



Celcuity Inc. Reports Release of Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Update

March 25, 2026

- The U.S. Food and Drug Administration (“FDA”) accepted Celcuity’s New Drug Application (“NDA”) and granted Priority Review with a Prescription Drug User Fee Act (“PDUFA”) goal date of July 17, 2026, for gedatolisib in HR+/HER2-/PIK3CA wild-type (“WT”) advanced breast cancer (“ABC”)
- Results from PIK3CA WT cohort of Phase 3 VIKTORIA-1 study of gedatolisib regimens in HR+/HER2- ABC published in *Journal of Clinical Oncology*
- Topline results from the PIK3CA mutant cohort of the Phase 3 VIKTORIA-1 study are expected to be released in the second quarter of 2026
- Management to host webcast and conference call today, March 25, 2026, at 4:30 p.m. EDT

MINNEAPOLIS, March 25, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced financial results for the fourth quarter and full year ended December 31, 2025, and other recent business developments.

“We expect this year to be a transformative one for Celcuity. We plan to release topline results from the PIK3CA mutant cohort of our Phase 3 VIKTORIA-1 study in the second quarter of 2026, which, if positive, could potentially advance the standard-of-care second line therapy for a significant number of patients with HR+/HER2- advanced breast cancer,” said Brian Sullivan, CEO and co-founder of Celcuity. “Additionally, our efforts remain on track to launch gedatolisib commercially in anticipation of its potential FDA approval in the third quarter of 2026.”

Fourth Quarter 2025 Business Highlights and Other Recent Developments

- In December 2025, updated efficacy and safety results from the Phase 3 VIKTORIA-1 PIK3CA WT cohort were presented at the 2025 San Antonio Breast Cancer Symposium including patient sub-group analyses, safety analyses and patient reported outcomes for well-being measures.
 - For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, median progression free survival (“PFS”) was 16.6 months with the gedatolisib triplet (gedatolisib + fulvestrant + palbociclib) versus 1.9 months for fulvestrant (HR=0.14; 95% CI: 0.08-0.28; p<0.0001).
 - The gedatolisib triplet delayed time to definitive deterioration versus fulvestrant according to patient reported outcomes for well-being measures that included mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (the EQ-5D-5L score). The median time to definitive deterioration was 23.7 months (HR=0.39; 95% CI: 0.25-0.67; p = 0.0003) for patients treated with the gedatolisib triplet versus 4.0 months for fulvestrant. Additionally, for the first 8 cycles of treatment, the patients’ assessment of their well-being remained stable relative to their assessment prior to starting treatment with gedatolisib.
 - As reported earlier, the gedatolisib triplet was generally well tolerated in the trial with mostly low-grade treatment-related adverse events (“TRAEs”). The most common Grade 3+ TRAEs for the gedatolisib triplet and fulvestrant included neutropenia (62.3% and 0.8% of patients, respectively); stomatitis (19.2% and 0%); rash (4.6% and 0%); and hyperglycemia (2.3% and 0%). No patients experienced Grade 4 hyperglycemia. TRAEs led to the discontinuation of study treatment in 2.3% of patients in the gedatolisib triplet group and 0% in the fulvestrant group.
- In January 2026, the FDA accepted for filing Celcuity’s NDA for gedatolisib in HR+/HER2- PIK3CA WT ABC. The FDA granted Priority Review and assigned a PDUFA goal date of July 17, 2026.
- In March 2026, efficacy and safety results from the PIK3CA WT cohort of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib were published in the *Journal of Clinical Oncology*. The cohort consisted of patients with HR+/HER2-/PIK3CA WT ABC whose disease progressed while on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor.
- As reported previously, the results from the VIKTORIA-1 Phase 3 PIK3CA WT cohort, established several new milestones in the history of drug development for HR+/HER2- ABC:
 - The hazard ratio for the gedatolisib triplet is more favorable than has ever been reported by any Phase 3 trial for patients with HR+/HER2- ABC.

- The 7.3 months incremental improvements in median PFS for the gedatolisib triplet over fulvestrant is higher than has ever been reported by any Phase 3 trial for patients with HR+/HER2- ABC receiving at least their second line of endocrine therapy-based regimen.
- Gedatolisib is the first inhibitor targeting the PI3K/AKT/mTOR (“PAM”) pathway to demonstrate positive Phase 3 results in patients with HR+/HER2-/PIK3CA WT ABC whose disease progressed on or after treatment with a CDK4/6 inhibitor.
- Median duration of response (“DOR”) of 17.5 months and incremental objective response rate (“ORR”) improvement of 31% relative to control for the gedatolisib triplet is the highest reported for an endocrine therapy-based regimen in second line HR+/HER2- ABC.

Fourth Quarter and Full Year 2025 Financial Results

Unless otherwise stated, all comparisons are for the fourth quarter and full year ended December 31, 2025, compared to the fourth quarter and full year ended December 31, 2024.

Total operating expenses were \$49.2 million for the fourth quarter of 2025, compared to \$36.4 million for the fourth quarter of 2024. Operating expenses for the full year 2025 were \$172.2 million, compared to \$113.3 million for the full year 2024.

