November 7, 2024

Rigel Reports Third Quarter 2024 Financial Results and Provides Business Update

- *Third quarter total revenue of $55.3 million, which includes TAVALISSE® net product sales of $26.3 million, REZLIDHIA® net product sales of $5.5 million and GAVRETO® net product sales of $7.1 million*
- *Entered into an agreement with Kissei to develop and commercialize REZLIDHIA in all potential indications in Japan, the Republic of Korea and Taiwan, recording an upfront cash payment of $10.0 million during the third quarter*
- *Initial data from the ongoing Phase 1b study evaluating R289, a dual IRAK1/4 inhibitor, in LR-MDS to be presented at the 66th ASH Annual Meeting*
- *Conference call and webcast scheduled today at 4:30 p.m. Eastern Time*

SOUTH SAN FRANCISCO, Calif., Nov. 7, 2024 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today reported financial results for the third quarter ended September 30, 2024, including sales of TAVALISSE® (fostamatinib disodium hexahydrate) for the treatment of chronic immune thrombocytopenia (ITP); REZLIDHIA® (olutasidenib) for the treatment of relapsed or refractory (R/R) mutated isocitrate dehydrogenase-1 (m*IDH1*) acute myeloid leukemia (AML); and GAVRETO® (pralsetinib) for the treatment of metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) and advanced or metastatic thyroid cancer, and recent business progress.

"2024 has been a significant year for Rigel, marked by the acquisition of GAVRETO, our third commercial product, strong revenue growth across our commercial portfolio, and the advancement of our development pipeline," said Raul Rodriguez, Rigel's president and CEO. "This great progress is underpinned by our focus on financial discipline, resulting in positive third-quarter and year-to-date net income. As we close out the year, we will continue driving momentum in our commercial portfolio and hematology and oncology development pipeline."

Third Quarter 2024 Business Update

Commercial Update

- Commercial strength continues for all products with record bottles shipped to patients and clinics and total bottles sold.

- GAVRETO became commercially available from Rigel in June 2024. Third-quarter results reflect the successful transition of existing patients on therapy to Rigel's product. For the fourth quarter, the focus will be on continuing to transition patients.
- The following table summarizes total bottles shipped for the third quarter:

	TAVALISSE	REZLIDHIA	GAVRETO*
Bottles shipped to patients and clinics	2,797	444	717
Change in bottles remaining in distribution channel	(4)	(15)	35
Total bottles shipped	2,793	429	752

*GAVRETO bottle count represents 60-count bottle equivalent

- In September, Rigel entered into an exclusive license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to develop and commercialize REZLIDHIA in all potential indications in Japan, the Republic of Korea and Taiwan. Under the terms of the agreement, Rigel received an upfront cash payment of $10.0 million from Kissei, with the potential for up to an additional $152.5 million in development, regulatory and commercial milestone payments.
- In late October, Rigel issued a Dear Health Care Provider (DHCP) letter related to a new safety signal for GAVRETO after consultation with the U.S. Food and Drug Administration (FDA). The DHCP letter has been posted to the GAVRETO Healthcare Provider website at www.gavreto-hcp.com.

Clinical and Development Update

- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289[1], a novel and selective dual IRAK1/4 inhibitor, in patients with R/R lower-risk myelodysplastic syndrome (LR-MDS). Enrollment in the fifth dose level (500mg / 250mg split dose) is underway.
- In early November, Rigel announced six poster presentations highlighting data from the company's commercial and clinical-stage hematology and oncology portfolio at the upcoming 66th American Society of Hematology (ASH) Annual Meeting and Exposition. Initial data from the ongoing Phase 1b study evaluating R289 in patients with R/R LR-MDS indicate that R289 was generally well tolerated in a heavily pretreated LR-MDS patient population, the majority of whom were high transfusion burden at study entry. As of the data cutoff, 14 of 19 patients were evaluable for efficacy and per International Working Group (IWG) 2018, RBC-transfusion independence (RBC-TI)/hematologic improvement (HI-E) occurred in 36% of patients receiving R289 doses ≥500 mg QD, with a median duration of RBC-TI of 29 weeks. RBC-TI >24 weeks was achieved in 2 high transfusion burden patients following 3 and 5 prior therapies, including a hypomethylating agent. The company will also present additional data for olutasidenib in patients with R/R m*IDH1* AML and MDS.
- In September, Rigel announced the first patient was enrolled in a Phase 1b/2 triplet therapy trial of decitabine and venetoclax in combination with REZLIDHIA in patients with m*IDH1* AML, which is being sponsored and conducted by The University of Texas MD Anderson Cancer Center (MD Anderson). This is the first trial in Rigel's multi-year strategic development alliance with MD Anderson.
- A paper detailing the differences in molecular structure, binding characteristics and clinical outcomes between olutasidenib and ivosidenib, including response rates in patients previously treated with ivosidenib or venetoclax, was published by Dr. Justin M. Watts, Associate Professor of Medicine, Division of Hematology, Chief, Leukemia

