August 6, 2024

Rigel Reports Second Quarter 2024 Financial Results and Provides Business Update

- Second quarter total revenue of $36.8 million, which includes TAVALISSE® net product sales of $26.4 million, REZLIDHIA® net product sales of $5.2 million and GAVRETO® net product sales of $1.9 million
- Successfully completed NDA transfer of GAVRETO for the treatment of RET fusion-positive metastatic non-small cell lung cancer and advanced or metastatic thyroid cancer, with product available from Rigel beginning June 27, 2024
- Conference call and webcast scheduled today at 4:30 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 6, 2024 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today reported financial results for the second quarter ended June 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 (mIDH1) 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.

"In the second quarter, we advanced key strategic initiatives including the successful transfer of GAVRETO to our commercial portfolio, enabling us to bring this important treatment option to current and newly prescribed patients without interruption," said Raul Rodriguez, Rigel's president and CEO. "The addition of GAVRETO, combined with record revenues from TAVALISSE and REZLIDHIA, has allowed us to approach net income break even. We look to maintain our financial discipline as we expand our commercial reach and advance our development programs."

Second Quarter 2024 Business Update

Commercial Update

- Commercial strength continues with record TAVALISSE and REZLIDHIA bottles shipped to patients and clinics and total bottles sold.
- In June 2024, Rigel announced the completion of the transfer of the New Drug

Application (NDA) for the U.S. rights to GAVRETO. GAVRETO became commercially available from Rigel in the U.S. beginning June 27, 2024, ahead of the company's July 1 target for commercial availability.

- The following table summarizes total bottles shipped for the second quarter:

	TAVALISSE	REZLIDHIA	GAVRETO*
Bottles shipped to patients and clinics	2,672	424	-
Change in bottles remaining in distribution channel	50	(23)	228
Total bottles shipped	2,722	401	228

*GAVRETO bottle count represents 60-count bottle equivalent

Clinical and Development Update

- Rigel continues to advance its Phase 1b clinical trial evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289[1], a novel and selective IRAK1/4 inhibitor, in patients with relapsed/refractory lower-risk myelodysplastic syndrome (LR-MDS). Enrollment in the fourth dose level (250 mg twice daily) of the trial is underway. Preliminary data are expected by the end of 2024.
- In early August, The University of Texas MD Anderson Cancer Center, with Rigel's support, opened enrollment for a Phase 1b/2 trial of decitabine and venetoclax in combination with olutasidenib in patients with IDH1-mutated AML (NCT06445959). This is the first trial in Rigel's multi-year strategic development collaboration with MD Anderson. The Phase 1b part of the trial seeks to determine the safety and tolerability and recommended Phase 2 dose of decitabine and venetoclax in combination with olutasidenib. The primary objective of the Phase 2 part of the trial is to determine the complete remission rate in both newly diagnosed and relapsed/refractory patients.
- In late July, City of Hope National Medical Center opened enrollment for a pilot trial of olutasidenib as maintenance therapy following allogeneic hematopoietic cell transplantation (HCT). The primary objective of the trial is to evaluate the safety and tolerability of olutasidenib as post-HCT maintenance therapy in patients with mIDH1 AML, myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML).
- Rigel presented the final long-term efficacy data from the registrational Phase 2 trial of REZLIDHIA in heavily pretreated patients with R/R mIDH1 AML, including those receiving prior venetoclax, in an oral presentation and 4 posters at the EHA2024 Hybrid Congress. In addition, the company presented 3 posters at the2024 ASCO Annual Meeting, which included safety and efficacy of olutasidenib treatment in elderly patients with R/R mIDH1 AML and an overview of the Phase 1b trial of R289 in patients with LR-MDS.
- Dr. Jorge E. Cortes, Director, Georgia Cancer Center, Cecil F. Whitaker Jr., GRA Eminent Scholar Chair in Cancer, and Phase 2 trial investigator, was published in the *Expert Review of Hematology* in May outlining the drug profile and summarizing key safety and efficacy data for olutasidenib, including in patients previously treated with venetoclax or ivosidenib.

Second Quarter 2024 and Year-To-Date Financial Update

For the second quarter ended June 30, 2024, total revenues were $36.8 million, consisting of $26.4 million in TAVALISSE net product sales, $5.2 million in REZLIDHIA net product sales, $1.9 million in GAVRETO net product sales, and $3.4 million in contract revenue from collaborations. TAVALISSE net product sales grew 24% compared to $21.3 million in the

same period of 2023. REZLIDHIA net product sales grew 102% compared to $2.6 million in the same period of 2023. GAVRETO became commercially available from Rigel on June 27, 2024. Contract revenue from collaborations consisted of $2.2 million from Kissei Pharmaceutical Co., Ltd. (Kissei) related to delivery of drug supplies, $1.1 million from Grifols S.A. (Grifols) related to earned royalties, and $0.1 million from Medison Pharma Trading AG (Medison) related to delivery of drug supplies and earned royalties.