Research and development (“R&D”) expenses were \$37.6 million for the fourth quarter of 2025, compared to \$33.5 million for the prior-year period. Of the \$4.1 million increase in R&D expenses, \$8.6 million was related to increased employee and consulting expenses, of which \$5.3 million related to commercial headcount additions and other launch-related activities. These amounts were partially offset by a \$4.5 million decrease primarily related to costs supporting ongoing activities for the VIKTORIA-1 Phase 3 trial.

R&D expenses for the full year 2025 were \$145.0 million, compared to \$104.2 million for the prior year. Of the \$40.8 million increase in R&D expenses, \$26.7 million was related to increased employee and consulting expenses, of which \$13.1 million related to commercial headcount additions and other launch-related activities. The remaining \$14.1 million increase was primarily related to activities supporting our ongoing clinical trials, a development milestone payment under the license agreement with Pfizer, and other commercial launch-related activities.

General and administrative (“G&A”) expenses were \$11.6 million for the fourth quarter of 2025, compared to \$3.0 million for the prior year period. Of the \$8.6 million increase, \$6.9 million was related to increased employee-related and consulting expenses, of which \$5.4 million related to non-cash stock-based compensation. The remaining \$1.7 million increase was primarily related to professional fees, expanding infrastructure costs, and other administrative expenses.

G&A expenses for the full year 2025 were \$27.2 million, compared to \$9.1 million for the prior year. Of the \$18.1 million increase in G&A expenses, \$14.9 million was related to increased employee-related and consulting expenses, of which \$10.4 million related to non-cash stock-based compensation. The remaining \$3.2 million increase was primarily related to professional fees, expanding infrastructure costs, and other administrative expenses.

Net loss for the fourth quarter of 2025 was \$51.0 million, or \$0.97 per share, compared to a net loss of \$36.7 million, or \$0.85 per share, for the fourth quarter of 2024. Net loss for the full year 2025 was \$177.0 million, or \$3.79 per share, compared to a net loss of \$111.8 million, or \$2.83 per share, in 2024. Non-GAAP adjusted net loss for the fourth quarter of 2025 was \$38.4 million, or \$0.73 per share, compared to non-GAAP adjusted net loss of \$32.3 million, or \$0.75 per share, for the fourth quarter of 2024. Non-GAAP adjusted net loss for the full year 2025 was \$150.8 million, or \$3.22 per share, compared to non-GAAP adjusted net loss of \$101.9 million, or \$2.58 per share, for 2024. Non-GAAP adjusted net loss excludes stock-based compensation expense, non-cash interest expense, and non-cash interest income. Because these items have no impact on Celcuity’s cash position, management believes non-GAAP adjusted net loss better enables Celcuity to focus on cash used in operations. For a reconciliation of financial measures calculated in accordance with generally accepted accounting principles in the United States (“GAAP”) to non-GAAP financial measures, please see the financial tables at the end of this press release.

Net cash used in operating activities for the fourth quarter of 2025 was \$36.4 million, compared to \$27.8 million for the fourth quarter of 2024. Net cash used in operating activities for the full year 2025 was \$153.3 million, compared to \$83.5 million for the full year 2024. Cash, cash equivalents and short-term investments were \$441.5 million at the end of fiscal year 2025 and are expected to finance our operations through 2027.

Webcast and Conference Call Information

To participate in the teleconference, domestic callers should dial 1-800-717-1738 and international callers should dial 1-646-307-1865. A live webcast presentation can also be accessed using the weblink below. A replay of the webcast will be available on the Celcuity website following the live event. https://viaavid.webcasts.com/starthere.jsp?ei=1751140&tp_key=9ff20687c4.

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing the development of targeted therapies for the treatment of multiple

solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades the PI3K/AKT/mTOR ("PAM") pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3K α , AKT, or mTORC1 alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant, with or without palbociclib, in patients with HR+/HER2- advanced breast cancer ("ABC"), has completed enrollment, and the company has reported detailed results for the *PIK3CA* wild-type cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC, is ongoing. A Phase 1/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is ongoing. More detailed information about Celcuity's active clinical trials can be found at ClinicalTrials.gov. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com. Follow us on [LinkedIn](#) and [X](#).

Forward Looking Statements

This press release contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of clinical trial data; the status and timing of the FDA's review of our New Drug Application for gedatolisib, including the PDUFA goal date assigned by the FDA; the market opportunity for gedatolisib; our expectations regarding the timing of and our ability to obtain FDA approval to commercialize gedatolisib; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib; our anticipated use of cash; and the strength of our balance sheet. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. The forward-looking statements included in this press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our clinical results are based on an ongoing analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in our clinical trials or the FDA's review of our NDA for gedatolisib; our ability to obtain and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; the development of therapies and tools competitive with gedatolisib; and our ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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Celcuity Inc. Balance Sheets *(in thousands)*

