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

August 14, 2024

- *Announced plan to initiate Phase 3 VIKTORIA-2 trial evaluating gedatolisib combined with fulvestrant plus a CDK4/6 inhibitor as first-line treatment for patients with HR+, HER2- advanced breast cancer; expect to enroll first patient in Q2 2025*
- *Expect to reach enrollment target for VIKTORIA-1 PIK3CA WT cohort in Q4 2024 and report topline data for this cohort in late Q4 2024 or Q1 2025*
- *Raised $129 million in gross proceeds from equity and debt financings; extending runway of current operational activities through 2026*
- *Management to host webcast and conference call today, August 14, 2024, at 4:30 p.m. ET*

MINNEAPOLIS, Aug. 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 second quarter ended June 30, 2024 and other recent business developments.

“We made significant strides advancing the clinical development of gedatolisib this quarter. Overall enrollment in VIKTORIA-1 remains robust and on-track relative to our previous projections,” said Brian Sullivan, CEO and co-founder of Celcuity. “We also initiated efforts to launch VIKTORIA-2, a Phase 3 study to evaluate gedatolisib as a first-line treatment option for patients with HR+, HER2- advanced breast cancer.”

“In our VIKTORIA-1 study, while overall enrollment is on track, the proportion of patients who have PIK3CA wild-type tumors, versus those with PIK3CA mutations, has recently shifted lower than our original estimates. As a result, we expect to reach the enrollment target for the PIK3CA wild-type cohort in the fourth quarter, rather than the third quarter, as we originally forecasted. In light of this, we expect topline data for the PIK3CA WT cohort to shift to sometime between late Q4 2024 and Q1 2025.”

Second Quarter 2024 Business Highlights and Other Recent Developments

- The VIKTORIA-1 Phase 3 trial expects to provide topline data for the *PIK3CA* wild-type cohort in late Q4 2024 or Q1 2025 and for the *PIK3CA* mutant cohort 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.
  - Enrollment of the PIK3CA wild-type cohort is more than 80% complete and expected to reach the enrollment target during Q4 2024. The PIK3CA wild-type cohort represents approximately 60% of the total patients enrolled to date in VIKTORIA-1.
- In May, the Company announced its plan to initiate VIKTORIA-2, a Phase 3 study to evaluate 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.
  - A safety run-in study to evaluate the safety of gedatolisib combined with ribociclib and fulvestrant will precede initiation of the Phase 3 portion of the study.
  - The Phase 3 portion of the study is expected to enroll approximately 638 patients at up to 200 sites across North America, Europe, Latin America, and Asia.
  - First patient enrollment is expected in the second quarter of 2025.
- During the quarter, the Company secured a combined total of $129 million in gross proceeds from equity and debt financings, which extended the cash runway for current clinical development program activities through 2026.
- The Phase 1b/2 trial, evaluating gedatolisib in combination with darolutamide for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC), remains on track to report preliminary data in the first half of 2025.
  - 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.
- Three manuscripts reporting clinical and nonclinical results for gedatolisib were published recently.
  - In April, *The Lancet Oncology* published results from the dose expansion groups of its Phase 1b study evaluating gedatolisib in combination with palbociclib and endocrine therapy in HR+/HER2- advanced breast cancer. The

published manuscript is available online and on the publications section of Celcuity's website.
- In June, *npj Breast Cancer* published results of nonclinical studies showing gedatolisib's superior potency and efficacy versus single-node PI3K/AKT/mTOR inhibitors in breast cancer models. The article is available online and on the publications section of Celcuity's website.
- In August, *Molecular Oncology* published results of nonclinical studies in prostate cancer models showing gedatolisib's superior potency and efficacy versus single-node PI3K/AKT/mTOR inhibitors. The article is available online and will soon be available on the publications section of Celcuity's website.

Second Quarter 2024 Financial Results

Unless otherwise stated, all comparisons are for the second quarter ended June 30, 2024, compared to the second quarter ended June 30, 2023.

Total operating expenses were $24.3 million for the second quarter of 2024, compared to $15.1 million for the second quarter of 2023.

