



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

May 15, 2023

- **Presented updated results for treatment-naïve patients from Phase 1b study of gedatolisib at the ESMO Breast Cancer Annual Congress - median progression free survival (PFS) was 48.6 months**
- **Presented nonclinical prostate cancer data at ASCO GU Cancers Symposium demonstrating the superior therapeutic effect of gedatolisib compared to other PI3K, AKT, and mTOR inhibitors regardless of PTEN or P13K mutational status**
- **Presented nonclinical gynecological cancer data at AACR demonstrating the superior therapeutic effect of gedatolisib compared to other PI3K, AKT, and mTOR inhibitors regardless of PTEN, P13K, or AKT mutational status**
- **Management to host webcast and conference call today, May 15, 2023, at 4:30 p.m. ET**

MINNEAPOLIS, MN / ACCESSWIRE / May 15, 2023 / Celcuity Inc. (Nasdaq:CELG), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today reported financial results for the first quarter ended March 31, 2023 and provided other recent corporate updates.

"I am very pleased with the execution to date of our VIKTORIA-1 Phase 3 clinical trial enrollment activities at our trial sites. Our team is relentlessly focused and keeping us on track to deliver initial data in the second half of 2024," said Brian Sullivan, CEO and Co-Founder of Celcuity.

"The updated median progression free survival (mPFS) data for treatment-naïve HR+/HER2- advanced breast cancer patients we presented last week at the ESMO Breast Cancer Congress is very encouraging. The reported mPFS of 48.6 months compares very favorably to published data for available standards of care in this setting. In addition, the findings from the various nonclinical studies we presented at ASCO-GU and AACR further highlight the benefit of inhibiting all Class I PI3K isoforms and MTOR1/MTORC2 and provide important input as we prioritize our clinical development plans."

First Quarter 2023 Business Highlights and Other Recent Developments

- Site activation and patient enrollment activities for the VIKTORIA-1 Phase 3 clinical trial remained on track to enable primary analysis of the PIK3CA WT sub-group in the second half of 2024. 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 February 2023, the Company presented data from nonclinical studies evaluating gedatolisib and various PI3K, AKT, and mTOR inhibitors in prostate cancer cell lines at the American Society of Clinical Oncology Genitourinary Cancers Symposium. The studies demonstrated gedatolisib's superior potency and efficacy relative to the various PI3K, AKT, and mTOR inhibitors, regardless of the cell lines' PTEN or PI3K status.
- In April 2023, Celcuity presented a poster at the American Association for Cancer Research (AACR) Annual Meeting reporting results from nonclinical studies evaluating gedatolisib and various PI3K, AKT, mTOR inhibitors in endometrial, ovarian and cervical cancer cell lines. The studies demonstrated 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 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. The presentation reported efficacy and safety data in treatment-naïve patients with HR+/HER2- advanced breast cancer enrolled in Escalation Arm A and Expansion Arm A. Median progression-free survival (mPFS) and median duration of response (mDOR) data was updated as of March 16, 2023. For treatment-naïve patients in Escalation Arm A (n=11) and Expansion Arm A (n=30), median PFS was 45.8 months and 48.6 months, respectively. When treatment-naïve patients from both arms were combined (n=41), mPFS was 48.6 months and mDOR was 46.9 months. Median PFS in Expansion Arm A had not yet been reached when this data was reported at the San Antonio Breast Cancer Symposium last December.
- 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.

First Quarter 2023 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2023, compared to the first quarter ended March 31, 2022.

Total operating expenses were \$12.5 million for the first quarter of 2023, compared to \$7.5 million for the first quarter of 2022. Net cash used in operating activities for the first quarter of 2023 was \$12.9 million, compared to \$5.9 million for the first quarter of

2022.

Research and development (R&D) expenses were \$11.3 million for the first quarter of 2023, compared to \$6.7 million for the first quarter of 2022. The approximately \$4.6 million increase was primarily the result of activities supporting the VIKTORIA-1 pivotal trial.

General and administrative (G&A) expenses were \$1.3 million for the first quarter of 2023, compared to \$0.8 million for the first quarter of 2022. The approximately \$0.5 million increase was the result of non-cash based compensation and fees associated with being a public company.

