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

August 9, 2021

- ***Raised approximately $56.3 million of gross proceeds from a follow-on public offering of common stock in early July to provide funding for clinical development activities***
- ***After follow-on offering, Celcuity had approximately $94.4 million of cash on hand***
- ***Expanded clinical development and clinical operations capabilities with appointment of two new senior executives and the addition of other key team members***
- ***In a Phase 1 study evaluating gedatolisib combined with paclitaxel and carboplatin, 65% of patients (11/17) had an objective response, including three complete responses***
- ***Management to host webcast and conference call today, August 9, 2021, at 4:30 p.m. ET / 1:30 p.m. PT***

MINNEAPOLIS, MN / ACCESSWIRE / August 9, 2021 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic and therapeutic strategy for treating patients with cancer, today announced financial results for the second quarter ended June 30, 2021 and summarized recent business progress.

"Celcuity's recent follow-on equity offering strengthens our balance sheet and provides additional funding to support clinical development activities for the advancement of gedatolisib, a potential first-in-class PI3K/mTOR inhibitor," said Brian Sullivan, CEO and co-founder of Celcuity. "We are also very excited about the progress we made expanding our clinical development and clinical operations teams. This positions us well to initiate, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating gedatolisib in combination with palbociclib and an endocrine therapy in patients with ER+/HER2- advanced or metastatic breast cancer in the first half of 2022."

Second Quarter 2021 Business Highlights and Other Recent Developments

- In early April, Celcuity entered into a worldwide licensing agreement with Pfizer for the exclusive right to develop and commercialize gedatolisib.
- Celcuity closed two significant financings to support development of gedatolisib. In early April, Celcuity entered into a debt financing agreement with Innovatus Life Sciences Lending Fund I, LP to provide up to $25.0 million in term loans with the first tranche of $15.0 million funded at closing. In early July, Celcuity completed a follow-on public offering that raised gross proceeds of approximately $56.3 million.
- In April, Celcuity presented results of studies evaluating gedatolisib, inavolisib (a PI3K-α inhibitor), and navitoclax (a BCL inhibitor) in breast and ovarian patient tumors in two posters at the American Association for Cancer Research (AACR) Annual Meeting. The results showed that gedatolisib inhibited nine times more signaling test activity in tumors with hyperactive RAS network signaling, on average, than inavolisib, when evaluated at equal concentrations with the CELsignia test.
- In June, Celcuity announced the addition of Igor Gorbatchevsky, MD, as VP of Clinical Development and Jill Krause as VP of Clinical Operations to Celcuity's leadership team. Dr. Gorbatchevsky has over two decades of hands-on oncology drug development experience, including successful regulatory IND and NDA/BLA filings across several drug classes. Ms. Krause has deep clinical operations expertise, including over nine years of experience managing and executing trials in breast cancer. Since joining Celcuity, Dr. Gorbatchevsky and Ms. Krause have each added key members to their respective teams.
- In July, results from a 17-patient Phase 1 study that evaluated the safety and preliminary activity of gedatolisib combined with carboplatin and paclitaxel were published in the journal, Clinical Cancer Research[1] . The study was designed to explore the hypothesis that inhibition of the PI3K/mTOR pathway can promote sensitivity to platinum-based treatment. The objective response rate (ORR) was 65% (11/17) patients: eight partial responses (PR) and three complete responses (CR) were reported. The stable disease rate was 17% (3/17). Promising results were observed in patients with advanced clear cell ovarian carcinoma (CCOC), a tumor type with poor prognosis generally considered to be chemo resistant. The ORR in patients with CCOC was 80% (8/10), of which 3/10 (30%) reported a CR. Among nine previously platinum-treated patients, 45% (4/9) had a PR (two patients with CCOC, one low grade serous ovarian cancer and one NSCLC). The drug combination was found to be tolerable with a manageable safety profile.

Second Quarter 2021 Financial Results

Unless otherwise stated, all comparisons are for the second quarter ended June 30, 2021, compared to the second quarter ended June 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 second quarter ended June 30, 2021.

Total operating expenses were $13.6 million for the second quarter of 2021, compared to $2.2 million for the second quarter of 2020.

