Celcuity Inc. Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 23, 2023

- ***Dosing of first patient in VIKTORIA-1 in the fourth quarter triggered closing of $100 million PIPE financing and drawdown of $20 million term loan tranche, which extends cash runway through 2025***
- ***Updated clinical data from the Phase 1b advanced breast cancer trial with gedatolisib was presented at SABCS in December - median PFS was 42.3 months in treatment naïve advanced breast cancer patients***
- ***Preclinical data reporting therapeutic effects of gedatolisib and other PI3K/AKT/mTOR inhibitors in prostate cancer cell lines was presented at ASCO-GU in February***
- ***An abstract was published in advance of the AACR Annual Meeting 2023 reporting therapeutic effects of gedatolisib and other PI3K/AKT/mTOR inhibitors in gynecological cell lines***
- ***Management to host webcast and conference call today, March 23, 2023, at 4:30 p.m. ET***

MINNEAPOLIS, MN / ACCESSWIRE / March 23, 2023 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today announced financial results for the fourth quarter and full year ended December 31, 2022 and other recent business developments.

"We achieved a number of critical milestones in the fourth quarter. Most importantly, we dosed the first patient in our Phase 3 VIKTORIA-1 trial of gedatolisib in advanced breast cancer. This milestone, in turn, triggered the closing of our $100 million PIPE financing and a $20 million drawdown on our term loan," said Brian Sullivan, CEO and Co-Founder of Celcuity. "These financings significantly strengthen our balance sheet and are expected to provide the capital we need to fund operations through 2025."

Fourth Quarter 2022 Business Highlights and Other Recent Developments

- In December, the first patient was dosed in the Phase 3 VIKTORIA-1 clinical trial. VIKTORIA-1 is evaluating the safety and efficacy of Celcuity's lead drug product candidate, gedatolisib, an investigational pan-PI3K/mTOR inhibitor, in combination with fulvestrant with or without palbociclib in adults with HR+/HER2- advanced breast cancer whose disease progressed while receiving prior CDK4/6 therapy. Patient enrollment is currently in progress. Gedatolisib was previously granted Breakthrough Therapy designation in July 2022 from the U.S. Food and Drug Administration for the treatment of patients with HR+/HER2- advanced breast cancer whose disease progressed during treatment with a CDK4/6 therapy and a non-steroidal aromatase inhibitor.
- The dosing of the first patient in the VIKTORIA-1 clinical trial triggered the closing of a $100 million private placement and drawdown of a $20 million term loan tranche in December. Proceeds from the private placement, combined with the debt facility and the company's current cash, cash equivalents and marketable securities, are expected to be sufficient to fund Celcuity's current operating plan through 2025.
- In December 2022, Celcuity presented updated efficacy and safety results from a Phase 1b trial evaluating gedatolisib during a Spotlight Poster Discussion at the 2022 San Antonio Breast Cancer Symposium (SABCS). The presentation reported that patient sub-groups with and without PIK3CA mutations achieved comparable efficacy in the four expansion arms of the Phase 1b study. Additionally, median progression free survival of 42.3 months was reported for patients who were treatment naïve in the advanced setting, which compares favorably to published data for current standard-of-care regimens for this patient population.
- In February 2023, the company presented data from preclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR inhibitors in prostate cancer cell lines at the American Society of Clinical Oncology Genitourinary Cancers Symposium. The presentation demonstrated gedatolisib's superior potency and efficacy across different prostate cancer cell lines relative to other PI3K/AKT/mTOR inhibitors regardless of PTEN or PI3K status.
- In March 2023, an abstract reporting data from preclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR inhibitors in gynecological cancer lines was published in advance of the American Association for Cancer Research (AACR) Annual Meeting 2023 to be held April 14-19, 2023. A poster will be presented at the meeting on April 18, 2023 in Orlando, Florida.
- 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 second half of 2023.

Fourth Quarter and Full Year 2022 Financial Results

Unless otherwise stated, all comparisons are for the fourth quarter and full year ended December 31, 2022, compared to the fourth quarter and full year ended December 31, 2021.

Total operating expenses were $11.6 million for the fourth quarter of 2022, compared to $6.3 million for the fourth quarter of 2021. Operating expenses for the full year 2022 were $39.4 million, compared to $28.4 million for the full year 2021.

Research and development (R&D) expenses were $10.6 million for the fourth quarter of 2022, compared to $5.5 million for the prior-year period. The increase was primarily the result of activities supporting the initiation of the VIKTORIA-1 pivotal trial.

R&D expenses for the full year 2022 were $35.3 million, compared to $25.8 million for the prior year. The increase in R&D expenses included a $10.0 million reduction in gedatolisib licensing related expenses. This reduction was offset by increases in other research and development expenses, which included employee and consulting expenses, increased expenses for existing clinical trials and for activities supporting the initiation of the VIKTORIA-1 pivotal trial.

General and administrative (G&A) expenses were $1.0 million for the fourth quarter of 2022, compared to $0.8 million for the prior-year period. The increase in G&A expenses arose primarily from non-cash stock-based compensation.

G&A expenses for the full year 2022 were $4.1 million, compared to $2.6 million for the prior year. The increase arose primarily from non-cash stock-based compensation.

