November 4, 2025

Rigel Reports Third Quarter 2025 Financial Results and Provides Business Update

- *Third quarter 2025 total revenue of approximately $69.5 million, including record net product sales of $64.1 million and contract revenues from collaborations of $5.4 million*
- *Generated $27.9 million of net income in the third quarter of 2025*
- *Completed enrollment in the dose escalation phase and enrolled the first patient in the dose expansion phase of the ongoing Phase 1b study evaluating R289, Rigel's dual IRAK1/4 inhibitor, in lower-risk MDS*
- *Oral presentation featuring updated data from the dose escalation phase of the R289 Phase 1b study to be presented at the ASH Annual Meeting in December*
- *Updated 2025 Outlook: Total revenue of approximately $285 to $290 million, which includes net product sales of $225 to $230 million*
- *Conference call and webcast scheduled today at 4:30 p.m. Eastern Time*

SOUTH SAN FRANCISCO, Calif., Nov. 4, 2025 /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, 2025, including sales of TAVALISSE® (fostamatinib disodium hexahydrate), GAVRETO® (pralsetinib) and REZLIDHIA® (olutasidenib), and recent business progress.

"Our strong third-quarter performance demonstrates our strategic focus on commercial execution, pipeline development, and financial discipline. We are raising our full-year 2025 guidance due to our outstanding commercial performance year-to-date," said Raul Rodriguez, Rigel's president and CEO. "Our development pipeline continues to advance, including our ongoing Phase 1b study evaluating R289 for the treatment of patients with lower-risk MDS. With enrollment complete in the dose escalation phase of the study, we look forward to presenting updated data in an oral presentation at ASH in December. We're also excited to have reached the next milestone of this program with the initiation of the dose expansion phase of the study."

Third Quarter 2025 Business Update

Commercial

- Net product sales were $64.1 million, an increase of 65% from the same period of 2024.
- TAVALISSE was commercially launched in South Korea in July by JW Pharmaceutical

Corporation, the licensing partner of Kissei Pharmaceutical Co., Ltd. (Kissei), Rigel's partner in certain Asian countries.

Clinical Development

- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289[1], a potent 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 phase of the study was completed in July. In October, Rigel announced the first patient was enrolled in the dose expansion phase of the study, where up to 40 patients will be randomized to either 500 mg once daily or 500 mg twice daily to determine the recommended Phase 2 dose for future clinical trials.
- Rigel announced one oral presentation and four poster presentations highlighting data from its commercial and clinical-stage hematology and oncology portfolio at the upcoming 67th American Society of Hematology (ASH) Annual Meeting and Exposition. The abstract with updated data from the ongoing Phase 1b study of R289 showed R289 continues to be generally well tolerated in a heavily pretreated lower-risk MDS patient population, the majority of whom were high transfusion burden at study entry, and preliminary signs of efficacy in dose levels of at least 500 mg once daily and higher. Updated data as of an October 28, 2025, data cut off will be presented in the oral presentation. The company will also present additional data for olutasidenib in patients with R/R mutated isocitrate dehydrogenase-1 (m*IDH1*) acute myeloid leukemia (AML).
- The fifth study under the strategic alliance between Rigel and The University of Texas MD Anderson Cancer Center opened for enrollment in September. This Phase 2 multi-arm, multi-center, open-label, non-randomized clinical study will evaluate olutasidenib in combination with co-targeted therapies in patients with R/R *IDH1*-mutated myeloid malignancies harboring activated signaling pathway mutations (NCT07032727). The primary objectives of the study are to evaluate safety and the composite complete remission rate.
- In October, the first patient was enrolled in the CONNECT Phase 2 TarGeT-D study evaluating olutasidenib in combination with temozolomide, followed by olutasidenib monotherapy as a maintenance regimen for newly-diagnosed adolescent and young adult patients with a high-grade glioma harboring an *IDH1* mutation (NCT06161974).

Corporate

- Eli Lilly and Company (Lilly) continues to advance ocadusertib (previously R552 or LY3871801), an investigational, potent and selective receptor-interacting protein kinase 1 (RIPK1) inhibitor. Enrollment in the Phase 2a clinical trial in adult patients with moderately to severely active rheumatoid arthritis is ongoing. Rigel will continue to be entitled to receive milestones and tiered royalty payments on future net sales of ocadusertib.
- In early October, Rigel received notification from Lilly that it will terminate the central nervous system (CNS) disease program related to the collaboration between the two companies, which will become effective 60 days following notification.

