Celcuity Inc. Reports Third Quarter 2025 Financial Results and Provides Corporate Update

November 12, 2025

- *Presented detailed efficacy and safety results from the PIK3CA wild-type ("WT") cohort of the Phase 3 VIKTORIA-1 clinical trial at a late breaking oral presentation at the 2025 European Society for Medical Oncology ("ESMO") Congress*
- *Presented updated clinical results from the Phase 1b portion of a clinical trial evaluating gedatolisib in combination with Nubeqa® (darolutamide) in men with metastatic castration resistant prostate cancer ("mCRPC") at a poster session at ESMO*
- *Completed enrollment of the PIK3CA mutant cohort of the Phase 3 VIKTORIA-1 clinical trial and expect topline data to be available sometime in late Q1 2026 or during Q2 2026*
- *Submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for gedatolisib, based on data from the PIK3CA WT cohort, is on track to be completed during the fourth quarter of 2025*
- *Management to host webcast and conference call today, November 12, 2025, at 4:30 p.m. ET*

MINNEAPOLIS, Nov. 12, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced financial results for the third quarter ended September 30, 2025 and other recent business developments.

"We made significant clinical and regulatory progress in the third quarter," said Brian Sullivan, CEO and co-founder of Celcuity. "At the ESMO Congress, we presented potentially practice-changing safety and efficacy results for the gedatolisib regimens from the *PIK3CA* wild-type cohort of our Phase 3 VIKTORIA-1 trial at a late breaking oral presentation. We remain on track to submit the New Drug Application for gedatolisib later this year based on data from the *PIK3CA* wild-type cohort. The *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 clinical trial is fully enrolled with topline data expected in late Q1 2026 or during Q2 2026."

"There is an urgent need for more efficacious therapies than those currently available for patients with HR+, HER2- advanced breast cancer who have received prior treatment with a CDK4/6 inhibitor. With our strengthened balance sheet, and unprecedented efficacy results in this patient population, we are well positioned to bring gedatolisib to patients should we get FDA approval."

Third Quarter 2025 Business Highlights and Other Recent Developments

- The Company announced positive topline data for both primary endpoints of the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial that evaluated gedatolisib plus fulvestrant with and without palbociclib versus fulvestrant in patients with HR+, HER2- advanced breast cancer ("ABC") whose disease had progressed on or after prior treatment with a CDK4/6 inhibitor. Detailed safety and efficacy results were subsequently presented at a late breaking oral presentation at the 2025 ESMO Congress. The results demonstrate the potential for the gedatolisib regimens to be practice changing for patients with HR+, HER2- ABC.
    - The gedatolisib-triplet (gedatolisib, fulvestrant, and palbociclib) reduced the risk of disease progression or death by 76% compared to fulvestrant based on a hazard ratio ("HR") of 0.24. The median progression free survival ("PFS") was 9.3 months with the gedatolisib triplet versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months.
    - The gedatolisib doublet (gedatolisib and fulvestrant) reduced the risk of disease progression or death by 67% compared to fulvestrant based on a hazard ratio of 0.33. The median PFS was 7.4 months with the gedatolisib doublet versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months.
    - Clinical benefit of the gedatolisib regimens was consistent across patient subgroups.
    - The gedatolisib triplet and doublet were 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, gedatolisib doublet, and fulvestrant groups included neutropenia (52.3%, 0%, and 0.8% of patients, respectively); stomatitis (19.2%, 12.3%, and 0% of patients, respectively); rash (4.6%, 5.4%, and 0% of patients, respectively); and hyperglycemia (2.3%, 2.3%, and 0% of patients, respectively).
    - Study treatment discontinuation due to TRAEs was reported in 2.3% of patients treated with the gedatolisib triplet and 3.1% of patients with the gedatolisib doublet.
    - The *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 clinical trial is fully enrolled with topline data expected sometime in late Q1 2026 or during Q2 2026.
- Updated data from a Phase 1b study evaluating gedatolisib plus darolutamide in men with mCRPC was presented at a

