



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

November 14, 2024

- *The PIK3CA wild-type cohort of the Phase 3 VIKTORIA-1 trial is 100% enrolled; expect to report topline data for this cohort in late Q1 2025 or Q2 2025*
- *Approximately \$264 million in cash, cash equivalents and investments at end of Q3 2024 expected to fund current clinical development program activities through 2026*
- *Management to host webcast and conference call today, November 14, 2024, at 4:30 p.m. ET*

MINNEAPOLIS, Nov. 14, 2024 (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, 2024 and other recent business developments.

"Enrollment in our VIKTORIA-1 study remains robust and on-track. The *PIK3CA* wild-type cohort is 100% enrolled, and enrollment in the *PIK3CA* mutant cohort is on plan," said Brian Sullivan, CEO and co-founder of Celcuity. "Based on our current forecast of reaching the event thresholds that will trigger primary analysis in both the *PIK3CA* wild-type and mutant cohorts, we expect to report topline data for the *PIK3CA* wild-type cohort sometime in late Q1 2025 or during Q2 2025 and to report topline data for the *PIK3CA* mutant cohort in the second half of 2025."

Third Quarter 2024 Business Highlights and Other Recent Developments

- The VIKTORIA-1 Phase 3 clinical trial expects to provide topline data for the *PIK3CA* wild-type cohort in late Q1 2025 or during Q2 2025 and for the *PIK3CA* mutant cohort in the second half of 2025.
 - VIKTORIA-1 is 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.
 - The *PIK3CA* wild-type cohort is 100% enrolled and enrollment of the *PIK3CA* mutant cohort is on-track relative to plan.
- The VIKTORIA-2 Phase 3 clinical trial remains on track to enroll its first patient in Q2 2025.
 - The VIKTORIA-2 study is a global Phase 3 open-label randomized clinical trial 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 the initiation of the Phase 3 portion of the trial, a safety run-in study will be conducted in 12-36 participants to assess the safety profile of gedatolisib in combination with ribociclib and fulvestrant.
 - Site qualification activities to support activation of up to 200 sites across North America, Europe, Latin America, and Asia are on track.
- 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 expected to report preliminary data in Q2 2025.
- Overall survival data from the B2151009 Phase 1b clinical trial will be presented at the San Antonio Breast Cancer Symposium (SABCS), taking place December 10-13, 2024. Details of the poster presentation are as follows:
 - Abstract Title: Overall survival in patients with HR+/HER2- advanced breast cancer treated in a phase 1b trial evaluating gedatolisib in combination with palbociclib and endocrine therapy (SESS-1510)
 - Presentation Number: P4-08-25
 - Date/Time: Thursday, December 12, 5:30 PM CST
- Additional nonclinical data further characterizing the mechanism of action of gedatolisib and its effect on breast cancer cell metabolic functions will also be presented at the SABCS.
 - Abstract Title: Mechanism of action of gedatolisib in combination with fulvestrant and/or palbociclib in estrogen receptor positive breast cancer models (SESS-989)
 - Abstract Title: Different effects of gedatolisib versus single-node PI3K/AKT/mTOR pathway inhibitors on breast cancer cell metabolic functions (SESS-997)
- In October, *Cancers* published results of nonclinical studies in gynecological cancer cell line models highlighting the differences between single-node inhibitors of the PI3K/AKT/mTOR pathway and gedatolisib. The published manuscript is available online and on the publications section of Celcuity's [website](#).

Third Quarter 2024 Financial Results

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

September 30, 2023.

Total operating expenses were \$30.1 million for the third quarter of 2024, compared to \$18.9 million for the third quarter of 2023.

Research and development (R&D) expenses were \$27.6 million for the third quarter of 2024, compared to \$17.5 million for the prior-year period. Of the approximately \$10.1 million increase in R&D expenses, \$6.3 million primarily related to activities supporting the VIKTORIA-1 Phase 3 trial, the Phase 1b/2 trial and the initiation of the VIKTORIA-2 Phase 3 trial, and \$3.8 million was related to increased employee and consulting expenses.

General and administrative (G&A) expenses were \$2.5 million for the third quarter of 2024, compared to \$1.4 million for the prior-year period. Employee and consulting related expenses accounted for \$0.9 million of the increase. Professional fees and other administrative expenses accounted for the remaining increase of approximately \$0.2 million.

Net loss for the third quarter of 2024 was \$29.8 million, or \$0.70 loss per share, compared to a net loss of \$18.4 million, or \$0.83 loss per share, for the third quarter of 2023. Non-GAAP adjusted net loss for the third quarter of 2024 was \$27.6 million, or \$0.65 loss per share, compared to non-GAAP adjusted net loss of \$17.3 million, or \$0.78 loss per share, for the third quarter of 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 third quarter of 2024 was \$20.6 million, compared to \$12.7 million for the third quarter of 2023.

