Celcuity Inc. Reports Release of First Quarter 2026 Financial Results and Provides Corporate Update

May 14, 2026

- *Phase 3 VIKTORIA-1 trial achieved primary endpoint with clinically meaningful improvement in progression-free survival in PIK3CA mutant cohort; detailed data for gedatolisib regimens will be presented at the 2026 ASCO Annual Meeting*
- *Phase 3 VIKTORIA-2 trial expanded to include a second study evaluating gedatolisib as first-line treatment in patients with endocrine-sensitive HR+/HER2- advanced breast cancer*
- *Development of a gedatolisib formulation for subcutaneous injection underway; first patent application submitted to the U.S. Patent and Trademark Office*
- *Management to host webcast and conference call today, May 14, 2026, at 4:30 p.m. EDT*

MINNEAPOLIS, May 14, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications, today announced financial results for the first quarter ended March 31, 2026 and other recent business developments.

"With positive results in both cohorts of the pivotal VIKTORIA-1 study, we believe gedatolisib regimens have the potential to advance the standard of care in the second-line setting for a significant number of patients with HR+/HER2- advanced breast cancer, regardless of *PIK3CA* status," said Brian Sullivan, CEO and co-founder of Celcuity. "We are on track to launch gedatolisib commercially in anticipation of its potential FDA approval in the third quarter of 2026, and we look forward to bringing this important therapy to physicians treating patients with advanced breast cancer."

Mr. Sullivan added, "Our positive Phase 3 results, combined with our promising Phase 1b clinical trial results in treatment-naive late-stage patients, provide a strong scientific rationale to evaluate gedatolisib combinations as first-line therapy. By expanding our VIKTORIA-2 study to enable evaluation of treatment-naive patients who have endocrine-sensitive breast cancer, we are positioning gedatolisib regimens to potentially be available for nearly all patients in the first-line setting, irrespective of their endocrine sensitivity or *PIK3CA* status."

First Quarter 2026 Business Highlights and Other Recent Developments

- Celcuity reported positive topline results from the *PIK3CA* mutant-type ("MT") cohort of the Phase 3 VIKTORIA-1 clinical trial evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-") ("HR+/HER2-"), *PIK3CA* MT locally advanced or metastatic breast cancer ("ABC").
  - The primary efficacy analysis of gedatolisib combined with fulvestrant and palbociclib (the "gedatolisib triplet") demonstrated a statistically significant and clinically meaningful improvement in progression-free survival ("PFS") compared with alpelisib, a PI3Kα inhibitor, and fulvestrant.
  - The secondary endpoint comparing gedatolisib in combination with fulvestrant (the "gedatolisib doublet") versus alpelisib plus fulvestrant, which was not part of the primary efficacy analysis in the hierarchical order, also demonstrated a statistically significant and clinically meaningful improvement in PFS.
  - Both gedatolisib regimens were generally well tolerated, with manageable safety profiles, and no new safety signals.
  - Detailed data for the gedatolisib triplet and doublet regimens will be presented in a late-breaking abstract ("LBA") oral session on June 2, 2026, at the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, Illinois.
  - Celcuity intends to submit these data to the FDA in the third quarter as a supplemental New Drug Application ("sNDA") and to submit VIKTORIA-1 data to other regulatory authorities outside the U.S. following the sNDA submission.
- The Phase 3 VIKTORIA-2 clinical trial now includes two studies, Study 1 and Study 2, each with independent statistical analysis plans that include primary endpoints for their respective intent-to-treat populations. Study 1, which is ongoing, is evaluating the efficacy and safety of gedatolisib in combination with palbociclib and fulvestrant in approximately 440 patients with endocrine-resistant HR+/HER2- ABC. Study 2, which was added in conjunction with a VIKTORIA-2 protocol amendment, is evaluating the efficacy and safety of gedatolisib in combination with palbociclib and letrozole in approximately 740 patients with treatment-naive endocrine-sensitive HR+/HER2- ABC. Eligible patients include those whose cancer relapsed or progressed 12 months or more after completion of adjuvant endocrine therapy, or those with de novo metastatic disease without prior endocrine therapy exposure. Approximately 60,000 adults are newly diagnosed each

year in the United States with endocrine-sensitive HR+/HER2- ABC.[1]
- To support its long-term lifecycle development plan, Celcuity submitted its first patent application to the United States Patent and Trademark Office ("USPTO") for a subcutaneous formulation of gedatolisib that would enable a patient to receive gedatolisib as an injection as an alternative to an infusion. Development of the subcutaneous gedatolisib formulation is ongoing with the goal of demonstrating clinical equivalence to the current intravenous formulation of gedatolisib. The subcutaneous formulation is aimed to support potential future indications for gedatolisib regimens that may result in duration of treatment periods greater than several years.
- In January 2026, the FDA accepted the submission of Celcuity's New Drug Application ("NDA") for gedatolisib in HR+/HER2- *PIK3CA* wild-type ("WT") ABC. The FDA granted Priority Review and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026.

First Quarter 2026 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2026, compared to the first quarter ended March 31, 2025.

Net loss for the first quarter of 2026 was $52.8 million, or $0.97 per share, compared to a net loss of $37.0 million, or $0.86 per share, for the first quarter of 2025. Non-GAAP adjusted net loss for the first quarter of 2026 was $46.8 million, or $0.86 per share, compared to non-GAAP adjusted net loss of $34.7 million, or $0.81 per share, for the first quarter of 2025. 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.

