

Rigel Reports Second Quarter 2025 Financial Results and Provides Business Update

- Second quarter 2025 total revenue of approximately \$101.7 million, which includes net product sales of \$58.9 million and contract revenues from collaborations of \$42.7 million
- Completed enrollment in the dose escalation part of the ongoing Phase 1b study evaluating R289, a dual IRAK1/4 inhibitor, in patients with R/R lower-risk MDS
- Generated \$59.6 million of net income in the second guarter of 2025
- Updated 2025 Outlook: Total revenue of approximately \$270 to \$280 million, which includes net product sales of \$210 to \$220 million
- Total revenue and net income are inclusive of \$40 million in non-cash contract revenue related to Rigel's agreement with Lilly
- Conference call and webcast scheduled today at 4:30 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 5, 2025 /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, 2025, including sales of TAVALISSE® (fostamatinib disodium hexahydrate), GAVRETO® (pralsetinib) and REZLIDHIA® (olutasidenib), and recent business progress.

"Our strategic and disciplined approach to building our business has generated another strong quarter for the company. In the second quarter, we grew net product sales by 76% year-over-year, generated \$59.6 million in net income and increased our cash balance to \$108.4 million. This strong performance has enabled us to raise our 2025 financial guidance," said Raul Rodriguez, Rigel's president and CEO. "We're also excited by the continued advancement of our hematology and oncology development pipeline. In July, we completed enrollment in the dose escalation part of our ongoing Phase 1b study evaluating R289 in patients with relapsed or refractory lower-risk MDS. Later this year, we plan to share updated data from that study and initiate the dose expansion part of the study."

Second Quarter 2025 Business Update

Commercial

• Net product sales were \$58.9 million, an increase of 76% from the same period of

2024.

 Rigel's partner Kissei Pharmaceutical Co., Ltd. (Kissei) announced that its licensing partner, JW Pharmaceutical Corporation, commercially launched TAVALISSE in South Korea in early July.

Corporate

• In April, Rigel notified Eli Lilly and Company (Lilly) that it would 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 the notification, Rigel recognized \$40.0 million in non-cash revenue resulting from the release of the remaining cost share liability in the second quarter. 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 the companies' CNS penetrant program.

Clinical Development

- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289¹, a novel and selective dual interleukin receptor-associated kinases 1 and 4 (IRAK1/4) inhibitor, in patients with relapsed or refractory (R/R) lower-risk myelodysplastic syndrome (MDS). Enrollment in the dose escalation part of the study was completed in July. The company expects to share updated data from the study later this year and plans to initiate the dose expansion part of the study in the second half of this year.
- Rigel <u>presented</u> 4 posters at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and 3 posters at the European Hematology Association (EHA) 2025 Congress. Presentations included the final data from the GAVRETO (pralsetinib) Phase 1/2 ARROW study in *RET* fusion-positive non-small cell lung cancer (NSCLC) and other solid tumors, and supportive data for REZLIHDIA (olutasidenib) in patients with mutated isocitrate dehydrogenase-1 (m/DH1) relapsed or refractory (R/R) acute myeloid leukemia (AML).

Key Publications

- A paper titled "Effectiveness of Olutasidenib versus Ivosidenib in Patients With Mutated Isocitrate Dehydrogenase 1 Acute Myeloid Leukemia Who Are Relapsed or Refractory to Venetoclax: The 2102-HEM-101 Trial Versus a US Electronic Health Record-Based External Control Arm," was published in June by Catherine Lai, M.D., MPH, lead author and associate professor of Clinical Medicine, Division of Hematology-Oncology, Department of Medicine at University of Pennsylvania, in <u>Leukemia & Lymphoma</u>.
- A paper titled "Olutasidenib Alone or Combined with Azacitidine in Patients with Mutant *IDH1* Myelodysplastic Syndrome," was published in July by Jorge E. Cortes, M.D., lead author and director, Georgia Cancer Center, Cecil F. Whitaker Jr., GRA Eminent Scholar Chair in Cancer, in <u>Blood Advances</u>. This is the first full report of the safety and clinical activity of an mIDH1 inhibitor plus hypomethylating agent (HMA) combination in patients with treatment-naïve and R/R MDS. The paper showed olutasidenib, alone or in combination with azacitidine, induced a high rate of clinically meaningful complete remission and hematologic improvement responses with durable remission duration, accompanied by low rates of serious treatment-emergent-adverse

events in patients with intermediate-, high- or very high-risk MDS harboring mIDH1.

Second Quarter 2025 and Year-to-Date Financial Update

For the second quarter ended June 30, 2025, total revenues were \$101.7 million, consisting of \$58.9 million in net product sales and \$42.7 million in contract revenues from collaborations. Net product sales grew 76% compared to \$33.5 million in the same period of 2024. TAVALISSE net product sales were \$40.1 million, growth of 52% compared to \$26.4 million in the same period of 2024. GAVRETO net product sales were \$11.8 million compared to \$1.9 million in the same period of 2024. GAVRETO became commercially available from Rigel in late June 2024. REZLIDHIA net product sales were \$7.0 million, growth of 36% compared to \$5.2 million in the same period of 2024. Contract revenues from collaborations primarily consisted of \$40.0 million in non-cash revenue resulting from the release of the remaining cost share liability related to the agreement with Lilly for the development and commercialization of ocadusertib, \$2.0 million of revenue from Grifols S.A. (Grifols) related to delivery of drug supplies and earned royalties, \$0.4 million of revenue from Kissei related to the delivery of drug supplies, and \$0.2 million of revenue from Medison Pharma (Medison) related to delivery of drug supplies and earned royalties.

