



## Celcuity Inc. Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

March 31, 2025

- *The **PIK3CA** wild-type cohort of the VIKTORIA-1 Phase 3 trial is on track to report topline data in Q2 2025*
- *VIKTORIA-2 Phase 3 remains on track to enroll its first patient in Q2 2025*
- *Presented encouraging preliminary overall survival data from the Phase 1b study evaluating gedatolisib in combination with palbociclib and endocrine therapy at the 2024 SABCS*
- *Approximately \$235.1 million in cash, cash equivalents and short-term investments at end of Q4 2024 expected to fund current clinical development program activities through 2026*
- *Management to host webcast and conference call today, March 31, 2025, at 4:30 p.m. ET*

MINNEAPOLIS, March 31, 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 fourth quarter ended December 31, 2024 and other recent business developments.

“We expect 2025 to be a transformational year for Celcuity as we anticipate reporting several clinical data readouts, including primary analysis for the **PIK3CA** wild-type cohort of the VIKTORIA-1 trial. We expect to share topline data in Q2 2025,” said Brian Sullivan, CEO and co-founder of Celcuity. “In addition, we anticipate reporting topline data for the Phase 1b/2 trial in metastatic castration resistant prostate cancer in late Q2 2025, and topline data for the **PIK3CA** mutant-type cohort of the VIKTORIA-1 trial in Q4 2025. We also remain on track to enroll the first patient for our VIKTORIA-2 Phase 3 trial in Q2 2025.”

### Fourth Quarter 2024 Business Highlights and Other Recent Developments

- The VIKTORIA-1 Phase 3 clinical trial 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 is 100% enrolled for the **PIK3CA** wild-type cohort. We expect to provide topline data in Q2 2025.
  - Enrollment for the **PIK3CA** mutant cohort remains on track and topline data is expected in Q4 of 2025.
- The VIKTORIA-2 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 remains on track to enroll its first patient in Q2 2025.
  - A safety run-in study preceding the initiation of the Phase 3 portion of the study will be conducted in 12-36 participants to assess the safety profile of gedatolisib in combination with ribociclib and fulvestrant.
  - Site selection activities are completed. We expect to activate approximately 200 sites across North America, Europe, Latin America, and Asia-Pacific.
  - The Phase 3 portion of the study is expected to enroll approximately 638 patients.
- The Phase 1b/2 clinical trial, evaluating gedatolisib in combination with darolutamide for the treatment of patients with metastatic castration resistant prostate cancer (“mCRPC”), is ongoing and remains on track to report preliminary data in late Q2 2025.
  - The study is expected to enroll up to 54 patients with mCRPC whose disease progressed while on or after treatment with an androgen receptor signaling inhibitor.
- In December 2024, Celcuity presented overall survival data from a Phase 1b trial, which evaluated gedatolisib in combination with palbociclib and either letrozole or fulvestrant, in patients with HR+, HER2- advanced or metastatic breast cancer during a poster session at the 2024 San Antonio Breast Cancer Symposium (SABCS). Median overall survival was 77.3 months among patients with HR+, HER2- advanced breast cancer who were treatment-naïve in the advanced setting and 33.9 months among patients previously treated with a CDK4/6 inhibitor.
  - Results compare favorably to published data for currently available first- or second-line standard-of-care treatment regimens for patients with HR+, HER2- advanced breast cancer and highlight the promising clinical development strategy of simultaneously inhibiting the ER, CDK4/6, and PAM (PI3K/AKT/mTOR) signaling pathways.

### Fourth Quarter and Full Year 2024 Financial Results

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

fourth quarter and full year ended December 31, 2023.

Total operating expenses were \$36.4 million for the fourth quarter of 2024, compared to \$19.7 million for the fourth quarter of 2023. Operating expenses for the full year 2024 were \$113.3 million, compared to \$66.2 million for the full year 2023.

Research and development (“R&D”) expenses were \$33.5 million for the fourth quarter of 2024, compared to \$18.1 million for the prior-year period. Of the approximately \$15.4 million increase in R&D expenses, \$9.9 million primarily related to costs supporting ongoing activities for the VIKTORIA-1 Phase 3 trial and the CELC-G-201 Phase 1b/2 trial, along with the commencement of the VIKTORIA-2 Phase 3 trial. The remaining \$5.5 million primarily relates to increased employee and consulting expenses.

R&D expenses for the full year 2024 were \$104.2 million, compared to \$60.6 million for the prior year. Of the approximately \$43.6 million increase in R&D expenses, \$30.7 million was related to costs supporting ongoing activities for the VIKTORIA-1 Phase 3 trial and the CELC-G-201 Phase 1b/2 clinical trial, along with the commencement of the VIKTORIA-2 Phase 3 trial. The remaining \$12.9 million increase in R&D expenses was primarily related to increased employee and consulting expenses.

General and administrative (“G&A”) expenses were \$3.0 million for the fourth quarter of 2024, compared to \$1.6 million for the prior year period. Of the approximately \$1.4 million increase, \$1.1 million was related to increased employee-related expenses, and \$0.3 million was related to professional fees, expanding infrastructure costs and other administrative expenses.

G&A expenses for the full year 2024 were \$9.1 million, compared to \$5.6 million for the prior year. Of the approximately \$3.4 million increase in G&A expenses, \$2.6 million was related to increased employee-related expenses, and \$0.8 million was related to professional fees, expanding infrastructure costs, and other administrative expenses.

