

May 6, 2025



## Rigel Reports First Quarter 2025 Financial Results and Provides Business Update

- *First quarter 2025 total revenue of approximately \$53.3 million, which includes net product sales of \$43.6 million and contract revenues from collaborations of \$9.8 million*
- *Generated \$11.4 million of net income in the first quarter of 2025*
- *R289 granted Orphan Drug designation for the treatment of MDS and Fast Track designation for the treatment of previously-treated transfusion dependent lower-risk MDS by the FDA*
- *2025 Outlook: Total revenue of approximately \$200 to \$210 million*
- *Conference call and webcast scheduled today at 4:30 p.m. Eastern Time*

SOUTH SAN FRANCISCO, Calif., May 6, 2025 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today reported financial results for the first quarter ended March 31, 2025, including sales of TAVALISSE<sup>®</sup> (fostamatinib disodium hexahydrate), GAVRETO<sup>®</sup> (pralsetinib) and REZLIDHIA<sup>®</sup> (olutasidenib), and recent business progress.

"Our first quarter results reflect the continued strength of our growing commercial business. This robust year-over-year revenue growth coupled with our continued financial discipline enabled us to generate more than \$11 million in net income this quarter. These results uniquely position us to invest in our pipeline, including our ongoing Phase 1b clinical study evaluating R289 in patients with relapsed or refractory lower-risk MDS," said Raul Rodriguez, Rigel's president and CEO. "With a strong start to the year, we are focused on continuing our commercial growth, and building and advancing our development pipeline, including sharing data from the dose escalation portion of our R289 study later this year."

### **First Quarter 2025 Business Update**

#### **Commercial**

- Net product sales of \$43.6 million, an increase of 68% from the same period of 2024. Year-over-year commercial strength was driven by the expansion of the commercial portfolio, including the successful integration of GAVRETO.
- Rigel's partner Kissei Pharmaceutical Co., Ltd. (Kissei) announced in January that the Korean Ministry of Food and Drug Safety approved TAVALISSE for the treatment of thrombocytopenia in adult patients with chronic idiopathic thrombocytopenic purpura who have had an insufficient response to a previous treatment. In the first quarter,

Rigel recognized \$3.0 million in regulatory milestone revenue in connection with this approval.

## Clinical Development

- R289<sup>1</sup>, a novel and selective dual interleukin receptor-associated kinases 1 and 4 (IRAK1/4) inhibitor, was granted [Orphan Drug](#) designation for the treatment of myelodysplastic syndromes by the U.S. Food and Drug Administration (FDA) in January. R289 was previously granted [Fast Track](#) designation for the treatment of previously-treated transfusion dependent lower-risk myelodysplastic syndrome (MDS) by the FDA.
- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289 in patients with relapsed or refractory (R/R) lower-risk MDS. Enrollment in the sixth dose level (500 mg twice daily) is ongoing.

## Corporate

- Dr. Mark Frohlich [joined](#) Rigel's Board of Directors as an independent director and member of the Board of Director's Corporate Governance, Health Care Compliance Oversight and Nominating Committee, and the Scientific and Clinical Trial Advisory Committee, effective March 6, 2025.
- In March, Rigel [announced](#) it entered into a settlement agreement with Annora Pharma Private Ltd., Hetero Labs Ltd., and Hetero USA, Inc. (collectively "Annora") resolving patent litigation related to TAVALISSE. The litigation resulted from submission by Annora of an Abbreviated New Drug Application to the FDA seeking approval to market a generic version of TAVALISSE in the United States. Under the terms of the settlement agreement, Annora will have a license to sell its generic product in Q2 2032 or earlier under certain circumstances. In accordance with the agreement, the parties terminated all ongoing litigation between Rigel and Annora regarding TAVALISSE patents pending in New Jersey.
- In late April, Rigel notified Eli Lilly and Company (Lilly) that it will not exercise its opt-in right related to the development and commercialization of ocadusertib (previously R552) for the treatment of non-central nervous system (CNS) diseases. As a result of this notification, in the second quarter of 2025, Rigel expects to recognize approximately \$40.0 million in non-cash revenue resulting from the release of the remaining cost share liability currently on the balance sheet. Per the agreement with Lilly, Rigel will continue to be entitled to receive milestone and tiered royalty payments on future net sales of ocadusertib and its CNS penetrant program.

## **First Quarter 2025 Financial Update**

For the first quarter ended March 31, 2025, total revenues were \$53.3 million, consisting of \$43.6 million in net product sales and \$9.8 million in contract revenues from collaborations. Net product sales grew 68% compared to \$26.0 million in the same period of 2024. TAVALISSE net product sales were \$28.5 million, growth of 35% compared to \$21.1 million in the same period of 2024. GAVRETO net product sales were \$9.0 million. GAVRETO became commercially available from Rigel in June 2024. REZLIDHIA net product sales were \$6.1 million, growth of 25% compared to \$4.9 million in the same period of 2024. Contract revenues from collaborations primarily consisted of \$4.7 million of revenue from

Grifols S.A. related to delivery of drug supplies and earned royalties, \$4.6 million of revenue from Kissei related to the milestone payment and delivery of drug supplies and \$0.4 million of revenue from Medison Pharma related to delivery of drug supplies and earned royalties.