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 165,703	\$ 22,515
Investments	275,794	212,589
Other current assets	24,162	9,467
Total current assets	465,659	244,571
Property and equipment, net	499	336
Operating lease right-of-use assets	51	216
Other non-current assets	349	—
Total assets	<u>\$ 466,558</u>	<u>\$ 245,123</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,407	\$ 9,366
Accrued expenses	37,691	22,185
Operating lease liabilities, current	54	172

Total current liabilities	44,152	31,723
Operating lease liabilities, non-current	—	54
Convertible debt	195,324	—
Note payable, non-current	126,527	97,727
Total liabilities	366,003	129,504
Total stockholders' equity	100,555	115,619
Total liabilities and stockholders' equity	<u>\$ 466,558</u>	<u>\$ 245,123</u>

Celcuity Inc.
Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2025	2024	2025	2024
	(unaudited)			
Operating expenses:				
Research and development	\$ 37,631	\$ 33,471	\$ 144,995	\$ 104,203
General and administrative	11,570	2,959	27,197	9,064
Total operating expenses	<u>49,201</u>	<u>36,430</u>	<u>172,192</u>	<u>113,267</u>
Loss from operations	<u>(49,201)</u>	<u>(36,430)</u>	<u>(172,192)</u>	<u>(113,267)</u>
Other (expense) income:				
Interest expense	(6,166)	(3,275)	(17,148)	(10,280)
Interest income	4,394	3,052	12,298	11,768
Other (expense) income, net	<u>(1,772)</u>	<u>(223)</u>	<u>(4,850)</u>	<u>1,488</u>
Net loss before income taxes	<u>(50,973)</u>	<u>(36,653)</u>	<u>(177,042)</u>	<u>(111,779)</u>
Income taxes	—	—	—	—
Net loss	<u>\$ (50,973)</u>	<u>\$ (36,653)</u>	<u>\$ (177,042)</u>	<u>\$ (111,779)</u>
Net loss per share, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (0.85)</u>	<u>\$ (3.79)</u>	<u>\$ (2.83)</u>
Weighted average common shares outstanding, basic and diluted	<u>52,539,744</u>	<u>42,873,934</u>	<u>46,757,691</u>	<u>39,449,393</u>

Cautionary Statement Regarding Non-GAAP Financial Measures

This press release contains references to non-GAAP adjusted net loss and non-GAAP adjusted net loss per share. Management believes these non-GAAP financial measures are useful supplemental measures for planning, monitoring, and evaluating operational performance as they exclude stock-based compensation expense, non-cash interest expense, and non-cash interest income from net loss and net loss per share. Management excludes these items because they do not impact Celcuity's cash position, which management believes better enables Celcuity to focus on cash used in operations. However, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share are not recognized measures under GAAP and do not have a standardized meaning prescribed by GAAP. As a result, management's method of calculating non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may differ materially from the method used by other companies. Therefore, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may not be comparable to similarly titled measures presented by other companies. Investors are cautioned that non-GAAP adjusted net loss and non-GAAP adjusted net loss per share should not be construed as alternatives to net loss, net loss per share or other statements of operations data (which are determined in accordance with GAAP) as an indicator of Celcuity's performance or as a measure of liquidity and cash flows.

Celcuity Inc.
Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and
GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share
(in thousands, except share and per share amounts)

	Three Months Ended	Year Ended
	December 31,	December 31,

	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
GAAP net loss	\$ (50,973)	\$ (36,653)	\$ (177,042)	\$ (111,779)
Adjustments to net loss:				
Stock-based compensation				
Research and development ⁽¹⁾	3,124	1,404	8,409	4,405
General and administrative ⁽²⁾	6,332	911	12,974	2,583
Non-cash interest expense ⁽³⁾	1,602	803	4,241	2,695
Non-cash interest income ⁽⁴⁾	1,470	1,263	630	150
Non-GAAP adjusted net loss	<u>\$ (38,445)</u>	<u>\$ (32,272)</u>	<u>\$ (150,788)</u>	<u>\$ (101,946)</u>
GAAP net loss per share - basic and diluted	\$ (0.97)	\$ (0.85)	\$ (3.79)	\$ (2.83)
Adjustments to net loss:				
Stock-based compensation				
Research and development	0.06	0.03	0.18	0.11
General and administrative	0.12	0.02	0.29	0.07
Non-cash interest expense	0.03	0.02	0.09	0.07
Non-cash interest income	0.03	0.03	0.01	—
Non-GAAP adjusted net loss per share - basic and diluted	<u>\$ (0.73)</u>	<u>\$ (0.75)</u>	<u>\$ (3.22)</u>	<u>\$ (2.58)</u>
Weighted average common shares outstanding, basic and diluted	<u>52,539,744</u>	<u>42,873,934</u>	<u>46,757,691</u>	<u>39,449,393</u>

(1) To reflect a non-cash charge to operating expenses for research and development stock-based compensation.

(2) To reflect a non-cash charge to operating expenses for general and administrative stock-based compensation.

(3) To reflect a non-cash charge to other expense for amortization of debt issuance costs and discount and payment-in-kind interest related to the issuance of a note payable.

(4) To reflect a non-cash adjustment to other income for accretion on investments and change in accrued interest income.