Net loss for the first quarter of 2023 was \$11.9 million, or \$0.55 loss per share, compared to a net loss of \$7.9 million, or \$0.53 loss per share, for the first quarter of 2022. Non-GAAP adjusted net loss for the first quarter of 2023 was \$10.2 million, or \$0.47 loss per share, compared to non-GAAP adjusted net loss for the first quarter of 2022 of \$7.0 million, or \$0.47 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 March 31, 2023, Celcuity had cash, cash equivalents and short-term investments of \$157.5 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 first quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-877-407-0784 and international callers should dial 1-201-689-8560. A live webcast presentation can also be accessed using this weblink: https://viaavid.webcasts.com/starthere.jsp?ei=1608732&tp_key=14b504baff. 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). 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](https://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. 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, 2023 | December 31, 2022 |
|---|------------------------------|------------------------------|
| | (unaudited) | |
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 33,639,218 | \$ 24,571,557 |
| Investments | 123,839,227 | 144,015,954 |
| Deposits | 22,009 | 22,009 |
| Deferred transaction costs | 35,597 | 33,195 |
| Payroll tax receivable | 38,263 | 203,665 |
| Prepaid assets | <u>6,525,368</u> | <u>6,344,157</u> |
| Total current assets | 164,099,682 | 175,190,537 |
| Property and equipment, net | 223,343 | 260,294 |
| Operating lease right-of-use assets | <u>551,933</u> | <u>246,266</u> |
| Total Assets | <u>\$ 164,874,958</u> | <u>\$ 175,697,097</u> |
| Liabilities and Stockholders' Equity: | | |
| Current Liabilities: | | |
| Accounts payable | \$ 2,569,913 | \$ 2,627,076 |
| Finance lease liabilities | 981 | 2,449 |
| Operating lease liabilities | 194,895 | 191,749 |
| Accrued expenses | <u>3,040,178</u> | <u>4,060,280</u> |
| Total current liabilities | 5,805,967 | 6,881,554 |
| Operating lease liabilities | 363,961 | 61,002 |
| Note payable, non-current | <u>35,478,262</u> | <u>34,983,074</u> |
| Total Liabilities | <u>41,648,190</u> | <u>41,925,630</u> |
| Total Stockholders' Equity | <u>123,226,768</u> | <u>133,771,467</u> |
| Total Liabilities and Stockholders' Equity | <u>\$ 164,874,958</u> | <u>\$ 175,697,097</u> |

Celcuity Inc. Condensed Statements of Operations (unaudited)

| | Three Months Ended March 31, | |
|-----------------------------|---------------------------------|---------------------|
| | <u>2023</u> | <u>2022</u> |
| Operating expenses: | | |
| Research and development | \$ 11,278,493 | \$ 6,696,313 |
| General and administrative | <u>1,269,044</u> | <u>811,292</u> |
| Total operating expenses | <u>12,547,537</u> | <u>7,507,605</u> |
| Loss from operations | <u>(12,547,537)</u> | <u>(7,507,605)</u> |
| Other income (expense) | | |
| Interest expense | (1,242,012) | (435,001) |
| Interest income | <u>1,851,132</u> | <u>8,159</u> |
| Other income (expense), net | <u>609,120</u> | <u>(426,842)</u> |

| | | |
|---|-------------------------|------------------------|
| Net loss before income taxes | <u>(11,938,417)</u> | <u>(7,934,447)</u> |
| Income tax benefits | - | - |
| Net loss | <u>\$ (11,938,417)</u> | <u>\$ (7,934,447)</u> |
| Net loss per share, basic and diluted | \$ (0.55) | \$ (0.53) |
| Weighted average common shares outstanding, basic and diluted | 21,680,877 | 14,917,187 |

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 March 31, | |
|---|---------------------------------|-------------------------------|
| | <u>2023</u> | <u>2022</u> |
| GAAP net loss | <u>\$ (11,938,417)</u> | <u>\$ (7,934,447)</u> |
| Adjustments: | | |
| Stock-based compensation | | |
| Research and development ⁽¹⁾ | 654,471 | 450,520 |
| General and administrative ⁽²⁾ | 618,811 | 305,751 |
| Non-cash interest expense ⁽³⁾ | <u>495,188</u> | <u>197,098</u> |
| Non-GAAP adjusted net loss | <u>\$ (10,169,947)</u> | <u>\$ (6,981,078)</u> |
| GAAP net loss per share - basic and diluted | \$ (0.55) | \$ (0.53) |
| Adjustment to net loss (as detailed above) | <u>0.08</u> | <u>0.06</u> |
| Non-GAAP adjusted net loss per share | <u>\$ (0.47)</u> | <u>\$ (0.47)</u> |
| Weighted average common shares outstanding, basic and diluted | 21,680,877 | 14,917,187 |

(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.

SOURCE: Celcuity Inc.

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