Net loss for the fourth quarter of 2024 was \$36.7 million, or \$0.85 loss per share, compared to a net loss of \$18.8 million, or \$0.65 loss per share, for the fourth quarter of 2023. Net loss for the full year 2024 was \$111.8 million, or \$2.83 loss per share, compared to a net loss of \$63.8 million, or \$2.69 loss per share, in 2023. Non-GAAP adjusted net loss for the fourth quarter of 2024 was \$32.3 million, or \$0.75 loss per share, compared to non-GAAP adjusted net loss of \$17.6 million, or \$0.61 loss per share, for the fourth quarter of 2023. Non-GAAP adjusted net loss for the full year 2024 was \$101.9 million, or \$2.58 loss per share, compared to non-GAAP adjusted net loss of \$57.8 million, or \$2.44 loss per share, for 2023. 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 2024 was \$27.8 million, compared to \$18.5 million for the fourth quarter of 2023. Net cash used in operating activities for the full year 2024 was \$83.5 million, compared to \$53.8 million for the full year 2023. Cash, cash equivalents and short-term investments were approximately \$235.1 million at the end of fiscal year 2024 and are expected 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 fourth quarter and full year 2024 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://viaavid.webcasts.com/starthere.jsp?ei=1704367&tp\\_key=f99d4186f3](https://viaavid.webcasts.com/starthere.jsp?ei=1704367&tp_key=f99d4186f3). 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 PI3K $\alpha$ , 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](https://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](http://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; 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, and its CELsignia platform; 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**

	<u>December 31, 2024</u>	<u>December 31, 2023</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 22,514,823	\$ 30,662,774
Investments	212,588,960	149,919,974
Other current assets	9,467,247	10,007,849
<b>Total current assets</b>	<u>244,571,030</u>	<u>190,590,597</u>
Property and equipment, net	336,515	228,782
Operating lease right-of-use assets	215,502	400,019
<b>Total Assets</b>	<u><b>\$ 245,123,047</b></u>	<u><b>\$ 191,219,398</b></u>
<b>Liabilities and Stockholders' Equity:</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 9,366,007	\$ 5,076,699
Operating lease liabilities	171,952	184,950
Accrued expenses	22,184,948	8,927,094
<b>Total current liabilities</b>	<u>31,722,907</u>	<u>14,188,743</u>
Operating lease liabilities	53,969	225,922
Note payable, non-current	97,727,136	37,035,411
<b>Total Liabilities</b>	<u>129,504,012</u>	<u>51,450,076</u>
<b>Total Stockholders' Equity</b>	<u>115,619,035</u>	<u>139,769,322</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u><b>\$ 245,123,047</b></u>	<u><b>\$ 191,219,398</b></u>

**Celcuity Inc.  
 Statements of Operations**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
<b>Operating expenses:</b>				
Research and development	\$ 33,471,213	\$ 18,081,194	\$ 104,203,230	\$ 60,594,005
General and administrative	2,958,918	1,648,079	9,063,721	5,636,326
Total operating expenses	36,430,131	19,729,273	113,266,951	66,230,331
Loss from operations	(36,430,131)	(19,729,273)	(113,266,951)	(66,230,331)
Other (expense) income				
Interest expense	(3,275,161)	(1,397,247)	(10,280,445)	(5,326,387)
Interest income	3,052,251	2,278,048	11,768,291	7,777,602
Other (expense) income, net	(222,910)	880,801	1,487,846	2,451,215
<b>Net loss before income taxes</b>	<b>(36,653,041)</b>	<b>(18,848,472)</b>	<b>(111,779,105)</b>	<b>(63,779,116)</b>
Income tax benefits	-	-	-	-
<b>Net loss</b>	<b>\$ (36,653,041)</b>	<b>\$ (18,848,472)</b>	<b>\$ (111,779,105)</b>	<b>\$ (63,779,116)</b>
Net loss per share, basic and diluted	\$ (0.85)	\$ (0.65)	\$ (2.83)	\$ (2.69)
Weighted average common shares outstanding, basic and diluted	42,873,934	28,900,075	39,449,393	23,679,472

#### 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

	Three Months Ended December 31,		Years Ended	
	2024	2023	2024	2023
GAAP net loss	\$ (36,653,041)	\$ (18,848,472)	\$ (111,779,105)	\$ (63,779,116)
Adjustments:				
Stock-based compensation				
Research and development <sup>(1)</sup>	1,403,877	745,629	4,404,518	2,700,318
General and administrative <sup>(2)</sup>	911,404	496,904	2,583,823	2,201,116
Non-cash interest expense <sup>(3)</sup>	803,222	528,637	2,694,361	2,052,336
Non-cash interest income <sup>(4)</sup>	1,262,841	(554,126)	150,421	(993,457)
<b>Non-GAAP adjusted net loss</b>	<b>\$ (32,271,697)</b>	<b>\$ (17,631,428)</b>	<b>\$ (101,945,982)</b>	<b>\$ (57,818,803)</b>

GAAP net loss per share - basic and diluted	\$ (0.85)	\$ (0.65)	\$ (2.83)	\$ (2.69)
Adjustment to net loss (as detailed above)	0.10	0.04	0.25	0.25
<b>Non-GAAP adjusted net loss per share</b>	<b>\$ (0.75)</b>	<b>\$ (0.61)</b>	<b>\$ (2.58)</b>	<b>\$ (2.44)</b>

Weighted average common shares outstanding, basic and diluted	42,873,934	28,900,075	39,449,393	23,679,472
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- (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.



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