



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

May 15, 2024

- *The Phase 3 VIKTORIA-1 trial remains on track to report topline data from PIK3CA wild type patient sub-group in the second half of 2024*
- *First patient dosed in a Phase 1b/2 clinical trial evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer*
- *\$177.7 million in cash, cash equivalents and short-term investments expected to provide runway into the first half of 2026*
- *Management to host webcast and conference call today, May 15, 2024, at 4:30 p.m. ET*

MINNEAPOLIS, May 15, 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 first quarter ended March 31, 2024 and other recent business developments.

"We continued to execute well this quarter. Our VIKTORIA-1 study remains on-track, and we dosed the first patient in our Phase 1b/2 trial in metastatic castration resistant prostate cancer," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "With the addition of a Chief Commercial Officer to our executive team, we began the foundational work needed to prepare for the potential commercial launch of gedatolisib. We look forward to presenting topline data from the PIK3CA wild type patient sub-group later this year."

First Quarter 2024 Business Highlights and Other Recent Developments

- The VIKTORIA-1 Phase 3 trial remains on track to provide topline data for the PIK3CA wild type patient sub-group in the second half of 2024 and for the PIK3CA mutant patient sub-group in the first 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 Phase 3 VIKTORIA-1 clinical trial is enrolling patients at approximately 220 sites in 23 countries in North and South America, Europe, and Asia.
- The Phase 1b/2 clinical trial evaluating gedatolisib in combination with darolutamide for the treatment of metastatic castration resistant prostate cancer (mCRPC) was initiated in the fourth quarter of 2023. In February 2024, the first patient was dosed.
 - Enrollment is ongoing and the trial is expected to enroll up to 54 patients with mCRPC whose disease progressed after treatment with an androgen receptor signaling inhibitor.
 - The Phase 1b/2 trial is on track to provide initial preliminary data in the first half of 2025.
- In February 2024, the Company appointed Eldon Mayer as Chief Commercial Officer to enable Celcuity to begin laying the groundwork for the potential commercial launch of gedatolisib.

First Quarter 2024 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2024, compared to the first quarter ended March 31, 2023.

Total operating expenses were \$22.5 million for the first quarter of 2024, compared to \$12.6 million for the first quarter of 2023.

Research and development (R&D) expenses were \$20.7 million for the first quarter of 2024, compared to \$11.3 million for the prior-year period. Of the approximately \$9.4 million increase in R&D expenses, \$7.9 million primarily related to activities supporting the VIKTORIA-1 Phase 3 trial and the initiation of the CELC-G-201 Phase 1b/2 clinical trial, and \$1.5 million was related to increased employee and consulting expenses.

General and administrative (G&A) expenses were \$1.8 million for the first quarter of 2024, compared to \$1.3 million for the prior-year period. Employee-related expenses accounted for \$0.3 million of the increase. Professional fees and other administrative expenses accounted for the remaining increase of approximately \$0.2 million.

Net loss for the first quarter of 2024 was \$21.6 million, or \$0.64 loss per share, compared to a net loss of \$11.9 million, or \$0.55 loss per share, for the first quarter of 2023. Non-GAAP adjusted net loss for the first quarter of 2024 was \$19.9 million, or \$0.59 loss per share, compared to non-GAAP adjusted net loss of \$11.9 million, or \$0.55 loss per share, for the first 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 first quarter of 2024 was \$17.1 million, compared to \$12.9 million for the first quarter of 2023.

At March 31, 2024, Celcuity reported cash, cash equivalents and short-term investments of \$177.7 million. We expect cash, cash equivalents, investments and drawdown on our debt facility to fund current operational activities into the first half of 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 2024 financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-888-886-7786 or 1-416-764-8658. A live webcast presentation can also be accessed using this weblink: https://viaid.webcasts.com/starthere.jsp?ei=1664947&tp_key=8c4820dec8. 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. The company's CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies. Further information about Celcuity can be found at www.celcuity.com. Follow us on [LinkedIn](https://www.linkedin.com/company/celcuity) and [Twitter](https://twitter.com/celcuity).

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; our strategy, marketing and commercialization plans; 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, 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

March 31, 2024

December 31, 2023

(unaudited)

Assets

Current Assets:

Cash and cash equivalents	\$ 31,214,741	\$ 30,662,774
Investments	146,447,843	149,919,974
Other current assets	9,860,535	10,007,849
Total current assets	187,523,119	190,590,597

Property and equipment, net	306,024	228,782
Operating lease right-of-use assets	351,911	400,019
Total Assets	\$ 188,181,054	\$ 191,219,398

Liabilities and Stockholders' Equity:

Current Liabilities:

Accounts payable	\$ 5,276,690	\$ 5,076,699
Operating lease liabilities	181,882	184,950
Accrued expenses	11,237,509	8,927,094
Total current liabilities	16,696,081	14,188,743
Operating lease liabilities	182,079	225,922
Note payable, non-current	37,566,230	37,035,411
Total Liabilities	54,444,390	51,450,076

Stockholders' Equity:

Preferred stock	505	854
Common stock	30,774	25,506
Additional paid-in capital	315,393,843	299,818,965
Accumulated deficit	(181,688,458)	(160,076,003)
Total Stockholders' Equity	133,736,664	139,769,322
Total Liabilities and Stockholders' Equity	\$ 188,181,054	\$ 191,219,398

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

Three Months Ended March 31,

	2024	2023
Operating expenses:		
Research and development	\$ 20,647,559	\$ 11,278,493
General and administrative	1,846,276	1,269,044
Total operating expenses	22,493,835	12,547,537
Loss from operations	(22,493,835)	(12,547,537)
Other income (expense)		
Interest expense	(1,400,712)	(1,242,012)
Interest income	2,282,092	1,851,132
Other income (expense), net	881,380	609,120
Net loss before income taxes	(21,612,455)	(11,938,417)
Income tax benefits	-	-
Net loss	\$ (21,612,455)	\$ (11,938,417)
Net loss per share, basic and diluted	\$ (0.64)	\$ (0.55)
Weighted average common shares outstanding, basic and diluted	33,612,054	21,680,877

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 March 31,	
	2024	2023
GAAP net loss	\$ (21,612,455)	\$ (11,938,417)
Adjustments:		
Stock-based compensation		
Research and development ⁽¹⁾	832,180	654,471
General and administrative ⁽²⁾	499,166	618,811
Non-cash interest expense ⁽³⁾	530,819	495,188
Non-cash interest income ⁽⁴⁾	(153,845)	(1,697,811)
Non-GAAP adjusted net loss	\$ (19,904,135)	\$ (11,867,758)
GAAP net loss per share - basic and diluted	\$ (0.64)	\$ (0.55)
Adjustment to net loss (as detailed above)	0.05	0.00
Non-GAAP adjusted net loss per share	\$ (0.59)	\$ (0.55)
Weighted average common shares outstanding, basic and diluted	33,612,054	21,680,877

(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.