Total costs and expenses were \$40.6 million compared to \$36.4 million for the same period of 2024. The increase in costs and expenses was mainly due to higher cost of product sales, increased research and development costs driven by the timing of clinical activities related to olutasidenib and R289, and higher personnel-related costs and stock-based compensation expense.

Rigel reported net income of \$59.6 million, or \$3.33 basic and \$3.28 diluted per share, compared to a net loss of \$1.0 million, or \$0.06 basic and diluted per share, for the same period of 2024.

For the six months ended June 30, 2025, total revenues were \$155.0 million, consisting of \$102.5 million in net product sales and \$52.5 million in contract revenues from collaborations. Net product sales grew 72% compared to \$59.5 million in the same period of 2024. TAVALISSE net product sales were \$68.5 million, growth of 44% compared to \$47.5 million in the same period of 2024. GAVRETO net product sales were \$20.8 million compared to \$1.9 million in the same period of 2024. GAVRETO became commercially available from Rigel in late June 2024. REZLIDHIA net product sales were \$13.1 million, growth of 31% compared to \$10.0 million in the same period of 2024. Contract revenues from collaborations primarily consisted of \$40.0 million in non-cash revenue resulting from the release of the remaining cost share liability related to the agreement with Lilly for the development and commercialization of ocadusertib, \$6.7 million of revenue from Grifols related to delivery of drug supplies and earned royalties, \$5.1 million of revenue from Kissei related to a milestone payment and delivery of drug supplies and \$0.6 million of revenue from Medison related to delivery of drug supplies and earned royalties.

Total costs and expenses were \$81.1 million compared to \$72.9 million for the same period of 2024. The increase in costs and expenses was mainly due to higher cost of product sales, increased research and development costs driven by the timing of clinical activities related to olutasidenib and R289, and higher personnel-related costs. These increases were partially offset by decreased stock-based compensation expense primarily from performance-based stock awards.

Rigel reported net income of \$71.1 million, or \$3.98 basic and \$3.91 diluted per share, compared to a net loss of \$9.3 million, or \$0.53 basic and diluted per share, for the same period of 2024.

Cash, cash equivalents and short-term investments as of June 30, 2025 was \$108.4 million, compared to \$77.3 million as of December 31, 2024.

2025 Outlook

Rigel is updating its 2025 total revenue guidance to approximately \$270 to \$280 million, an increase from the previous range of approximately \$200 to \$210 million, which includes:

- Net product sales of approximately \$210 to \$220 million, an increase from the previous range of approximately \$185 to \$192 million.
- Contract revenues from collaborations of approximately \$60 million, an increase from the previous range of approximately \$15 to \$18 million.

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

The above total revenues and contract revenues from collaborations are inclusive of \$40 million in non-cash contract revenue related to Rigel's agreement with Lilly.

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 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.² RET fusions are implicated in approximately 1-2% of patients with NSCLC.³

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 2025.⁴

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.^{5,6} 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.⁷ 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 <u>here</u> 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 <u>here</u> 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 <u>here</u> for Important Safety Information and Full Prescribing Information, including Boxed WARNING, for REZLIDHIA.

To report side effects of prescription drugs to the FDA, visit<u>www.fda.gov/medwatch</u> 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.

- 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, continued advancement and updated results of the dose escalation portion of our R289 study, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 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)

	Thr	Three Months Ended June 30,		Six Months End		nded	ded June 30,	
		2025		2024		2025		2024
D			(unaudited)					
Revenues:	\$		\$		\$		\$	
Product sales, net	φ	58,948	φ	33,450	φ	102,498	φ	59,453
Contract revenues from collaborations		42,737		3,391		52,520		6,922
Total revenues		101,685		36,841		155,018		66,375
Costs and expenses:		,		22,211		,		,
Cost of product sales								
·		4,504		2,807		8,913		4,832
Research and development (see Note A)		6,821		5,540		15,257		11,566
Selling, general and administrative (see Note A)		29,257		28,047		56,972		56,496
Total costs and expenses		40,582		36,394		81,142		72,894
Income (loss) from operations		61,103		447		73,876		(6,519)
Interest income		753		552		1,344		1,145
Interest expense		(1,874)		(2,029)		(3,727)		(3,903)
Income (loss) before income taxes		59,982		(1,030)		71,493		(9,277)
Provision for income taxes		369				434		_
	\$	E0 C42	\$	(4.020)	\$	74.050	\$	(0.077)
Net income (loss)		59,613		(1,030)		71,059		(9,277)
Net income (loss) per share								
	\$		\$		\$		\$	
Basic		3.33		(0.06)		3.98		(0.53)
	\$		\$		\$		\$	
Diluted		3.28		(0.06)		3.91		(0.53)
Weighted average shares used in computing net income (loss) per share								
Basic		17,885		17,549		17,848		17,534
Diluted		18,162		17,549		18,168		17,534
Note A								
Stock-based compensation expense included in:								
etes. Sassa compensation expense included in	\$		\$		\$		\$	
Selling, general and administrative	*	2,759	~	2,223	*	5,211	Ψ.	6,707
Research and development		517		305		1,389		955
	\$		\$		\$		\$	
		3,276		2,528		6,600		7,662
	====							

SUMMARY BALANCE SHEET DATA (in thousands)

	As of June 30, 2025		As of December 31, 2024 (1)	
Cash, cash equivalents and short-term investments	(unai	udited) 108.378	\$	77.321
Total assets		206,736		163,976
Stockholders' equity (1) Derived from audited financial statements		81,934		3,288

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