poster session at the 2025 ESMO Congress.
    - In this Phase 1b study, 38 patients with mCRPC were randomly assigned to receive 600 mg darolutamide twice daily combined with either 120 mg gedatolisib in Arm 1 or 180 mg gedatolisib in Arm 2.
    - The six-month radiographic PFS ("rPFS") rate and median rPFS for patients from both arms combined was 67% and 9.1 months, respectively. For patients treated with 120 mg gedatolisib, the six-month rPFS rate was 74% and median rPFS was 9.5 months. For patients treated with 180 mg gedatolisib, the six-month rPFS rate was 61% and the median rPFS was 7.4 months.
    - The combination of gedatolisib and darolutamide was generally well tolerated in the trial with mostly low-grade TRAEs. No dose limiting toxicities were observed in either arm. The only Grade 3 TRAEs for patients from both arms combined included rash (5.3%), stomatitis (2.6%), and pruritus (2.6%); no Grade 3 hyperglycemia was reported. Additionally, no Grade 4 or 5 TRAEs were observed, and no patients discontinued study treatment due to a TRAE.
- The FDA accepted the Company's request to submit an NDA for gedatolisib under the Real-Time Oncology Review ("RTOR") program based on data from the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial. The Company made its first NDA pre-submission in September 2025 and completion of the NDA submission is targeted for the fourth quarter of 2025.
- In July 2025, the first patient was dosed in VIKTORIA-2, a Phase 3 clinical trial evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as a first-line treatment for patients with HR+/HER2- ABC who are endocrine therapy resistant.
- In July 2025, the Company conducted a concurrent public offering of 2.750% convertible senior notes due 2031, common stock and pre-funded warrants. The net proceeds from the offerings were $287 million, after deducting underwriting discounts and commissions and the Company's offering expenses.
- In September 2025, the Company entered into an amendment to its existing senior secured term loan facility with an affiliate of Innovatus Capital Partners, LLC ("Innovatus"), and Oxford Finance LLC and certain of its affiliates (together, "Oxford"). The amendment increases the total term loan facility size to $500 million, including $350 million in committed capital and up to $150 million at the mutual discretion of Celcuity and its lenders.
    - With the release of the topline data from the *PIK3CA* WT cohort of the VIKTORIA-1 Phase 3 clinical trial, Celcuity achieved the Term D milestone under the term loan facility and was eligible to draw an additional $30 million. In connection with the amendment, the $30.0 million Term D loan was disbursed and the Company received net proceeds of $27.8 million.
    - The upsized facility strengthens Celcuity's ability to manage its capital structure efficiently while providing additional funding to support commercial launch preparations for gedatolisib and other strategic initiatives.
- In the third quarter of 2025, investors exercised warrants generating cash proceeds of $12.8 million. The warrants were issued pursuant to a private placement that closed on December 9, 2022 and had an expiration date of 75 days from the release of the topline data from the *PIK3CA* WT cohort of the VICTORIA-1 Phase 3 clinical trial.

Third Quarter 2025 Financial Results

Unless otherwise stated, all comparisons are for the third quarter ended September 30, 2025, compared to the third quarter ended September 30, 2024.

Total operating expenses were $42.8 million for the third quarter of 2025, compared to $30.1 million for the third quarter of 2024.

Research and development ("R&D") expenses were $34.9 million for the third quarter of 2025, compared to $27.6 million for the prior-year period. Of the approximately $7.3 million increase in R&D expenses, $5.6 million was related to increased employee and consulting expenses, $3.2 million of which related to commercial headcount additions and other launch-related activities. The remaining $1.7 million increase was primarily related to activities supporting our ongoing clinical trials.

General and administrative ("G&A") expenses were $7.9 million for the third quarter of 2025, compared to $2.5 million for the prior-year period. Of the approximately $5.4 million increase in general and administrative expenses, $4.9 million was related to increased employee and consulting expenses. Of this $4.9 million increase, $4.0 million was related to non-cash, stock-based compensation. The remaining $0.5 million of the $5.4 million increase was primarily related to professional fees, expanding infrastructure and other administrative expenses.

Net loss for the third quarter of 2025 was $43.8 million, or $0.92 loss per share, compared to a net loss of $29.8 million, or $0.70 loss per share, for the third quarter of 2024. Non-GAAP adjusted net loss for the third quarter of 2025 was $37.2 million, or $0.78 loss per share, compared to non-GAAP adjusted net loss of $27.6 million, or $0.65 loss per share, for the third quarter of 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 third quarter of 2025 was $44.8 million, compared to $20.6 million for the third quarter of 2024.

