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

May 14, 2025

- *The primary completion date of the PIK3CA wild-type cohort of the VIKTORIA-1 Phase 3 trial is expected in June 2025 and a topline data readout is anticipated in the third quarter of 2025*
- *Enrollment is ongoing in the PIK3CA mutant cohort of the VIKTORIA-1 Phase 3 trial and a topline data readout is anticipated in the fourth quarter of 2025*
- *VIKTORIA-2 Phase 3 trial remains on track to dose its first patient in the second quarter of 2025*
- *Initiating a clinical trial collaboration with the Dana Farber Cancer Institute and Massachusetts General Hospital to evaluate gedatolisib in combination with abemaciclib and letrozole in patients with endometrial cancer*
- *Approximately $206 million in cash, cash equivalents and investments at March 31, 2025 is expected to fund current clinical development program activities through 2026*
- *Management to host webcast and conference call today, May 14, 2025, at 4:30 p.m. ET*

MINNEAPOLIS, May 14, 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 first quarter ended March 31, 2025 and other recent business developments.

“We continue to make steady progress across our pipeline with several critical data catalysts anticipated this year,” said Brian Sullivan, CEO and co-founder of Celcuity. “We now expect to report topline data for the *PIK3CA* wild-type cohort of the VIKTORIA-1 trial in the third quarter of this year and to report topline data for the *PIK3CA* mutant cohort in the fourth quarter of 2025. If our topline data from the WT cohort is positive, we expect the data will support the filing of our first new drug application and, if approved, our transition to a commercial stage company.”

First Quarter 2025 Business Highlights and Other Recent Developments

- Based on evaluation of blinded event rates in the ongoing VIKTORIA-1 Phase 3 clinical trial, the primary completion date for the *PIK3CA* wild-type patient cohort is projected to occur in June 2025 with topline data now anticipated to be available in the third quarter of 2025.
    - Enrollment is ongoing in the *PIK3CA* mutant cohort of the VIKTORIA-1 trial and remains on track to report topline data in the fourth quarter of 2025.
    - VIKTORIA-1 is a global Phase 3 study evaluating gedatolisib in combination with fulvestrant with and without palbociclib in adults with HR+, HER2- advanced breast cancer who have received prior treatment with a CDK4/6 inhibitor.
- Site activation activities are underway globally for the VIKTORIA-2 Phase 3 clinical trial and dosing of the first patient is anticipated to occur in the second quarter of 2025.
    - VIKTORIA-2 is a global, Phase 3 open-label randomized study evaluating the efficacy and safety of gedatolisib in combination with fulvestrant plus a CDK4/6 inhibitor, either ribociclib or palbociclib, in comparison to fulvestrant plus a CDK4/6 inhibitor as a first-line treatment for patients with HR+/HER2- advanced breast cancer who are endocrine therapy resistant.
    - Prior to initiating the Phase 3 portion of the study, a safety run-in will be conducted in 12-36 participants to assess the safety of gedatolisib in combination with ribociclib and fulvestrant.
- The CELC-G-201 study is on track to report topline data for the Phase 1b portion of the trial late in the second quarter of 2025.
    - CELC-G-201 is a Phase 1b/2 evaluating gedatolisib in combination with darolutamide for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC) whose disease progressed while on or after treatment with an androgen receptor signaling inhibitor.
    - The Phase 1b portion of the trial will assess the safety and tolerability of gedatolisib in combination with darolutamide and is expected to identify the recommended phase 2 dose regimen.
- Initiating a clinical trial collaboration with the Dana Farber Cancer Institute and Massachusetts General Hospital to evaluate gedatolisib in combination with abemaciclib and letrozole in patients with endometrial cancer
    - In a prior Phase 2 study, gedatolisib was evaluated as a monotherapy in patients with endometrial cancer.

First Quarter 2025 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2025, compared to the first quarter ended March 31, 2024.

Total operating expenses were $36.1 million for the first quarter of 2025, compared to $22.5 million for the first quarter of 2024.

Research and development (“R&D”) expenses were $32.2 million for the first quarter of 2025, compared to $20.6 million for the prior-year period. Of the approximately $11.6 million increase in R&D expenses, $5.9 million primarily related to increased employee and consulting expenses. The remaining $5.7 million primarily related to activities supporting our ongoing clinical trials.