Section at the University of Miami Health System, in *Current Treatment Options in Oncology* in October 2024.

Third Quarter 2024 and Year-To-Date Financial Update

For the third quarter ended September 30, 2024, total revenues were $55.3 million, consisting of $26.3 million in TAVALISSE net product sales, $5.5 million in REZLIDHIA net product sales, $7.1 million in GAVRETO net product sales, and $16.4 million in contract revenue from collaborations. TAVALISSE net product sales grew 8% compared to $24.5 million in the same period of 2023. REZLIDHIA net product sales grew 107% compared to $2.7 million in the same period of 2023. GAVRETO became commercially available from Rigel in June 2024. Contract revenue from collaborations consisted of $13.0 million from Kissei Pharmaceutical Co., Ltd. (Kissei) related to an upfront fee from sublicensing olutasidenib and delivery of drug supplies, as well as $3.3 million from Grifols S.A. (Grifols) and $0.1 million from Medison Pharma Trading AG (Medison) related to delivery of drug supplies and earned royalties.

Total costs and expenses were $41.3 million compared to $32.6 million for the same period of 2023. The increase in costs and expenses was mainly due to higher cost of product sales, driven primarily by increased products sales, a sublicensing revenue fee to Forma, increased royalties and amortization of intangible assets. In addition, there were increases in personnel-related costs and commercial-related expenses.

Rigel reported net income of $12.4 million, or $0.71 basic and $0.70 diluted per share, compared to a net loss of $5.7 million, or $0.33 basic and diluted per share, for the same period of 2023. The basic and diluted share and per share amounts for the prior period have been restated to reflect the 1-for-10 reverse stock split effected on June 27, 2024 on a retroactive basis.

For the nine months ended September 30, 2024, total revenues were $121.7 million, consisting of $73.8 million in TAVALISSE net product sales, $15.6 million in REZLIDHIA net product sales, $9.0 million in GAVRETO net product sales, and $23.3 million in contract revenue from collaborations. TAVALISSE net product sales grew 8% compared to $68.1 million in the same period of 2023. REZLIDHIA net product sales grew 133% compared to $6.7 million in the same period of 2023. As mentioned above, GAVRETO became commercially available from Rigel in June 2024. Contract revenue from collaborations consisted of $17.5 million from Kissei related to an upfront fee from sublicensing olutasidenib and delivery of drug supplies, as well as $5.5 million from Grifols and $0.2 million from Medison related to delivery of drug supplies and earned royalties.

Total costs and expenses were $114.1 million compared to $103.5 million for the same period of 2023. The increase in costs and expenses was mainly due to higher cost of product sales driven primarily by increased products sales, a sublicensing revenue fee to Forma, increased royalties and amortization of intangible assets. In addition, there were increases in personnel-related costs, stock-based compensation expense and commercial-related expenses. These increases were partially offset by decreased research and development costs due to the timing of clinical trial activities related to R289, the company's dual IRAK 1/4 inhibitor program, as well as reduced trial activities related to the completed Phase 3 clinical trials of fostamatinib in patients with COVID-19 and in patients with warm antibody hemolytic anemia (wAIHA).

Rigel reported net income of $3.1 million, or $0.18 basic and diluted per share, compared to a net loss of $25.8 million, or $1.49 basic and diluted per share, for the same period of 2023. As discussed above, the share and per share amounts for the prior period have been restated to reflect the 1-for-10 reverse stock split on a retroactive basis for the periods presented.