At September 30, 2024, Celcuity reported cash, cash equivalents and short-term investments of \$264.1 million.

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 2024 financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-800-717-1738 or 1-646-307-1865. A live webcast presentation can also be accessed using this weblink: https://viaid.webcasts.com/starthere.jsp?ei=1688854&tp_key=0b14db1255. 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 development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR 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 enrolling patients. 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 expected to begin enrolling patients in the second quarter of 2025. 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; 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, 2023 filed with the Securities and Exchange Commission on March 27, 2024. 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.
 Condensed Balance Sheets**

	<u>September 30, 2024</u> (unaudited)	<u>December 31, 2023</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 12,603,289	\$ 30,662,774
Investments	251,455,468	149,919,974
Other current assets	8,379,682	10,007,849
Total current assets	<u>272,438,439</u>	<u>190,590,597</u>
Property and equipment, net	338,787	228,782
Operating lease right-of-use assets	259,744	400,019
Total Assets	<u><u>\$ 273,036,970</u></u>	<u><u>\$ 191,219,398</u></u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 9,158,778	\$ 5,076,699
Operating lease liabilities	175,226	184,950
Accrued expenses	16,974,725	8,927,094
Total current liabilities	<u>26,308,729</u>	<u>14,188,743</u>
Operating lease liabilities	95,699	225,922
Note payable, non-current	96,923,914	37,035,411
Total Liabilities	<u>123,328,342</u>	<u>51,450,076</u>
Total Stockholders' Equity	<u>149,708,628</u>	<u>139,769,322</u>
Total Liabilities and Stockholders' Equity	<u><u>\$ 273,036,970</u></u>	<u><u>\$ 191,219,398</u></u>

**Celcuity Inc.
 Condensed Statements of Operations
 (unaudited)**

	<u>Three Months Ended September</u> <u>30,</u>		<u>Nine Months Ended September</u> <u>30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Operating expenses:				
Research and development	\$ 27,587,483	\$ 17,488,236	\$ 70,732,017	\$ 42,512,811
General and administrative	2,472,416	1,409,801	6,104,803	3,988,248
Total operating expenses	<u>30,059,899</u>	<u>18,898,037</u>	<u>76,836,820</u>	<u>46,501,059</u>

Loss from operations	(30,059,899)	(18,898,037)	(76,836,820)	(46,501,059)
Other (expense) income				
Interest expense	(3,343,989)	(1,372,132)	(7,005,284)	(3,929,140)
Interest income	3,612,099	1,865,629	8,716,040	5,499,555
Other income, net	268,110	493,497	1,710,756	1,570,415
Net loss before income taxes	(29,791,789)	(18,404,540)	(75,126,064)	(44,930,644)
Income tax benefits	-	-	-	-
Net loss	\$ (29,791,789)	\$ (18,404,540)	\$ (75,126,064)	\$ (44,930,644)
Net loss per share, basic and diluted	\$ (0.70)	\$ (0.83)	\$ (1.96)	\$ (2.05)
Weighted average common shares outstanding, basic and diluted	42,793,047	22,117,626	38,299,548	21,920,147

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 September		Nine Months Ended September	
	30, 2024	2023	30, 2024	2023
GAAP net loss	\$ (29,791,789)	\$ (18,404,540)	\$ (75,126,064)	\$ (44,930,644)
Adjustments:				
Stock-based compensation				
Research and development ⁽¹⁾	1,190,424	660,706	3,000,641	1,954,689
General and administrative ⁽²⁾	740,777	447,931	1,672,418	1,704,213
Non-cash interest expense ⁽³⁾	730,741	520,794	1,891,139	1,523,699
Non-cash interest income ⁽⁴⁾	(473,584)	(480,520)	(1,112,420)	(439,331)
Non-GAAP adjusted net loss	\$ (27,603,431)	\$ (17,255,629)	\$ (69,674,286)	\$ (40,187,374)
GAAP net loss per share - basic and diluted	\$ (0.70)	\$ (0.83)	\$ (1.96)	\$ (2.05)
Adjustment to net loss (as detailed above)	0.05	0.05	0.14	0.22
Non-GAAP adjusted net loss per share	\$ (0.65)	\$ (0.78)	\$ (1.82)	\$ (1.83)

Weighted average common shares outstanding, basic and diluted

42,793,047	22,117,626	38,299,548	21,920,147
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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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