General and administrative (“G&A”) expenses were $3.9 million for the first quarter of 2025, compared to $1.8 million for the prior-year period. Increased employee and consulting expenses accounted for $1.6 million of the increase. Professional fees, expanding infrastructure and other administrative expenses accounted for the remaining increase of approximately $0.5 million.

Net loss for the first quarter of 2025 was $37.0 million, or $0.86 loss per share, compared to a net loss of $21.6 million, or $0.64 loss per share, for the first quarter of 2024. Non-GAAP adjusted net loss for the first quarter of 2025 was $34.7 million, or $0.81 loss per share, compared to non-GAAP adjusted net loss of $19.9 million, or $0.59 loss per share, for the first 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 first quarter of 2025 was $35.9 million, compared to $17.1 million for the first quarter of 2024.

At March 31, 2025, Celcuity reported cash, cash equivalents and short-term investments of $205.7 million. We expect cash, cash equivalents, investments and drawdowns on our debt facility to fund current clinical development program activities through 2026.

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 first 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=1715314&tp_key=61a8c66165 . 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 PI3K/AKT/mTOR (“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- advanced breast cancer is currently enrolling patients. More detailed information about the VIKTORIA-1 study can be found at ClinicalTrials.gov . 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. 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- advanced breast cancer is currently recruiting patients. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com . Follow us on LinkedIn and Twitter .

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" including, but not limited to, the design of our clinical trials; the timing of initiating and enrolling patients in, and receiving results and data from, our clinical trials; the costs and expected results from any ongoing or planned clinical trials; the market opportunity for gedatolisib; the ability of our clinical trial data to support the filing of our first new drug application; our expectations regarding our ability to obtain U.S. Food and Drug Administration approval to commercialize gedatolisib; revenue expectations; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to Celcuity's lead product candidate, gedatolisib; our anticipated use of cash; and the strength of our balance sheet. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends" or "continue," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements are subject to numerous risks, uncertainties, and conditions, many of which are beyond the control of Celcuity. These include, but are not limited to, unforeseen delays in our clinical trials, our ability to obtain and maintain regulatory approvals to commercialize our products, and the market acceptance of such products, the development of therapies and tools competitive with our products, our ability to access capital upon favorable terms or at all, and those risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission on March 31, 2025. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

Celcuity undertakes no obligation to update these statements for revisions or changes after the date of this press release, except as required by law.

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Celcuity Inc.
Balance Sheets
(in thousands)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,478	$ 22,515
Investments	189,213	212,589
Other current assets	11,906	9,467
Total current assets	217,597	244,571
Property and equipment, net	358	336
Operating lease right-of-use assets	172	216
Total Assets	**$ 218,127**	**$ 245,123**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 9,932	$ 9,366
Operating lease liabilities	169	172
Accrued expenses	22,818	22,185
Total current liabilities	32,919	31,723
Operating lease liabilities	13	54
Note payable, non-current	98,527	97,727
Total Liabilities	131,459	129,504
Total Stockholders' Equity	86,668	115,619
Total Liabilities and Stockholders' Equity	**$ 218,127**	**$ 245,123**

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 32,227	$ 20,647

General and administrative	3,906	1,846
Total operating expenses	36,133	22,493
Loss from operations	(36,133)	(22,493)
Other (expense) income		
Interest expense	(3,183)	(1,401)
Interest income	2,319	2,282
Other (expense) income, net	(864)	881
Net loss before income taxes	**(36,997)**	**(21,612)**
Income tax benefits	-	-
Net loss	**$ (36,997)**	**$ (21,612)**
Net loss per share, basic and diluted	$ (0.86)	$ (0.64)
Weighted average common shares outstanding, basic and diluted	43,052,757	33,612,054

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 March 31,	
	2025	**2024**
GAAP net loss	$ (36,997)	$ (21,612)
Adjustments:		
Stock-based compensation		
Research and development [1]	1,505	832
General and administrative [2]	939	499
Non-cash interest expense [3]	800	531
Non-cash interest income [4]	(946)	(154)
Non-GAAP adjusted net loss	**$ (34,699)**	**$ (19,904)**
GAAP net loss per share - basic and diluted	$ (0.86)	$ (0.64)
Adjustment to net loss (as detailed above)	0.05	0.05
Non-GAAP adjusted net loss per share	**$ (0.81)**	**$ (0.59)**
Weighted average common shares outstanding, basic and diluted	43,052,757	33,612,054

(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.

celcuity
EXPANDING TREATMENT OPTIONS