Total costs and expenses were \$40.6 million compared to \$36.5 million for the same period of 2024. The increase in costs and expenses was mainly due to increased personnel-related costs, and higher research and development costs driven by timing of clinical activities related to R289 and olutasidenib. In addition, cost of product sales increased, driven by increased product sales, higher royalties and amortization of intangible assets. These increases were partially offset by decreased stock-based compensation expenses.

Rigel reported net income of \$11.4 million, or \$0.64 basic and \$0.63 diluted per share, compared to a net loss of \$8.2 million, or \$0.47 basic and diluted per share, for the same period of 2024. 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.

Cash, cash equivalents and short-term investments as of March 31, 2025 was \$77.1 million, compared to \$77.3 million as of December 31, 2024.

### **2025 Outlook**

Rigel continues to anticipate 2025 total revenue of approximately \$200 to \$210 million, which includes:

- Net product sales of approximately \$185 to \$192 million.
- Contract revenues from collaborations of approximately \$15 to \$18 million.

The revenue ranges above exclude approximately \$40.0 million in non-cash revenue that Rigel expects to recognize in the second quarter of 2025 related to the release of the remaining cost share liability from Rigel's collaboration with Lilly for the development and commercialization of ocadusertib.

The company anticipates it will report positive net income for the full year 2025, while funding existing and new clinical development programs.

### **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](http://www.rigel.com). The webcast will be archived and available for replay after the call via the Rigel website.

### **About ITP**

In patients with immune thrombocytopenia (ITP), 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. Patients 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 NSCLC**

It is estimated that over 226,000 adults in the U.S. will be diagnosed with lung cancer in 2025. Lung cancer is the leading cause of cancer death in the U.S, with non-small cell lung cancer (NSCLC) being the most common type accounting for 85-90% of all lung cancer diagnoses.<sup>2</sup> RET fusions are implicated in approximately 1-2% of patients with NSCLC.<sup>3</sup>

### **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 22,010 new cases in the United States, most in adults, in 2025.<sup>4</sup>

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.<sup>5,6</sup> 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.<sup>7</sup> 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 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 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.**

### **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.

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

TAVALISSE, GAVRETO and REZLIDHIA 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](http://www.rigel.com).

1. R289 is an investigational compound not approved by the FDA.
2. The American Cancer Society. Key Statistics for Lung Cancer. Revised January 16, 2025. Accessed March 31, 2025: <https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html>
3. 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
4. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised March 4, 2025. Accessed March 31, 2025: <https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html>
5. Patel, A, et al. Outcomes of Patients With Acute Myeloid Leukemia Who Relapse After 5 Years of Complete Remission. 2021 Sep 7;28(7):811-814. doi: <https://doi.org/10.3727/096504020X15965357399750>
6. Thol F, Ganser, A. Treatment of Relapsed Acute Myeloid Leukemia. Curr. Treat. Options on Oncol. (2020) 21: 66. doi: <https://doi.org/10.1007/s11864-020-00765-5>
7. 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>

### **Forward Looking Statements**

*This press release contains forward-looking statements relating to, among other things, expected commercial and financial results, projected financial performance and outlook for 2025, expectations for growing our commercial business, potential investment in our pipeline, results of the dose escalation portion of our R289 study, non-cash revenue recognition relating to our agreement with Lilly, continued ability for developing and commercializing TAVALISSE, GAVRETO, and REZLIDHIA domestically and in certain international markets, 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 "anticipates", "plan", "outlook", "potential", "may", "look to", "expects", "will", "initial", "promising", 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 Annual Report on Form 10-K for the year ended December 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)

	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
	<b>(unaudited)</b>	
Revenues:		
Product sales, net	\$ 43,550	\$ 26,003
Contract revenues from collaborations	9,783	3,531
Total revenues	53,333	29,534
Costs and expenses:		
Cost of product sales	4,409	2,025
Research and development (see Note A)	8,436	6,026
Selling, general and administrative (see Note A)	27,715	28,449
Total costs and expenses	40,560	36,500
Income (loss) from operations	12,773	(6,966)
Interest income	591	593
Interest expense	(1,853)	(1,874)
Income (loss) before income taxes	11,511	(8,247)
Provision for income taxes	65	—
Net income (loss)	\$ 11,446	\$ (8,247)
Net income (loss) per share <sup>(1)</sup>		
Basic	\$ 0.64	\$ (0.47)
Diluted	\$ 0.63	\$ (0.47)
Weighted average shares used in computing net income (loss) per share <sup>(1)</sup>		
Basic	17,808	17,520
Diluted	18,169	17,520

**Note A**

Stock-based compensation expense included in:

Selling, general and administrative	\$ 2,452	\$ 4,484
Research and development	872	650
	\$ 3,324	\$ 5,134

(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 prior period presented.

**SUMMARY BALANCE SHEET DATA**  
(in thousands)

	<b>As of March 31,</b>	<b>As of December 31,</b>
	<b>2025</b>	<b>2024 <sup>(1)</sup></b>
	<b>(unaudited)</b>	
Cash, cash equivalents and short-term investments	\$ 77,099	\$ 77,321
Total assets	175,972	163,976
Stockholders' equity	18,567	3,288

(1) Derived from audited financial statements

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