At September 30, 2025, Celcuity reported cash, cash equivalents and short-term investments of $455.0 million. We expect cash, cash equivalents, investments and drawdowns on our debt facility to fund operations through 2027.

Webcast and Conference Call Information

The Celcuity management team will host a webcast/conference call at 4:30 p.m. ET today to discuss the third quarter 2025 financial results and provide a corporate update. 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=1736070&tp_key=9d6c00e337. 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 pursuing development of targeted therapies for 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 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. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC has completed enrollment and the company has reported detailed results for the *PIK3CA* WT cohort, and has completed enrollment of patients for the *PIK3CA* mutant cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- ABC is currently enrolling patients. 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 market opportunity for gedatolisib; the ability of our data to support the filing of an NDA with the FDA and the expected timing of such filing; 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; unforeseen delays in our planned 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, 2024, 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.
Condensed Balance Sheets
(in thousands)

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current Assets:		

Cash and cash equivalents	$ 74,252	$ 22,515
Investments	380,726	212,589
Other current assets	20,519	9,467
Total current assets	475,497	244,571
Property and equipment, net	417	336
Operating lease right-of-use assets	90	216
Total Assets	**$ 476,004**	**$ 245,123**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 11,418	$ 9,366
Operating lease liabilities	96	172
Accrued expenses	27,278	22,185
Total current liabilities	38,792	31,723
Operating lease liabilities	–	54
Note payable, non-current	125,166	97,727
Convertible Debt	195,083	–
Total Liabilities	359,041	129,504
Total Stockholders' Equity	116,963	115,619
Total Liabilities and Stockholders' Equity	**$ 476,004**	**$ 245,123**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 34,915	$ 27,588	$ 107,364	$ 70,732
General and administrative	7,934	2,472	15,627	6,105
Total operating expenses	42,849	30,060	122,991	76,837
Loss from operations	(42,849)	(30,060)	(122,991)	(76,837)
Other (expense) income				
Interest expense	(4,595)	(3,344)	(10,982)	(7,005)
Interest income	3,640	3,612	7,904	8,716
Other (expense) income, net	(955)	268	(3,078)	1,711
Net loss before income taxes	**(43,804)**	**(29,792)**	**(126,069)**	**(75,126)**
Income tax benefits	–	–	–	–
Net loss	**$ (43,804)**	**$ (29,792)**	**$ (126,069)**	**$ (75,126)**
Net loss per share, basic and diluted	$ (0.92)	$ (0.70)	$ (2.81)	$ (1.96)
Weighted average common shares outstanding, basic and diluted	47,589,731	42,793,047	44,785,236	38,299,548

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 September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
GAAP net loss	$ (43,804)	$ (29,792)	$ (126,069)	$ (75,126)
Adjustments:				
Stock-based compensation				
Research and development [1]	2,057	1,190	5,285	3,001
General and administrative [2]	4,722	741	6,642	1,672
Non-cash interest expense [3]	1,050	730	2,639	1,891
Non-cash interest income [4]	(1,180)	(474)	(840)	(1,113)
Non-GAAP adjusted net loss	**$ (37,155)**	**$ (27,605)**	**$ (112,343)**	**$ (69,675)**
GAAP net loss per share – basic and diluted	$ (0.92)	$ (0.70)	$ (2.81)	$ (1.96)
Adjustment to net loss:				
Stock -based compensation				
Research and development	0.04	0.03	0.12	0.08
General and administrative	0.10	0.02	0.15	0.04
Non-cash interest expense	0.02	0.01	0.06	0.05
Non-cash interest income	(0.02)	(0.01)	(0.02)	(0.03)
Non-GAAP adjusted net loss per share	**$ (0.78)**	**$ (0.65)**	**$ (2.50)**	**$ (1.82)**
Weighted average common shares outstanding, basic and diluted	47,589,731	42,793,047	44,785,236	38,299,548

(1) To reflect a non-cash charge to operating expense for Research and Development stock-based compensation.
(2) To reflect a non-cash charge to operating expense for General and Administrative stock-based compensation.
(3) To reflect a non-cash charge to other expense for amortization of debt issuance and discount costs and PIK interest related to the issuance of a note payable.
(4) To reflect a non-cash adjustment to other income for accretion on investments.