Celcuity Inc. Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 27, 2024

- *Dosed the first patient in a Phase 1b/2 trial evaluating gedatolisib in combination with darolutamide for the treatment of metastatic castration resistant prostate cancer*
- *Presented nonclinical data demonstrating the superior therapeutic effects of gedatolisib compared to other PI3K/AKT/mTOR inhibitors at the 2023 SABCS*
- *Raised $65 million from the sale of equity; expect cash, cash equivalents, investments and available funds under our debt facility, to fund current operational activities into first half of 2026*
- *Management to host webcast and conference call today, March 27, 2024, at 4:30 p.m. ET*

MINNEAPOLIS, March 27, 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 fourth quarter and full year ended December 31, 2023 and other recent business developments.

“In 2023, we made significant progress advancing development of gedatolisib while strengthening our balance sheet and adding to our leadership team,” said Brian Sullivan, CEO and Co-Founder of Celcuity. “Our Phase 3 VIKTORIA-1 trial remains on track to report topline data from the *PI3KCA* wild type patient sub-group in the second half of this year. We were also excited to begin development of gedatolisib for patients with metastatic castration resistant prostate cancer this past year. Enrollment has begun in our Phase 1b/2 trial evaluating gedatolisib in combination with darolutamide, and we look forward to sharing preliminary data from this trial in the first half of 2025.”

Fourth Quarter 2023 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.
  - The trial is expected to enroll up to 54 patients with mCRPC whose disease progressed after treatment with an androgen receptor signaling inhibitor.
- In December 2023, Celcuity presented data from nonclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR (PAM) inhibitors in breast cancer cell lines during a poster session at the 2023 San Antonio Breast Cancer Symposium (SABCS). In a panel of breast cancer cell lines, gedatolisib was found to be more cytotoxic and at least 300-fold more potent, on average, compared to the single node PAM inhibitors.
- In February 2024, Eldon Mayer was appointed Chief Commercial Officer. His 30 years of biopharmaceutical commercial experience includes senior leadership roles at several companies where he led the launch of their first drug.

Fourth Quarter and Full Year 2023 Financial Results

Unless otherwise stated, all comparisons are for the fourth quarter and full year ended December 31, 2023, compared to the fourth quarter and full year ended December 31, 2022.

Total operating expenses were $19.7 million for the fourth quarter of 2023, compared to $11.6 million for the fourth quarter of 2022. Operating expenses for the full year 2023 were $66.2 million, compared to $39.4 million for the full year 2022.

Research and development (R&D) expenses were $18.1 million for the fourth quarter of 2023, compared to $10.6 million for the prior-year period. Of the approximately $7.5 million increase in R&D expenses, $6.8 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 $0.7 million was related to increased employee and consulting expenses.

R&D expenses for the full year 2023 were $60.6 million, compared to $35.3 million for the prior year. Of the approximately $25.3

million increase in R&D expenses, $22.9 million was related to activities supporting the VIKTORIA-1 Phase 3 trial and the initiation of the CELC-G-201 Phase 1b/2 clinical trial. The remaining $2.4 million increase in R&D expenses was related to increased employee and consulting expenses.

General and administrative (G&A) expenses were $1.6 million for the fourth quarter of 2023, compared to $1.0 million for the prior-year period. Employee-related expenses accounted for $0.5 million of the increase. The remaining increase resulted from professional fees and other expenses associated with compliance related activities that support financing and clinical operations.

G&A expenses for the full year 2023 were $5.6 million, compared to $4.1 million for the prior year. Of the approximately $1.5 million increase in G&A expenses, $1.1 million was related to increased employee-related expenses, and $0.4 million was related to professional fees and other expenses associated with compliance related activities that support financing and clinical operations.

Net loss for the fourth quarter of 2023 was $18.8 million, or $0.65 loss per share, compared to a net loss of $11.6 million, or $0.69 loss per share, for the fourth quarter of 2022. Net loss for the full year 2023 was $63.8 million, or $2.69 loss per share, compared to a net loss of $40.4 million, or $2.64 loss per share, in 2022. Non-GAAP adjusted net loss for the fourth quarter of 2023 was $17.6 million, or $0.61 loss per share, compared to non-GAAP adjusted net loss of $10.3 million, or $0.61 loss per share, for the fourth quarter of 2022. Non-GAAP adjusted net loss for the full year 2023 was $57.8 million, or $2.44 loss per share, compared to non-GAAP adjusted net loss of $35.0 million, or $2.27 loss per share, for 2022. 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 2023 was $18.5 million, compared to $9.5 million for the fourth quarter of 2022. Net cash used in operating activities for the full year 2023 was $53.8 million, compared to $36.0 million for the full year 2022.