Cash, cash equivalents and short-term investments as of September 30, 2024 was $61.1 million, compared to $49.1 million as of June 30, 2024, and $56.9 million as of December 31, 2023.

Conference Call and Webcast with Slides Today at 4:30pm Eastern Time

Rigel will hold a live conference call and webcast today at 4:30pm Eastern Time (1:30pm Pacific Time).

Participants can access the live conference call by dialing (877) 407-3088 (domestic) or (201) 389-0927 (international). The conference call 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.[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 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.[5] RET fusions are implicated in approximately 1-2% of patients with NSCLC.[6]

About TAVALISSE®
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.

Please click here for Important Safety Information and Full Prescribing Information for TAVALISSE.

About REZLIDHIA®
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.

Please click here for Important Safety Information and Full Prescribing Information, including Boxed WARNING, for REZLIDHIA.

About GAVRETO®
GAVRETO 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 and 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).*

*Thyroid 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).

Please click here for Important Safety Information and Full Prescribing Information for GAVRETO.

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

TAVALISSE, REZLIDHIA and GAVRETO are registered trademarks 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 June 5, 2024. Accessed June 30, 2024: 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 June 30, 2024: 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. *How I treat refractory and early relapsed acute myeloid leukemia*. Blood (2015) 126 (3): 319-27. Accessed June 30, 2024. doi: https://doi.org/10.1182/blood-2014-10-551911
5. The American Cancer Society. Key Statistics for Lung Cancer. Revised January 29, 2024. Accessed June 30, 2024: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html
6. 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 for developing and commercializing REZLIDHIA in certain international markets, study results relating to safety and tolerability of R289 for the treatment of lower-risk myeloid dysplastic syndrome, expectations for development of Rigel's commercial portfolio and hematology and oncology pipeline, and expectations for Rigel's partnering and collaboration efforts. 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", "look to", "expects", "will", "initial", 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, olutasidenib and pralsetinib; risks that the FDA, European Medicines Agency, PMDA or other regulatory authorities may make adverse decisions regarding fostamatinib, pralsetinib or olutasidenib; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that fostamatinib, pralsetinib 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 June 30, 2024 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)			
Revenues:				
Product sales, net	$ 38,927	$ 27,129	$ 98,380	$ 74,755
Contract revenues from collaborations	16,380	1,005	23,302	5,335
Government contract	—	—	—	1,000
Total revenues	55,307	28,134	121,682	81,090
Costs and expenses:				
Cost of product sales	8,026	1,268	12,858	3,320
Research and development (see Note A)	6,182	6,475	17,748	21,336
Selling, general and administrative (see Note A)	27,043	24,856	83,539	78,891
Total costs and expenses	41,251	32,599	114,145	103,547
Income (loss) from operations	14,056	(4,465)	7,537	(22,457)
Interest income	425	672	1,570	1,594
Interest expense	(2,060)	(1,899)	(5,963)	(4,965)
Net income (loss)	$ 12,421	$ (5,692)	$ 3,144	$ (25,828)
Net income (loss) per share [1]				
Basic	$ 0.71	$ (0.33)	$ 0.18	$ (1.49)
Diluted	$ 0.70	$ (0.33)	$ 0.18	$ (1.49)
Weighted average shares used in computing net income (loss) per share [1]				
Basic	17,600	17,436	17,556	17,389
Diluted	17,648	17,436	17,599	17,389
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 2,360	$ 1,596	$ 9,067	$ 5,127
Research and development	284	347	1,239	1,746
	$ 2,644	$ 1,943	$ 10,306	$ 6,873

(1) Share and per share amounts have been restated to reflect the 1-for-10 reverse stock split effected on June 27, 2024 on a retroactive basis for all periods presented.

SUMMARY BALANCE SHEET DATA
(in thousands)

	As of September, 2024	As of December 31, 2023[1]
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 61,114	$ 56,933
Total assets	139,419	117,225
Stockholders' deficit	(14,636)	(28,644)

(1) Derived from audited financial statements

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