Research and development (R&D) expenses were $22.5 million for the second quarter of 2024, compared to $13.8 million for the prior-year period. Of the approximately $8.7 million increase in R&D expenses, $6.6 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 $2.1 million was related to increased employee and consulting expenses.

General and administrative (G&A) expenses were $1.8 million for the second quarter of 2024, compared to $1.3 million for the prior-year period. Employee and consulting 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 second quarter of 2024 was $23.7 million, or $0.62 loss per share, compared to a net loss of $14.6 million, or $0.66 loss per share, for the second quarter of 2023. Non-GAAP adjusted net loss for the second quarter of 2024 was $22.2 million, or $0.58 loss per share, compared to non-GAAP adjusted net loss of $11.1 million, or $0.51 loss per share, for the second 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 second quarter of 2024 was $18.1 million, compared to $9.7 million for the second quarter of 2023.

At June 30, 2024, Celcuity reported cash, cash equivalents and short-term investments of $283.1 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 second 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://viavid.webcasts.com/starthere.jsp?ei=1678191&tp_key=c55c86e8c3. 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. 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 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.
Condensed Balance Sheets

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 30,458,800	$ 30,662,774
Investments	252,609,622	149,919,974
Other current assets	8,862,940	10,007,849
Total current assets	291,931,362	190,590,597
Property and equipment, net	308,444	228,782
Operating lease right-of-use assets	305,179	400,019
Total Assets	**$ 292,544,985**	**$ 191,219,398**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 6,203,132	$ 5,076,699
Operating lease liabilities	178,587	184,950
Accrued expenses	13,146,769	8,927,094
Total current liabilities	19,528,488	14,188,743
Operating lease liabilities	138,533	225,922
Note payable, non-current	96,193,172	37,035,411
Total Liabilities	115,860,193	51,450,076
Total Stockholders' Equity	176,684,792	139,769,322
Total Liabilities and Stockholders' Equity	**$ 292,544,985**	**$ 191,219,398**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,	Six Months Ended June 30,

	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 22,496,975	$ 13,746,082	$ 43,144,534	$ 25,024,575
General and administrative	1,786,111	1,309,403	3,632,387	2,578,447
Total operating expenses	24,283,086	15,055,485	46,776,921	27,603,022
Loss from operations	(24,283,086)	(15,055,485)	(46,776,921)	(27,603,022)
Other income (expense)				
Interest expense	(2,260,583)	(1,314,996)	(3,661,295)	(2,557,008)
Interest income	2,821,849	1,782,794	5,103,941	3,633,926
Other income (expense), net	561,266	467,798	1,442,646	1,076,918
Net loss before income taxes	**(23,721,820)**	**(14,587,687)**	**(45,334,275)**	**(26,526,104)**
Income tax benefits	-	-	-	-
Net loss	**$ (23,721,820)**	**$ (14,587,687)**	**$ (45,334,275)**	**$ (26,526,104)**
Net loss per share, basic and diluted	$ (0.62)	$ (0.66)	$ (1.26)	$ (1.22)
Weighted average common shares outstanding, basic and diluted	38,444,163	21,957,140	36,028,109	21,819,772

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net loss	$ (23,721,820)	$ (14,587,687)	$ (45,334,275)	$ (26,526,104)
Adjustments:				
Stock-based compensation				
Research and development [1]	978,037	639,511	1,810,216	1,293,982
General and administrative [2]	432,475	637,471	931,642	1,256,282
Non-cash interest expense [3]	629,579	507,717	1,160,398	1,002,905
Non-cash interest income [4]	(484,991)	1,656,623	(638,836)	(41,188)
Non-GAAP adjusted net loss	**$ (22,166,720)**	**$ (11,146,365)**	**$ (42,070,855)**	**$ (23,014,123)**
GAAP net loss per share - basic and diluted	$ (0.62)	$ (0.66)	$ (1.26)	$ (1.22)
Adjustment to net loss (as detailed above)	0.04	0.15	0.09	0.17

Non-GAAP adjusted net loss per share	**$ (0.58)**	**$ (0.51)**	**$ (1.17)**	**$ (1.05)**
Weighted average common shares outstanding, basic and diluted	38,444,163	21,957,140	36,028,109	21,819,772

(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 and interest receivable on investments.