- **Risk of Impaired Wound Healing:** Impaired wound healing can occur in patients who receive drugs that inhibit the vascular endothelial growth factor (VEGF) signaling pathway. Therefore, GAVRETO has the potential to adversely affect wound healing. Withhold GAVRETO for at least 5 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of GAVRETO after resolution of wound healing complications has not been established.

- **Embryo-Fetal Toxicity:** Based on findings from animal studies and its mechanism of action, GAVRETO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with GAVRETO and for 2 weeks after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with GAVRETO and for 1 week after the last dose.

- **Common adverse reactions (≥25%)** were musculoskeletal pain, constipation, hypertension, diarrhea, fatigue, edema, pyrexia, and cough. **Common Grade 3/4 laboratory abnormalities (≥2%)** were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased phosphate, decreased leukocytes, decreased sodium, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), decreased calcium (corrected), decreased platelets, increased alkaline phosphatase, increased potassium, decreased potassium, and increased bilirubin.

- Avoid coadministration of GAVRETO with **strong or moderate CYP3A inhibitors, P-gp inhibitors, or combined P-gp and strong or moderate CYP3A inhibitors**. If coadministration cannot be avoided, reduce the GAVRETO dose. Avoid coadministration of GAVRETO with **strong or moderate CYP3A inducers**. If coadministration cannot be avoided, increase the GAVRETO dose.

- **Lactation:** Advise women not to breastfeed during treatment with GAVRETO and for 1 week after the last dose.

- **Pediatric Use:** Monitor open growth plates in adolescent patients. Consider interrupting or discontinuing GAVRETO if abnormalities occur.

You may report side effects to the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**. You may also report side effects to Genentech at **1-888-835-2555**.

Please click here to see the full Prescribing Information and Patient Information for GAVRETO.

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. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised January 17, 2024. Accessed Feb. 19, 2024: https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html

2. Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3. Reviewed October 2021. Accessed Feb 19, 2024: https://media.leukaemiacare.org.uk/wp-content/uploads/Relapse-in-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf

3. Thol F, Schlenk RF, Heuser M, Ganser A. *How 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

4. The American Cancer Society. Key Statistics for Lung Cancer. Revised November 20, 2023. Accessed February 7, 2024: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html

5. Kato, S. et al. RET aberrations in diverse cancers: next-generation sequencing of 4,871 patients. Clin Cancer Res. 2017;23(8):1988-1997 doi: 10.1158/1078-0432.CCR-16-1679

Forward Looking Statements

This press release contains forward-looking statements relating to, among other things,expected commercial and financial results, 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, the transition and commercialization of pralsetinib for the treatment of non-small cell lung cancer and advanced thyroid cancer 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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RIGEL PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(unaudited)			
Revenues:				
Product sales, net	$ 29,539	$ 22,783	$ 104,294	$ 76,718
Contract revenues from collaborations	6,153	26,495	11,488	39,024
Government contract	100	2,000	1,100	4,500
Total revenues	35,792	51,278	116,882	120,242
Costs and expenses:				
Cost of product sales	3,790	342	7,110	1,749
Research and development (see Note A)	3,186	15,365	24,522	60,272
Selling, general and administrative (see Note A)	26,850	32,172	105,741	112,451
Restructuring charges	-	1,320	-	1,320
Total costs and expenses	33,826	49,199	137,373	175,792
Income (loss) from operations	1,966	2,079	(20,491)	(55,550)
Interest income	678	429	2,272	684
Interest expense	(1,907)	(1,107)	(6,872)	(3,707)
Net income (loss)	$ 737	$ 1,401	$ (25,091)	$ (58,573)
Net income (loss) per share				
Basic	$ 0.00	$ 0.01	$ (0.14)	$ (0.34)
Diluted	$ 0.00	$ 0.01	$ (0.14)	$ (0.34)
Weighted average shares used in computing net income (loss) per share				
Basic	174,376	172,851	173,897	172,406
Diluted	174,468	172,856	173,897	172,406
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,585	$ 3,426	$ 6,712	$ 10,217
Research and development	348	654	2,094	2,168
	$ 1,933	$ 4,080	$ 8,806	$ 12,385

SUMMARY BALANCE SHEET DATA
(in thousands)

	As of December 31,	
	2023	2022
Cash, cash equivalents and short-term investments	$ 56,933	$ 58,206
Total assets	117,225	134,279
Stockholders' deficit	(28,644)	(13,616)