Net loss for the fourth quarter of 2022 was $11.6 million, or $0.69 loss per share, compared to a net loss of $6.8 million, or $0.45 loss per share, for the fourth quarter of 2021. Net loss for the full year 2022 was $40.4 million, or $2.64 loss per share, compared to a net loss of $29.6 million, or $2.21 loss per share, in 2021. Non-GAAP adjusted net loss for the fourth quarter of 2022 was $10.2 million, or $0.60 loss per share, compared to non-GAAP adjusted net loss of $5.6 million, or $0.37 loss per share, for the fourth quarter of 2021. Non-GAAP adjusted net loss for the full year 2022 was $34.9 million, or $2.26 per share, compared to non-GAAP adjusted net loss of $21.4 million, or $1.60 per share, for 2021. Non-GAAP adjusted net loss excludes stock-based compensation expense, issuance of common stock and non-cash interest. 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 2022 was $9.5 million, compared to $6.1 million for the fourth quarter of 2021. Net cash used in operating activities for the full year 2022 was $36.0 million, compared to $20.3 million for the full year 2021.

At December 31, 2022, Celcuity had cash, cash equivalents and short-term investments of $168.6 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 fourth quarter and full year 2022 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://viavid.webcasts.com/starthere.jsp?ei=1601608&tp_key=796153253b. 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, 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 to be 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.
Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 24,571,557	$ 84,286,381
Investments	144,015,954	-
Deposits	22,009	22,009
Deferred transaction costs	33,195	22,144
Payroll tax receivable	203,665	298,764
Prepaid assets	6,344,157	722,677
Total current assets	175,190,537	85,351,975
Property and equipment, net	260,294	312,444
Operating lease right-of-use assets	246,266	241,901
Total Assets	**$ 175,697,097**	**$ 85,906,320**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 2,627,076	$ 1,507,099
Finance lease liabilities	2,449	5,850
Operating lease liabilities	191,749	189,858
Accrued expenses	4,060,280	802,893
Total current liabilities	6,881,554	2,505,700
Finance lease liabilities	-	2,449
Operating lease liabilities	61,002	61,771
Note payable, non-current	34,983,074	14,625,923
Total Liabilities	41,925,630	17,195,843
Total Stockholders' Equity	133,771,467	68,710,477
Total Liabilities and Stockholders' Equity	**$ 175,697,097**	**$ 85,906,320**

Celcuity Inc.
Statements of Operations

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 10,604,043	$ 5,491,041	$ 35,289,548	$ 25,758,006
General and administrative	1,035,161	829,851	4,101,543	2,597,909
Total operating expenses	11,639,204	6,320,892	39,391,091	28,355,915

Loss from operations	(11,639,204)	(6,320,892)	(39,391,091)	(28,355,915)
Other income (expense)				
Interest expense	(678,003)	(438,067)	(2,106,111)	(1,262,350)
Interest income	735,863	5,459	1,127,162	13,262
Loss on sale of fixed assets	-	-	-	(263)
Other income (expense), net	57,860	(432,608)	(978,949)	(1,249,351)
Net loss before income taxes	**(11,581,344)**	**(6,753,500)**	**(40,370,040)**	**(29,605,266)**
Income tax benefits	-	-	-	-
Net loss	**$ (11,581,344)**	**$ (6,753,500)**	**$ (40,370,040)**	**$ (29,605,266)**
Net loss per share, basic and diluted	$ (0.69)	$ (0.45)	$ (2.64)	$ (2.21)
Weighted average common shares outstanding, basic and diluted	16,872,018	14,910,963	15,418,543	13,382,553

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, issuance of common stock 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 December 31,		Years Ended December 31,	
	2022	**2021**	**2022**	**2021**
GAAP net loss	$ (11,581,344)	$ (6,753,500)	$ (40,370,040)	$ (29,605,266)
Adjustments:				
Stock-based compensation				
Research and development [1]	625,583	627,497	2,563,291	1,645,353
General and administrative [2]	513,838	293,106	2,074,914	964,582
Issuance of common stock, licensing agreement [3]	-	-	-	5,000,000
Non-cash interest expense [4]	254,884	198,114	850,831	567,822
Non-GAAP adjusted net loss	**$ (10,187,039)**	**$ (5,634,783)**	**$ (34,881,004)**	**$ (21,427,509)**
GAAP net loss per share - basic and diluted	$ (0.69)	$ (0.45)	$ (2.64)	$ (2.21)
Adjustment to net loss (as detailed above)	0.09	0.08	0.36	0.61

Warrant modification adjustment [5]	-	-	0.02	-
Non-GAAP adjusted net loss per share	**$ (0.60)**	**$ (0.37)**	**$ (2.26)**	**$ (1.60)**
Weighted average common shares outstanding, basic and diluted	16,872,018	14,910,963	15,418,543	13,382,553

(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 operating expense for the issuance of common stock related to a licensing agreement.

(4) 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.

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

SOURCE: Celcuity Inc.

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https://www.accesswire.com/745376/Celcuity-Inc-Reports-Fourth-Quarter-and-Full-Year-2022-Financial-Results-and-Provides-Corporate-Update