



Celcuity Inc. Reports Third Quarter 2023 Financial Results and Provides Corporate Updates

November 13, 2023

- Received FDA clearance of IND to evaluate gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer (mCRPC)
- Entered into a clinical trial collaboration and supply agreement with Bayer AG to provide Nubeqa[®] (darolutamide) for planned Phase 1b/2 clinical trial
- Raised \$50 million in private placement sale of equity
- Management to host webcast and conference call today, November 13, 2023, at 8:00 a.m. ET

MINNEAPOLIS, Nov. 13, 2023 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today reported financial results for the third quarter ended September 30, 2023 and provided other recent corporate updates.

"Despite the important role the PI3K/mTOR pathway plays in tumor types such as breast and prostate cancer, the available therapies that target this pathway have only reported limited improvements in outcomes for patients. Development of an optimized PI3K/mTOR inhibitor, like gedatolisib, thus represents, we believe, one of the most important opportunities to improve the standard of care in these cancers. With our Phase 3 program in HR+/HER2- advanced breast cancer, and our newly initiated Phase 1b/2 program in metastatic castration resistance prostate cancer, we are hoping to eventually impact over 200,000 patients globally," said Brian Sullivan, CEO and Co-Founder of Celcuity. "The equity financing we recently closed further supports these programs and extends our cash runway into mid-2026."

Third Quarter 2023 Business Highlights and Other Recent Developments

- The VIKTORIA-1 Phase 3 trial remains on track to provide initial data and analysis of the PIK3CA wild type patient sub-group in the second half of 2024 and data for the PIK3CA mutated patient sub-group in the first half of 2025.
 - The Phase 3 VIKTORIA-1 clinical trial is now recruiting patients at nearly 220 sites in 23 countries in North and South America, Europe, and Asia.
 - VIKTORIA-1 is evaluating gedatolisib in combination with fulvestrant, an endocrine therapy, with and without palbociclib, a CDK4/6 inhibitor, in adults with HR+, HER2- advanced breast cancer.
- The CELC-G-201 Phase 1b/2 clinical trial evaluating gedatolisib in combination with Nubeqa[®] (darolutamide) for the treatment of metastatic castration resistant prostate cancer (mCRPC) is on track to activate trial sites in the first quarter of 2024 and to report initial data in the first half of 2025.
 - The U.S. Food and Drug Administration (FDA) cleared an Investigational New Drug (IND) submission that enables Celcuity to proceed with a trial to evaluate gedatolisib in combination with darolutamide in August 2023.
 - We entered into a clinical trial collaboration and supply agreement with Bayer AG in August 2023 to provide Nubeqa[®] (darolutamide) at no cost.
 - The Phase 1b/2 trial will enroll up to 54 patients with mCRPC whose disease progressed after treatment with an androgen receptor inhibitor.
- Celcuity closed a private placement of equity that resulted in net proceeds of approximately \$50 million in October 2023.

Third Quarter 2023 Financial Results

Unless otherwise stated, all comparisons are for the third quarter ended September 30, 2023, compared to the third quarter ended September 30, 2022.

Total operating expenses were \$18.9 million for the third quarter of 2023, compared to \$10.6 million for the third quarter of 2022. Research and development (R&D) expenses were \$17.5 million for the third quarter of 2023, compared to \$9.6 million for the third quarter of 2022. Of the approximately \$7.9 million increase in R&D expenses, \$7.5 million was due to an increase in expenses related to the VIKTORIA-1 Phase 3 clinical trial, and \$0.4 million was related to increased employee-related expenses.

General and administrative expenses were \$1.4 million for the third quarter of 2023, compared to \$1.0 million for the third quarter of 2022. Employee-related expenses accounted for \$0.3 million of the increase. The remaining \$0.1 million increase resulted from professional fees and other expenses associated with being a public company.

Net loss for the third quarter of 2023 was \$18.4 million, or \$0.83 loss per share, compared to a net loss of \$10.9 million, or \$0.75

loss per share, for the third quarter of 2022. Non-GAAP adjusted net loss for the third quarter of 2023 was \$17.3 million, or \$0.78 loss per share, compared to non-GAAP adjusted net loss for the third quarter of 2022 of \$9.5 million, or \$0.63 loss per share. 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 2023 was \$12.7 million, compared to \$9.3 million for the third quarter of 2022. At September 30, 2023, Celcuity reported cash, cash equivalents and short-term investments of \$133.9 million.

