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

August 10, 2023

- *Phase 3 VIKTORIA-1 clinical trial is now recruiting patients at nearly 200 sites in 20 countries*
- *Presented updated results from Phase 1b study of gedatolisib in treatment-naïve advanced breast cancer at the ESMO Breast Cancer Annual Congress*
- *Median progression free survival (PFS) was 48.6 months in treatment-naïve patients with HR+/HER2- advanced breast cancer who were treated with gedatolisib in combination with palbociclib and letrozole*
- *Management to host webcast and conference call today, August 10, 2023, at 4:30 p.m. ET*

MINNEAPOLIS, Aug. 10, 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 second quarter ended June 30, 2023 and provided other recent corporate updates.

“Patient enrollment in the Phase 3 VIKTORIA-1 trial is progressing in-line with our planned timeline. Nearly 200 sites are now recruiting patients in 20 countries,” said Brian Sullivan, CEO and Co-Founder of Celcuity. “We are also very encouraged by the updated median PFS and DOR data we reported for gedatolisib in combination with letrozole and palbociclib in the first-line setting. These results continue to drive our confidence that gedatolisib can play an important role in improving outcomes for women with HR+/HER2- advanced breast cancer, regardless of PIK3CA-status.”

Second 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 200 sites in 20 countries.
  - 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.
- In May 2023, updated results from a Phase 1b trial evaluating gedatolisib, in combination with palbociclib and the aromatase inhibitor, letrozole, were presented at the 2023 European Society for Medical Oncology (ESMO) Breast Cancer Annual Congress, with data updated as of March 16, 2023.
  - For treatment-naïve patients from Escalation Arm A and Expansion Arm A (n=41), mPFS was 48.6 months, mDOR was 46.9 months, and ORR was 79%.
  - This data compares favorably to published data for current first-line standard-of-care treatments for patients with HR+/HER2- advanced breast cancer.
- In April 2023, Celcuity presented a poster at the American Association for Cancer Research (AACR) Annual Meeting demonstrating gedatolisib’s superior therapeutic activity relative to the various PI3K, AKT, and mTOR inhibitors, regardless of the cell lines’ PTEN, PI3K, or AKT mutational status in endometrial, ovarian and cervical cancer cell lines.
- Enrollment is ongoing in the FACT-1 and FACT-2 trials for CELsignia selected patients who have early-stage HR+/HER2- breast cancer with interim results expected in the first half of 2024.

Second Quarter 2023 Financial Results

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

Total operating expenses were $15.1 million for the second quarter of 2023, compared to $9.6 million for the second quarter of 2022. Net cash used in operating activities for the second quarter of 2023 was $9.7 million, compared to $11.3 million for the second quarter of 2022.

Research and development (R&D) expenses were $13.7 million for the second quarter of 2023, compared to $8.4 million for the second quarter of 2022. Of the approximately $5.4 million increase in research and development expenses, $0.5 million was related to increased employee and consulting expenses. The remaining $4.9 million increase in research and development expenses was primarily the result of activities supporting the VIKTORIA-1 pivotal trial.

General and administrative (G&A) expenses were $1.3 million for the second quarter of 2023, compared to $1.2 million for the second quarter of 2022.

Net loss for the second quarter of 2023 was $14.6 million, or $0.66 loss per share, compared to a net loss of $10.0 million, or $0.67 loss per share, for the second quarter of 2022. Non-GAAP adjusted net loss for the second quarter of 2023 was $12.8 million, or $0.58 loss per share, compared to non-GAAP adjusted net loss for the second quarter of 2022 of $8.3 million, or $0.55 per share. Non-GAAP adjusted net loss excludes stock-based compensation expense and non-cash interest expense. 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.

At June 30, 2023, Celcuity reported cash, cash equivalents and short-term investments of $146.2 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 second quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-888-886-7786 and international callers should dial 1-416-764-8658. A live webcast presentation can also be accessed using this weblink: https://viavid.webcasts.com/starthere.jsp?ei=1625068&tp_key=c09a941d3d . 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 . 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. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at 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 timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 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.

Contacts:

Celcuity Inc.
Brian Sullivan, bsullivan@celcuity.com
Vicky Hahne, vhahne@celcuity.com
763-392-0123

ICR Westwicke
Robert Uhl, robert.uhl@westwicke.com
(619) 228-5886

Celcuity Inc.
Condensed Balance Sheets

	June 30, 2023	December 31, 2022
	(unaudited)	

Assets		
Current Assets:		
Cash and cash equivalents	$ 32,238,702	$ 24,571,557
Investments	114,005,385	144,015,954
Deposits	22,009	22,009
Deferred transaction costs	79,088	33,195
Payroll tax receivable	-	203,665
Prepaid assets	6,461,156	6,344,157
Total current assets	152,806,340	175,190,537
Property and equipment, net	210,858	260,294
Operating lease right-of-use assets	499,993	246,266
Total Assets	**$ 153,517,191**	**$ 175,697,097**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 3,019,282	$ 2,627,076
Finance lease liabilities	-	2,449
Operating lease liabilities	191,333	191,749
Accrued expenses	3,871,135	4,060,280
Total current liabilities	7,081,750	6,881,554
Operating lease liabilities	317,120	61,002
Note payable, non-current	35,985,980	34,983,074
Total Liabilities	43,384,850	41,925,630
Total Stockholders' Equity	110,132,341	133,771,467
Total Liabilities and Stockholders' Equity	**$ 153,517,191**	**$ 175,697,097**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 13,746,082	$ 8,367,687	$ 25,024,575	$ 15,064,000
General and administrative	1,309,403	1,233,040	2,578,447	2,044,332
Total operating expenses	15,055,485	9,600,727	27,603,022	17,108,332
Loss from operations	(15,055,485)	(9,600,727)	(27,603,022)	(17,108,332)
Other income (expense)				
Interest expense	(1,314,996)	(455,445)	(2,557,008)	(890,446)
Interest income	1,782,794	95,646	3,633,926	103,805
Other income (expense), net	467,798	(359,799)	1,076,918	(786,641)
Net loss before income taxes	**(14,587,687)**	**(9,960,526)**	**(26,526,104)**	**(17,894,973)**
Income tax benefits	-	-	-	-
Net loss	**$ (14,587,687)**	**$ (9,960,526)**	**$ (26,526,104)**	**$ (17,894,973)**
Net loss per share, basic and diluted	$ (0.66)	$ (0.67)	$ (1.22)	$ (1.20)
Weighted average common shares outstanding, basic and diluted	21,957,140	14,930,538	21,819,772	14,923,900

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
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
GAAP net loss	$ (14,587,687)	$ (9,960,526)	$ (26,526,104)	$ (17,894,973)
Adjustments:				
Stock-based compensation				
Research and development [1]	639,511	810,664	1,293,982	1,261,183
General and administrative [2]	637,471	708,795	1,256,282	1,014,547
Non-cash interest expense [3]	507,717	188,439	1,002,906	385,537
Non-GAAP adjusted net loss	**$ (12,802,988)**	**$ (8,252,627)**	**$ (22,972,934)**	**$ (15,233,706)**
GAAP net loss per share - basic and diluted	$ (0.66)	$ (0.67)	$ (1.22)	$ (1.20)
Adjustment to net loss (as detailed above)	0.08	0.12	0.17	0.18
Non-GAAP adjusted net loss per share	**$ (0.58)**	**$ (0.55)**	**$ (1.05)**	**$ (1.02)**
Weighted average common shares outstanding, basic and diluted	21,957,140	14,930,538	21,819,772	14,923,900

(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.

celcuity
EXPANDING TREATMENT OPTIONS