celcuity

Celcuity Inc. Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 8, 2021

- ***On track to obtain FDA feedback and initiate a Phase 3 study for gedatolisib during the first half of 2022***
- ***Will present updated Phase 1b data during a Spotlight Poster Discussion Session at the 2021 San Antonio Breast Cancer Symposium in December 2021***
- ***Entered into clinical trial collaboration with University of Rochester Wilmot Cancer Center and Puma Biotechnology to evaluate new therapeutic option for metastatic breast cancer patients with brain metastases***
- ***Management to host webcast and conference call today, November 8, 2021, at 4:30 p.m. ET / 1:30 p.m. PT***

MINNEAPOLIS, MN / ACCESSWIRE / November 8, 2021 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company pursuing an integrated therapeutic and companion diagnostic strategy for treating patients with cancer, today announced financial results for the third quarter ended September 30, 2021 and summarized recent business progress.

"We made great progress advancing our gedatolisib program this past quarter. We initiated preparation for a Phase 3 clinical trial evaluating gedatolisib in combination with Ibrance and Faslodex in patients with ER+/HER2- advanced or metastatic breast cancer that we expect to activate in the first half of 2022," said Brian Sullivan, CEO and co-founder of Celcuity. "Site identification and feasibility activities are underway. We are excited to have the opportunity to present updated results from our Phase 1b clinical trial in patients with ER+/HER2- advanced breast cancer at the San Antonio Breast Cancer Symposium in December. Finally, we are pleased to have entered into another clinical trial collaboration to evaluate CELsignia® selected patients with advanced breast cancer. The collaboration with University of Rochester Wilmot Cancer Center and Puma represents an important opportunity to identify a potential new treatment for patients with breast cancer that has metastasized to the brain."

Third Quarter 2021 Business Highlights and Other Recent Developments

- Completed transfer of regulatory, clinical trial, and safety reporting responsibilities for gedatolisib from Pfizer to Celcuity ahead of schedule.
- Updated data from Celcuity's ongoing Phase 1b clinical trial for patients with ER+/HER2- advanced breast cancer will be presented at the San Antonio Breast Cancer Symposium during a Spotlight Poster Discussion Session on December 10, 2021. Rachel M. Layman, MD, an oncologist at the University of Texas MD Anderson Cancer Center who was a principal investigator for the clinical trial, will be the presenting author.
- Celcuity entered into a clinical trial collaboration agreement with the University of Rochester Wilmot Cancer Center and Puma Biotechnology in October 2021. This single arm Phase 2 trial will evaluate the efficacy and safety of Puma's pan-HER inhibitor, NERLYNX® (neratinib), and capecitabine, a chemotherapy, in patients selected with Celcuity's CELsignia HER2 Activity Test who have metastatic HER2-negative breast cancer that has progressed on prior treatments. Based on estimates of patient enrollment rates, Celcuity expects to obtain interim results 12 to 15 months after initiation of the trial followed by the final results 12 to 15 months later. Enrollment is planned to begin by mid-2022.
- Enrollment in the FACT-1 and FACT-2 trials that are evaluating CELsignia selected patients who have early-stage ER+/HER2- breast cancer was negatively impacted by COVID-19 related delays during the third quarter. Hospitalizations of patients with COVID-19 increased dramatically during this period which led hospitals to reduce clinical trial related activities. Interim results are now expected to be available in the second half of 2022.

Third Quarter 2021 Financial Results

Unless otherwise stated, all comparisons are for the third quarter ended September 30, 2021, compared to the third quarter ended September 30, 2020. The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and related notes on Form 10-Q for the third quarter ended September 30, 2021.

Total operating expenses were $5.6 million for the third quarter of 2021, compared to $2.5 million for the third quarter of 2020.

Research and development (R&D) expenses were $5.0 million for the third quarter of 2021, compared to $2.0 million for the third quarter of 2020. The increase in R&D expenses during the third quarter of 2021 compared to the prior year primarily resulted from costs associated with the development of gedatolisib. Employee related expenses, including consulting fees, accounted for $1.1 million of the increase. The remaining increase of $1.9 million in expenses is related to clinical trials, patent legal fees, and costs associated with the transfer of the gedatolisib-related activities from Pfizer to Celcuity.

General and administrative (G&A) expenses were $0.6 million for the third quarter of 2021, compared to $0.5 million for the third quarter of 2020. The increase in the third quarter of 2021 arose primarily from non-cash stock-based compensation.

Net loss for the third quarter of 2021 was $6.0 million, or $0.41 loss per share, compared to a net loss of $2.5 million for the third

quarter of 2020, or $0.24 loss per share. The Non-GAAP adjusted net loss for the third quarter of 2021 was $5.1 million compared to a non-GAAP adjusted net loss of $2.0 million for the third quarter of 2020. 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 (GAAP) in the United States 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 2021 was $4.0 million, compared to $1.6 million for the third quarter of 2020.