Webcast and Conference Call Information

The Celcuity management team will host a webcast/conference call at 8:00 a.m. ET today to discuss the third quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-877-407-0784 or 1-201-689-8560. A live webcast presentation can also be accessed using this weblink: https://viaavid.webcasts.com/starthere.jsp?ei=1639042&tp_key=7d2827005c. 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 expected to be initiated in the first quarter of 2024. 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 [Celcuity.com](https://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 adequacy of Celcuity's cash on hand to fund research and development expenses and other general corporate expenses, the timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 clinical trial and Phase 1b/2 CELC-G-201 clinical trial, the costs and expected results from any ongoing or planned clinical trials, the impact on gedatolisib and Celcuity of preliminary clinical trial results, any potential benefits resulting from Breakthrough Therapy designation for gedatolisib, and other expectations with respect to Celcuity's lead product candidate, gedatolisib and its CELsignia platform. 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, those risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 23, 2023, as may be updated by our quarterly reports on Form 10-Q. 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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	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	\$ 25,759,887	\$ 24,571,557
Investments	108,180,417	144,015,954
Other current assets	7,771,131	6,603,026
Total current assets	141,711,435	175,190,537
Property and equipment, net	223,378	260,294
Operating lease right-of-use assets	449,368	246,266
Total Assets	\$ 142,384,181	\$ 175,697,097
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 5,634,806	\$ 2,627,076
Finance lease liabilities	-	2,449
Operating lease liabilities	188,100	191,749
Accrued expenses	6,887,136	4,060,280
Total current liabilities	12,710,042	6,881,554
Operating lease liabilities	270,925	61,002
Note payable, non-current	36,506,774	34,983,074
Total Liabilities	49,487,741	41,925,630
Total Stockholders' Equity	92,896,440	133,771,467
Total Liabilities and Stockholders' Equity	\$ 142,384,181	\$ 175,697,097

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 17,488,236	\$ 9,621,505	\$ 42,512,811	\$ 24,685,505
General and administrative	1,409,801	1,022,050	3,988,248	3,066,382
Total operating expenses	18,898,037	10,643,555	46,501,059	27,751,887
Loss from operations	(18,898,037)	(10,643,555)	(46,501,059)	(27,751,887)
Other income (expense)				
Interest expense	(1,372,132)	(537,661)	(3,929,140)	(1,428,108)
Interest income	1,865,629	287,495	5,499,555	391,301
Other income (expense), net	493,497	(250,166)	1,570,415	(1,036,807)
Net loss before income taxes	(18,404,540)	(10,893,721)	(44,930,644)	(28,788,694)
Income tax benefits	-	-	-	-
Net loss	\$ (18,404,540)	\$ (10,893,721)	\$ (44,930,644)	\$ (28,788,694)
Net loss per share, basic and diluted	\$ (0.83)	\$ (0.75)	\$ (2.05)	\$ (1.95)
Weighted average common shares outstanding, basic and diluted	22,117,626	14,938,224	21,920,147	14,928,727

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 and non-cash interest 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 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss	\$ (18,404,540)	\$ (10,893,721)	\$ (44,930,644)	\$ (28,788,694)
Adjustments:				
Stock-based compensation				
Research and development ⁽¹⁾	660,706	676,524	1,954,689	1,937,707
General and administrative ⁽²⁾	447,931	546,530	1,704,213	1,561,077
Non-cash interest expense ⁽³⁾	520,794	210,409	1,523,699	595,947
Non-cash interest income ⁽⁴⁾	(480,520)	-	(439,331)	-
Non-GAAP adjusted net loss	\$ (17,255,629)	\$ (9,460,258)	\$ (40,187,374)	\$ (24,693,964)
GAAP net loss per share - basic and diluted	\$ (0.83)	\$ (0.75)	\$ (2.05)	\$ (1.95)
Adjustment to net loss (as detailed above)	0.05	0.10	0.22	0.27
Warrant modification adjustment ⁽⁵⁾	-	0.02	-	0.02
Non-GAAP adjusted net loss per share	\$ (0.78)	\$ (0.63)	\$ (1.83)	\$ (1.66)
Weighted average common shares outstanding, basic and diluted	22,117,626	14,938,224	21,920,147	14,928,727

(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.