Total costs and expenses were $36.4 million compared to $32.2 million for the same period of 2023. The increase in costs and expenses was partly due to higher cost of product sales, driven primarily by higher amortization of intangibles and royalties, increased personnel-related costs, and increased research and development costs due to the progress of clinical activities, including R289, the company's IRAK 1/4 inhibitor program.

Rigel reported a net loss of $1.0 million, or $0.06 per basic and diluted share, compared to a net loss of $6.6 million, or $0.38 per basic and diluted share, for the same period of 2023. The basic and diluted 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.

For the six months ended June 30, 2024, total revenues were $66.4 million, consisting of $47.5 million in TAVALISSE net product sales, $10.0 million in REZLIDHIA net product sales, $1.9 million in GAVRETO net product sales, and $6.9 million in contract revenue from collaborations. TAVALISSE net product sales grew 9% compared to $43.6 million in the same period of 2023. REZLIDHIA net product sales grew 150% compared to $4.0 million in the same period of 2023. As mentioned above, GAVRETO became commercially available from Rigel on June 27, 2024. Contract revenue from collaborations consisted of $4.5 million from Kissei related to delivery of drug supplies, $2.2 million from Grifols related to earned royalties, and $0.2 million from Medison related to delivery of drug supplies and earned royalties.

Total costs and expenses were $72.9 million compared to $70.9 million for the same period of 2023. The increase in costs and expenses was partly due to higher cost of product sales, driven primarily by higher amortization of intangibles and royalties, increased personnel-related costs and higher stock-based compensation expenses mainly from performance awards. 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 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 warm antibody hemolytic anemia (wAIHA).

Rigel reported a net loss of $9.3 million, or $0.53 per basic and diluted share, compared to a net loss of $20.1 million, or $1.16 per basic and diluted share, for the same period of 2023. As discussed above, the share and per share amounts have been restated to reflect the 1-for-10 reverse stock split on a retroactive basis for all periods presented.

Cash, cash equivalents and short-term investments as of June 30, 2024 was $49.1 million, compared to $49.6 million as of March 31, 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 related to the potential and

market opportunity of olutasidenib as a therapeutic for R/R AML and other conditions, the commercialization of fostamatinib for cITP, the commercialization of pralsetinib for the treatment of non-small cell lung cancer and advanced thyroid cancer, Rigel's ability to further develop its clinical stage product candidates and Rigel's partnering and collaboration efforts, as well as the progress of the Phase 1b clinical trial of R289 for the treatment of lower-risk myeloid dysplastic syndrome, olutasidenib's evaluation in acute myeloid leukemia (AML), including in patients receiving prior venetoclax, and in other hematologic cancers, and including olutasidenib as a maintenance therapy following allogeneic hematopoietic cell transplantation, and the use of decitabine and venetoclax in combination with olutasidenib for newly diagnosed or relapsed/refractory participants with IDH1-mutated myeloid malignancy. 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" 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 March 31, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(unaudited)			
Revenues:				
	$	$	$	$
Product sales, net	33,450	23,881	59,453	47,626
Contract revenues from collaborations	3,391	2,005	6,922	4,330
Government contract	—	1,000	—	1,000
Total revenues	36,841	26,886	66,375	52,956
Costs and expenses:				
Cost of product sales	2,807	1,075	4,832	2,052
Research and development (see Note A)	5,540	4,772	11,566	14,861
Selling, general and administrative (see Note A)	28,047	26,306	56,496	54,035
Total costs and expenses	36,394	32,153	72,894	70,948
Income (loss) from operations	447	(5,267)	(6,519)	(17,992)
Interest income	552	529	1,145	922
Interest expense	(2,029)	(1,862)	(3,903)	(3,066)
	$	$	$	$
Net loss	(1,030)	(6,600)	(9,277)	(20,136)
	$	$	$	$
Net loss per share, basic and diluted [1]	(0.06)	(0.38)	(0.53)	(1.16)
Weighted average shares used in computing net loss per share, basic and diluted [1]	17,549	17,356	17,534	17,365

Note A

Stock-based compensation expense included in:				
	$	$	$	$
Selling, general and administrative	2,223	1,796	6,707	3,531
Research and development	305	376	955	1,399
	$	$	$	$
	2,528	2,172	7,662	4,930

(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 June 30, 2024	As of December 31, 2023[1]
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 49,102	$ 56,933
Total assets	128,408	117,225
Stockholders' deficit	(29,914)	(28,644)

(1) Derived from audited financial statements

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