At September 30, 2021, Celcuity had cash and cash equivalents of $90.4 million, compared to cash and cash equivalents of $11.6 million at December 31, 2020.

Anticipated Milestones

Celcuity expects to achieve the following potential milestones over the next twelve months:

- Obtain formal feedback from the FDA on the design of its proposed Phase 3 clinical trial by early 2022.
- Initiate a Phase 3 clinical trial to evaluate gedatolisib in combination with Ibrance and Faslodex in patients with ER+/HER2- advanced breast cancer in the first half of 2022, subject to the FDA feedback.
- Provide an update on lifecycle development priorities for gedatolisib in the first half of 2022.
- Obtain interim results from the FACT-1 and FACT-2 trials in the second half of 2022.

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 third quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial (877) 407-0784 and international callers should dial (201) 689-8560. A live webcast presentation can also be accessed using this weblink: https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/46959/indexl.html. 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 seeking to extend the lives of cancer patients by pursuing an integrated therapeutic and companion diagnostic and strategy. Its 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. Its therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver its companion diagnostics can identify. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com.

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" that involve risks and uncertainties including, but not limited to, expectations with respect to receiving FDA feedback, plans to provide further details about clinical trial design, plans to commence clinical trials, and clinical trial results and any new treatment paradigms that may result therefrom. 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 conditions, many of which are beyond the control of Celcuity, which include, but are not limited to, the unknown impact of the COVID-19 pandemic on Celcuity's business and those other risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on February 16, 2021 and in Exhibit 99.4 to Celcuity's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2021. 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

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 90,366,812	$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	-	-
Payroll tax receivable	356,309	190,000
Prepaid assets	437,351	317,040
Total current assets	91,182,481	12,166,960
Property and equipment, net	365,533	558,876
Operating lease right-of-use assets	289,586	230,911
Total Assets	**$ 91,837,600**	**$ 12,956,747**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 1,746,425	$ 217,377
Finance lease liabilities	5,840	5,810
Operating lease liabilities	190,458	187,518
Accrued expenses	879,851	774,612
Total current liabilities	2,822,574	1,185,317
Finance lease liabilities	3,916	8,299
Operating lease liabilities	108,915	60,861
Note payable, non-current	14,427,809	-
Total Liabilities	17,363,214	1,254,477
Total Stockholders' Equity	74,474,386	11,702,270
Total Liabilities and Stockholders' Equity	**$ 91,837,600**	**$ 12,956,747**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 4,960,515	$ 1,962,610	$ 20,266,965	$ 5,576,250
General and administrative	639,271	517,465	1,768,058	1,428,578
Total operating expenses	5,599,786	2,480,075	22,035,023	7,004,828
Loss from operations	(5,599,786)	(2,480,075)	(22,035,023)	(7,004,828)
Other income (expense)				
Interest expense	(433,072)	(28)	(824,283)	(93)

Interest income	5,612	5,805	7,803	81,639
Loss on sale of fixed assets	-	-	(263)	-
Other income (expense), net	(427,460)	5,777	(816,743)	81,546
Net loss before income taxes	**(6,027,246)**	**(2,474,298)**	**(22,851,766)**	**(6,923,282)**
Income tax benefits	-	-	-	-
Net loss	**$ (6,027,246)**	**$ (2,474,298)**	**$ (22,851,766)**	**$ (6,923,282)**
Net loss per share, basic and diluted	$ (0.41)	$ (0.24)	$ (1.78)	$ (0.67)
Weighted average common shares outstanding, basic and diluted	14,877,619	10,273,567	12,867,484	10,262,636

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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
GAAP net loss	$ (6,027,246)	$ (2,474,298)	$ (22,851,766)	$ (6,923,282)
Adjustments:				
Stock-based compensation				
Research and development [1]	434,597	254,537	1,017,855	813,099
General and administrative [2]	265,319	194,410	671,476	523,690
Issuance of common stock, licensing agreement [3]	-	-	5,000,000	-
Non-cash interest expense [4]	194,741	-	369,709	-
Non-GAAP adjusted net loss	**$ (5,132,589)**	**$ (2,025,351)**	**$ (15,792,726)**	**$ (5,586,493)**
GAAP net loss per share - basic and diluted	$ (0.41)	$ (0.24)	$ (1.78)	$ (0.67)
Adjustment to net loss (as detailed above)	0.06	0.04	0.55	0.13
Non-GAAP adjusted net loss per share	**$ (0.35)**	**$ (0.20)**	**$ (1.23)**	**$ (0.54)**

Weighted average common shares outstanding, basic and diluted	14,877,619	10,273,567	12,867,484	10,262,636

(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.

SOURCE: Celcuity Inc.

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