

January 12, 2026



Rigel Provides Business Update and 2026 Outlook

- *Preliminary fourth quarter 2025 total revenue of approximately \$69.8 million, including net product sales of \$65.4 million and contract revenues of \$4.4 million*
- *In the dose escalation phase of the Phase 1b study of R289 in patients with lower-risk MDS, R289 continues to be generally well tolerated. RBC-TI was achieved by 33% (6/18) of evaluable transfusion dependent patients receiving R289 doses $\geq$ 500 mg QD, including 40% (2/5) in the 500 mg BID dose group*
- *Enrollment in the dose expansion phase of the Phase 1b study is ongoing and Rigel is on track to complete enrollment and select the recommended Phase 2 dose for future clinical studies in the second half of 2026*
- *2026 Outlook: Rigel anticipates full-year total revenue of approximately \$275 to \$290 million, including net product sales of \$255 to \$265 million, and positive net income for the full year*

SOUTH SAN FRANCISCO, Calif., Jan. 12, 2026 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today provided a business update including preliminary total revenue and net product sales for the fourth quarter of 2025, ongoing activity from the commercial business and development pipeline, and its financial outlook for 2026.



"2025 was an excellent year for Rigel, marked by strong commercial execution with record net product sales; significant financial progress, including continued profitability and generation of \$77 million in cash; and meaningful clinical advancement of R289 in lower-risk

MDS, where we shared encouraging Phase 1b data," said Raul Rodriguez, Rigel's president and CEO. "In 2026, we plan to continue to execute across all areas of the business — driving sustained commercial performance, supporting our expanding clinical programs with a solid financial foundation, delivering preliminary results from the dose expansion phase of our R289 study and continuing to explore opportunities to add new products to our portfolio."

Preliminary 2025 Financial Results and Business Update

Preliminary Financial Results

- While Rigel is still determining final results for the fourth quarter of 2025, the company expects to report fourth quarter total revenue of \$69.8 million, compared to \$57.6 million for the same period of 2024.
- Rigel expects to report fourth quarter of 2025 gross product sales of \$84.5 million. Net product sales are expected to be \$65.4 million, compared to \$46.5 million for the same period of 2024, including:
 - TAVALISSE[®] (fostamatinib disodium hexahydrate) net product sales of \$45.6 million compared to \$31.0 million for the same period of 2024.
 - GAVRETO[®] (pralsetinib) net product sales of \$10.2 million compared to \$8.1 million for the same period of 2024.
 - REZLIDHIA[®] (olutasidenib) net product sales of \$9.6 million compared to \$7.4 million for the same period of 2024.
- Contract revenues for the fourth quarter of 2025 are expected to be approximately \$4.4 million, consisting of \$4.1 million in contract revenues from collaborations and \$0.3 million in government contract revenue. Contract revenue from collaborations is expected to include \$3.4 million of revenue from Grifols S.A. related to delivery of drug supplies and earned royalties, \$0.3 million of revenue from Kissei Pharmaceutical Co., Ltd. related to delivery of drug supplies and \$0.2 million of revenue from Medison Pharma Trading AG related to earned royalties.
- For the full year, Rigel expects to report total revenue of \$294.3 million, including net product sales of \$232.0 million and contract revenues of \$62.3 million, compared to total revenue of \$179.3 million in 2024, which included net product sales of \$144.9 million and contract revenues of \$34.4 million. Expected 2025 contract revenues and total revenue include \$40.0 million in non-cash revenue recognized in the second quarter of 2025 resulting from the release of the remaining cost share liability related to the agreement with Lilly for the development and commercialization of ocadusertib.
- Rigel expects to report cash, cash equivalents, and short-term investments of approximately \$154.6 million as of December 31, 2025, compared to \$77.3 million as of December 31, 2024.

The above information is preliminary, has not been audited, and is subject to change upon the audit of Rigel's financial statements for the fourth quarter and year ended December 31, 2025. Rigel expects to provide complete fourth quarter and full year 2025 financial results in March 2026.

Commercial

- Rigel's commercial portfolio is expected to report preliminary full-year net product sales of \$232.0 million, growth of 60% compared to 2024.