Total operating expenses were $50.5 million for the first quarter of 2026, compared to $36.1 million for the first quarter of 2025.

Research and development ("R&D") expenses were $33.1 million for the first quarter of 2026, compared to $29.8 million for the prior year period. The $3.3 million increase in R&D expenses was primarily due to a $3.0 million increase in employee-related and consulting expenses. The remaining increase was primarily due to a $5.4 million increase in manufacturing and other costs, partially offset by a $5.1 million decrease in clinical trial costs, which was primarily driven by decreased costs for the VIKTORIA-1 Phase 3 clinical trial.

Selling, general and administrative ("SG&A") expenses were $17.4 million for the first quarter of 2026, compared to $6.3 million for the prior year period. The $11.1 million increase in SG&A expenses was primarily due to an $8.7 million increase in employee-related and consulting expenses, of which $6.6 million was due to commercial headcount additions and other launch-related activities, and a $2.4 million increase primarily due to software costs, professional fees and other costs.

Net cash used in operating activities for the first quarter of 2026 was $55.1 million, compared to $35.9 million for the prior year period. Cash, cash equivalents and short-term investments were $387.1 million at the end of the first quarter of 2026. We expect cash, cash equivalents, investments and drawdowns on our debt facility 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 this weblink: https://viavid.webcasts.com/starthere.jsp?ei=1760785&tp_key=2f73ec65ba. A replay of the webcast will be available on the Celcuity website following the live event.

About Celcuity

Celcuity is a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. Our lead therapeutic candidate is gedatolisib, a kinase inhibitor of the PI3K/AKT/mTOR ("PAM") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. Our Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, has reported detailed results for Study 1, which evaluated patients with *PIK3CA* WT tumors, and announced topline results for Study 2, which evaluated patients with *PIK3CA* MT tumors. Our Phase 3 clinical trial, VIKTORIA-2, is ongoing and incorporates two independent studies, Study 1 and Study 2, evaluating two separate cohorts of patients with ABC who are treatment-naive in the advanced setting. Study 1 is evaluating gedatolisib combined with palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib combined with palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. A Phase 1b/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 NDA for gedatolisib, including the PDUFA goal date assigned by the FDA; the ability of our data to support the filing of an sNDA with the FDA and comparable filings with other regulatory authorities outside the U.S.; our intent to present data at the 2026 ASCO Annual Meeting; 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, including subcutaneous formulations to support potential future indications for gedatolisib regimens; 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 topline 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, filed with the Securities and Exchange Commission on March 26, 2026, 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.

References:
1. Internal estimates using data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021

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Celcuity Inc.
Condensed Balance Sheets
(in thousands)

	March 31, 2026	December 31, 2025
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 145,191	$ 165,703
Investments	241,873	275,794
Other current assets	21,865	24,162
Total current assets	408,929	465,659
Property and equipment, net	619	499
Operating lease right-of-use assets	13	51
Other non-current assets	603	349
Total assets	$ 410,164	$ 466,558
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,454	$ 6,407
Accrued expenses	22,744	37,691
Operating lease liabilities, current	13	54
Total current liabilities	33,211	44,152

Convertible notes	195,566	195,324
Note payable	127,862	126,527
Total liabilities	356,639	366,003
Total stockholders' equity	53,525	100,555
Total liabilities and stockholders' equity	$ 410,164	$ 466,558

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

	Three Months Ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development [1]	$ 33,063	$ 29,759
Selling, general and administrative [1]	17,444	6,374
Total operating expenses	50,507	36,133
Loss from operations	(50,507)	(36,133)
Other (expense) income:		
Interest expense	(6,085)	(3,183)
Interest income	3,751	2,319
Other (expense) income, net	(2,334)	(864)
Net loss before income taxes	(52,841)	(36,997)
Income taxes	—	—
Net loss	$ (52,841)	$ (36,997)
Net loss per share, basic and diluted	$ (0.97)	$ (0.86)
Weighted average common shares outstanding, basic and diluted	54,462,826	43,052,757

(1) Certain prior period amounts have been reclassified from research and development expenses to selling, general and administrative expenses to conform to the current period presentation.

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
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2026	**2025**

GAAP net loss	$	(52,841)	$	(36,997)
Adjustments to net loss:				
Stock-based compensation				
Research and development [1], [2]		2,112		1,164
Selling, general and administrative [1], [3]		3,213		1,280
Non-cash interest expense [4]		1,577		800
Non-cash interest income [5]		(883)		(946)
Non-GAAP adjusted net loss	$	(46,822)	$	(34,699)
GAAP net loss per share - basic and diluted	$	(0.97)	$	(0.86)
Adjustments to net loss:				
Stock-based compensation				
Research and development		0.04		0.02
Selling, general and administrative		0.06		0.03
Non-cash interest expense		0.03		0.02
Non-cash interest income		(0.02)		(0.02)
Non-GAAP adjusted net loss per share - basic and diluted	$	(0.86)	$	(0.81)
Weighted average common shares outstanding, basic and diluted		54,462,826		43,052,757

(1) Certain prior period amounts have been reclassified from research and development expenses to selling, general and administrative expenses to conform to the current period presentation.

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

(3) To reflect a non-cash adjustment to operating expenses for selling, general and administrative stock-based compensation.

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

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