Third Quarter 2025 and Year-to-Date Financial Update

For the third quarter ended September 30, 2025, total revenues were $69.5 million, consisting of $64.1 million in net product sales and $5.4 million in contract revenues from collaborations. Net product sales grew 65% compared to $38.9 million in the same period of 2024. TAVALISSE net product sales were $44.7 million, growth of 70% compared to $26.3 million in the same period of 2024. GAVRETO net product sales were $11.1 million, growth of 56% compared to $7.1 million in the same period of 2024. REZLIDHIA net product sales were $8.3 million, growth of 50% compared to $5.5 million in the same period of 2024. Contract revenues from collaborations primarily consisted of $3.1 million of revenue from Grifols S.A. (Grifols) related to delivery of drug supplies and earned royalties, $1.8 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 $41.0 million compared to $41.3 million for the same period of 2024. The decrease in costs and expenses was mainly due to lower cost of product sales, as the prior period included a sublicensing fee. This decrease was partially offset by increased research and development costs driven by the timing of clinical activities related to olutasidenib and R289 and higher personnel-related costs.

Rigel reported net income of $27.9 million, or $1.55 basic and $1.46 diluted per share, compared to $12.4 million, or $0.71 basic and $0.70 diluted per share, for the same period of 2024.

For the nine months ended September 30, 2025, total revenues were $224.5 million, consisting of $166.6 million in net product sales and $57.9 million in contract revenues from collaborations. Net product sales grew 69% compared to $98.4 million in the same period of 2024. TAVALISSE net product sales were $113.3 million, growth of 54% compared to $73.8 million in the same period of 2024. GAVRETO net product sales were $31.9 million, growth of 252% compared to $9.0 million in the same period of 2024. GAVRETO became commercially available from Rigel in late June 2024. REZLIDHIA net product sales were $21.4 million, growth of 38% compared to $15.6 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, $9.9 million of revenue from Grifols related to delivery of drug supplies and earned royalties, $6.9 million of revenue from Kissei related to a milestone payment and delivery of drug supplies and $0.8 million of revenue from Medison related to delivery of drug supplies and earned royalties.

Total costs and expenses were $122.2 million compared to $114.1 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.

Rigel reported net income of $99.0 million, or $5.52 basic and $5.38 diluted per share, compared to $3.1 million, or $0.18 basic and diluted per share, for the same period of 2024.

Cash, cash equivalents and short-term investments as of September 30, 2025 was $137.1 million, compared to $77.3 million as of December 31, 2024.

2025 Outlook

Rigel is updating its 2025 total revenue guidance to approximately $285 to $290 million, an

increase from the previous range of approximately $270 to $280 million, which includes:

- Net product sales of approximately $225 to $230 million, an increase from the previous range of approximately $210 to $220 million.
- Contract revenues from collaborations of approximately $60 million.

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. 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 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, visitwww.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.

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 September 30, 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 September 30, 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

Thi s press release contains forward-looking statements relating to, among other things, expected commercial and financial results, increased projections of financial performance and outlook for 2025, expectations for growing our commercial business , continued enrollment of our R289 study, presentation of study data, development of ocadusertib, expectation of clinical outcomes, 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, ocadusertib 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, ocadusertib 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, 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.

Contact for Investors & Media:

Investors:
Rigel Pharmaceuticals, Inc.
650.624.1232
ir@rigel.com

Media:
David Rosen
Argot Partners
646.461.6387
david.rosen@argotpartners.com

RIGEL PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
			(unaudited)	
Revenues:				
Product sales, net	$ 64,067	$ 38,927	$ 166,565	$ 98,380
Contract revenues from collaborations	5,395	16,380	57,915	23,302
Total revenues	69,462	55,307	224,480	121,682
Costs and expenses:				
Cost of product sales	4,753	8,026	13,666	12,858
Research and development (see Note A)	7,353	6,182	22,610	17,748
Selling, general and administrative (see Note A)	28,936	27,043	85,908	83,539
Total costs and expenses	41,042	41,251	122,184	114,145
Income from operations	28,420	14,056	102,296	7,537
Interest income	1,094	425	2,438	1,570
Interest expense	(1,894)	(2,060)	(5,621)	(5,963)
Income before income taxes	27,620	12,421	99,113	3,144
(Benefit from) provision for income taxes	(280)	—	154	—
Net income	$ 27,900	$ 12,421	$ 98,959	$ 3,144
Net income per share				
Basic	$ 1.55	$ 0.71	$ 5.52	$ 0.18
Diluted	$ 1.46	$ 0.70	$ 5.38	$ 0.18
Weighted average shares used in computing net income per share				
Basic	18,038	17,600	17,912	17,556
Diluted	19,156	17,648	18,379	17,599
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 2,961	$ 2,360	$ 8,172	$ 9,067
Research and development	402	284	1,791	1,239
	$ 3,363	$ 2,644	$ 9,963	$ 10,306

SUMMARY BALANCE SHEET DATA
(in thousands)

	As of September 30, 2025	As of December 31, 2024 [1]
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 137,143	$ 77,321
Total assets	242,534	163,976
Stockholders' equity	117,609	3,288

(1) Derived from audited financial statements

View original content to download multimedia: https://www.prnewswire.com/news-releases/rigel-reports-third-quarter-2025-financial-results-and-provides-business-update-302604504.html

SOURCE Rigel Pharmaceuticals, Inc.