Clinical Development and Regulatory

- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289¹, a potent and selective dual inhibitor of interleukin receptor-associated kinases 1 and 4 (IRAK1/4) in patients with relapsed or refractory (R/R) lower-risk myelodysplastic syndrome (MDS). In October 2025, Rigel [announced](#) enrollment of the first patient in the dose expansion phase of the study, where up to 40 patients will be randomized to receive either 500 mg once daily (QD) or twice daily (BID) to determine the recommended Phase 2 dose for future clinical trials.
- Rigel is on track to complete enrollment of the dose expansion phase of the Phase 1b study and select the recommended Phase 2 dose for future clinical studies in the second half of 2026. The company anticipates sharing preliminary data from the dose expansion phase of the study by the end of 2026.
- Rigel [announced](#) updated data from the dose escalation phase of the ongoing Phase 1b clinical study of R289 at the 2025 American Society of Hematology (ASH) Annual Meeting and Exposition in December, indicating that R289 continued to be generally well tolerated in a heavily pretreated R/R lower-risk MDS patient population, the majority of whom were high transfusion burden (HTB) at baseline. Furthermore, red blood cell transfusion independence (RBC-TI ≥ 8 weeks) was achieved by 33% (6/18) of evaluable transfusion dependent patients receiving R289 doses of at least 500 mg QD and higher.
- Also at the ASH Annual Meeting, four posters were [presented](#) on olutasidenib, which included data that add to the growing body of evidence supporting the benefits of its use in patients with R/R mutated isocitrate dehydrogenase-1 (*mIDH1*) acute myeloid leukemia (AML).
- In October 2025, 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](#)).
- Rigel presented sub-analysis data from the ARROW study evaluating pralsetinib for the treatment of metastatic rearranged during transfection (*RET*) fusion-positive non-small cell lung cancer (NSCLC) at the 2025 North America Conference on Lung Cancer (NACLC) in December. The two poster presentations included efficacy and safety data for patients previously treated with immunotherapy and for patients from the United States. In the trial, median overall survival (OS) was 44.3 months for the overall patient population. Longer median OS was seen in patients treated in the United States (62.4 months).
- Rigel presented the first data release for pralsetinib from the TAPISTRY study ([NCT04589845](#)) in a poster presentation at the 2026 American Society of Clinical Oncology – Gastrointestinal Cancers Symposium (ASCO-GI) in January. The analysis reported results from the Phase 2 global, open-label, multicohort study, in which the efficacy and safety of pralsetinib was evaluated in a cohort of patients with *RET* fusion-positive solid tumors, including pancreatic, colorectal, and hepatobiliary cancers. Pralsetinib demonstrated robust and durable activity against *RET* fusion-positive solid tumors, including gastrointestinal (GI) tumors, and in the efficacy evaluable population showed an overall response rate (ORR) of 67% (26/39). These data validate *RET* fusions as a tissue-agnostic target with sensitivity to RET inhibition, suggesting the

potential therapeutic utility of pralsetinib in these patients.

- On December 22, 2025, the U.S. Food and Drug Administration (FDA) notified Rigel of the approval of a Prior Approval supplemental New Drug Application, which updated the U.S. Prescribing Information to add a boxed warning regarding serious infections, including opportunistic infections. Rigel previously communicated this risk information to healthcare providers via a Dear Healthcare Provider letter in October 2024. The FDA also notified Rigel that it has met its postmarketing commitment for GAVRETO from its September 2020 accelerated approval to submit the final report for the AcceleRET-Lung study.

Publication

- A paper titled "[Olutasidenib for Mutated *IDH1* Acute Myeloid Leukemia: Final Five-Year Results from the Phase 2 Pivotal Cohort](#)" was published in November 2025 by Jorge E. Cortes, M.D., Phase 2 trial investigator and Director, Georgia Cancer Center, Cecil F. Whitaker Jr., GRA Eminent Scholar Chair in Cancer, in the *Journal of Hematology & Oncology*. The publication reports the final 5-year data from the pivotal cohort of the registrational trial evaluating olutasidenib for the treatment of patients with R/R m/*IDH1* AML, which includes an additional two years of efficacy and safety data. These 5-year data further support the durable responses and manageable safety profile observed with olutasidenib in patients with R/R m/*IDH1* AML, including those previously treated with venetoclax-based regimens.

2026 Outlook

Rigel anticipates 2026 total revenue of approximately \$275 to \$290 million, including:

- Net product sales of approximately \$255 to \$265 million.
- Contract revenues of approximately \$20 to \$25 million.

The company anticipates it will report positive net income for the full year 2026, while funding existing and new clinical development programs.

Upcoming Investor Event

Raul Rodriguez, Rigel's president and CEO, will present a company overview at the 44th Annual J.P. Morgan Healthcare Conference in San Francisco, CA on Wednesday, January 14, 2026 at 3:00 p.m. PT (6:00 p.m. ET). To access the live webcast or archived recording, visit the Investor Relations section of the company's website at www.rigel.com.

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, including Boxed WARNING, 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, visit 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.

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 January 2, 2026: <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 January 2, 2026: <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, Ganzer, 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, Ganzer 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, financial and clinical results, increased projections of financial performance and outlook for 2026, expectations for growing our commercial business, continued enrollment of our R289 study, presentation of study data, expectation of clinical outcomes, continued ability for developing and commercializing TAVALISSE, GAVRETO, REZLIDHIA and R289 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, the finalization and audit of Rigel's fourth quarter and 2025 fiscal year financial results which could potentially result in changes or adjustments to the selected preliminary financial results and projections presented herein; risks and uncertainties associated with the commercialization and marketing of TAVALISSE, GAVRETO, and REZLIDHIA; risks that the FDA, European Medicines Agency, PMDA or other regulatory authorities may make adverse decisions regarding TAVALISSE, GAVRETO, REZLIDHIA or R289; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE, GAVRETO, REZLIDHIA or R289 may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop or market 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 September 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

📄 View original content to download multimedia <https://www.prnewswire.com/news-releases/rigel-provides-business-update-and-2026-outlook-302658090.html>

SOURCE Rigel Pharmaceuticals, Inc.