In October of 2023, Celcuity closed a private placement of equity that resulted in gross proceeds of approximately $50 million. In December 2023, Celcuity closed on an additional $15 million of gross proceeds through its at-the-market offering. The Company expects to use the net proceeds to advance the clinical development of gedatolisib and for general corporate purposes.

At December 31, 2023, Celcuity reported cash, cash equivalents and short-term investments of $180.6 million. We expect cash, cash equivalents, investments and available funds under our debt facility to provide adequate capital 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 fourth quarter and full year 2023 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://viavid.webcasts.com/starthere.jsp?ei=1655995&tp_key=04c7a07803 . 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 . 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 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; 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 to be 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.
Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 30,662,774	$ 24,571,557
Investments	149,919,974	144,015,954
Other current assets	10,007,849	6,603,026
Total current assets	190,590,597	175,190,537
Property and equipment, net	228,782	260,294
Operating lease right-of-use assets	400,019	246,266
Total Assets	**$ 191,219,398**	**$ 175,697,097**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 5,076,699	$ 2,627,076
Finance lease liabilities	-	2,449
Operating lease liabilities	184,950	191,749
Accrued expenses	8,927,094	4,060,280
Total current liabilities	14,188,743	6,881,554
Operating lease liabilities	225,922	61,002
Note payable, non-current	37,035,411	34,983,074
Total Liabilities	51,450,076	41,925,630
Total Stockholders' Equity	139,769,322	133,771,467
Total Liabilities and Stockholders' Equity	**$ 191,219,398**	**$ 175,697,097**

Celcuity Inc.
Statements of Operations

Three Months Ended December 31,		Years Ended December 31,	
2023	**2022**	**2023**	**2022**

Operating expenses:				
Research and development	$ 18,081,194	$ 10,604,043	$ 60,594,005	$ 35,289,548
General and administrative	1,648,079	1,035,161	5,636,326	4,101,543
Total operating expenses	19,729,273	11,639,204	66,230,331	39,391,091
Loss from operations	(19,729,273)	(11,639,204)	(66,230,331)	(39,391,091)
Other income (expense)				
Interest expense	(1,397,247)	(678,003)	(5,326,387)	(2,106,111)
Interest income	2,278,048	735,863	7,777,602	1,127,162
Other income (expense), net	880,801	57,860	2,451,215	(978,949)
Net loss before income taxes	**(18,848,472)**	**(11,581,344)**	**(63,779,116)**	**(40,370,040)**
Income tax benefits	-	-	-	-
Net loss	**$ (18,848,472)**	**$ (11,581,344)**	**$ (63,779,116)**	**$ (40,370,040)**
Net loss per share, basic and diluted	$ (0.65)	$ (0.69)	$ (2.69)	$ (2.64)
Weighted average common shares outstanding, basic and diluted	28,900,075	16,872,018	23,679,472	15,418,543

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 December 31,	
	2023	**2022**	**2023**	**2022**
GAAP net loss	$ (18,848,472)	$ (11,581,344)	$ (63,779,116)	$ (40,370,040)
Adjustments:				
Stock-based compensation				
Research and development [1]	745,629	625,583	2,700,318	2,563,291
General and administrative [2]	496,904	513,838	2,201,116	2,074,914
Non-cash interest expense [3]	528,637	254,884	2,052,336	850,831
Non-cash interest income [4]	(554,126)	(142,928)	(993,457)	(142,928)
Non-GAAP adjusted net loss	**$ (17,631,428)**	**$ (10,329,967)**	**$ (57,818,803)**	**$ (35,023,932)**
GAAP net loss per share - basic and diluted	$ (0.65)	$ (0.69)	$ (2.69)	$ (2.64)
Adjustment to net loss (as detailed above)	0.04	0.08	0.25	0.35

Warrant modification adjustment [5]	-	-	-	0.02
Non-GAAP adjusted net loss per share	**$ (0.61)**	**$ (0.61)**	**$ (2.44)**	**$ (2.27)**
Weighted average common shares outstanding, basic and diluted	28,900,075	16,872,018	23,679,472	15,418,543

(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.
(5) To reflect an adjustment to basic and diluted net loss per share related to a warrant modification.

celcuity
EXPANDING TREATMENT OPTIONS

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