Research and development (R&D) expenses were $13.1 million for the second quarter of 2021, compared to $1.8 million for the second quarter of 2020. The increase during the second quarter of 2021 compared to the prior year, primarily resulted from a $10.0 million upfront license fee related to the execution of the Pfizer license agreement, which included $5.0 million of non-cash expense for the issuance of common stock. The remaining increase in expenses related to compensation, clinical validation and laboratory studies and legal expenses.

General and administrative (G&A) expenses were $0.6 million for the second quarter of 2021, compared to $0.4 million for the second quarter of 2020. The increase in the second quarter of 2021 arose primarily from higher professional fees associated with being a public company, director and officer insurance and non-cash stock-based compensation.

Net loss for the second quarter of 2021 was $14.0 million, or $1.11 loss per share, compared to a net loss of $2.2 million, or $0.21 loss per share, for the second quarter of 2020. Non-GAAP adjusted net loss for the second quarter of 2021 was $8.3 million, or $0.66 loss per share, compared to non-GAAP adjusted net loss of $1.8 million, or $0.17 loss per share, for the second 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 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 2021 was $7.6 million, compared to $1.6 million for the second quarter of 2020.

At June 30, 2021, Celcuity had cash and cash equivalents of $41.6 million, compared to cash and cash equivalents of $11.6 million at December 31, 2020. On April 8, 2021, Celcuity paid an upfront license fee of $5.0 million in conjunction with the Pfizer gedatolisib license agreement and received $14.4 million of net proceeds from a debt financing agreement. On July 1, 2021, Celcuity completed a follow-on equity offering of common stock that resulted in gross proceeds of approximately $56.3 million. After the follow-on offering, Celcuity had approximately $94.4 million of cash on hand.

Anticipated Milestones

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

- Announce an additional clinical trial collaboration utilizing the CELsignia platform in the second half of 2021.
- Initiate a Phase 2/3 clinical trial for gedatolisib in patients with ER+/HER2- metastatic breast cancer in the first half of 2022, subject to feedback from the FDA.
- Provide an update on the lifecycle development plan for gedatolisib in the first half of 2022.
- Provide interim results from the FACT-1 and FACT-2 trials in late 2021 or early 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 second quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-844-369-8770 and international callers should dial 862-298-0840. A live webcast presentation can also be accessed using this weblink: https://www.webcaster4.com/Webcast/Page/2678/42136 . 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 companion diagnostic and therapeutic 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, expected FDA feedback for Celcuity's planned gedatolisib clinical trials, the timing, costs and results of Celcuity's expected clinical trials, Celcuity's expectations with respect to planned clinical collaborations, clinical trials and the timing and content of updates on the gedatolisib life cycle development plan and results of ongoing clinical trials. 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.

[1] Colombo, I. et al., Phase 1 Dose-Escalation Study of the dual PI3K-mTORC1/2 inhibitor Gedatolisib in combination with Paclitaxel and Carboplatin in Patients with Advanced Solid Tumors. Clin Cancer Res July 15 2021 DOI: 10.1158/1078-0432.CCR-21-1402

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Celcuity Inc.
Condensed Balance Sheets

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 41,638,623	$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	121,307	-
Payroll tax receivable	190,000	190,000
Prepaid assets	279,544	317,040
Total current assets	42,251,483	12,166,960
Property and equipment, net	415,080	558,876
Operating lease right-of-use assets	142,766	230,911
Total Assets	**$ 42,809,329**	**$ 12,956,747**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 647,172	$ 217,377
Finance lease liabilities	5,830	5,810
Operating lease liabilities	153,684	187,518
Accrued expenses	729,672	774,612
Total current liabilities	1,536,358	1,185,317
Finance lease liabilities	5,379	8,299
Operating lease liabilities	-	60,861
Note payable, non-current	14,233,068	-
Total Liabilities	15,774,805	1,254,477
Total Stockholders' Equity	27,034,524	11,702,270
Total Liabilities and Stockholders' Equity	**$ 42,809,329**	**$ 12,956,747**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 13,070,108	$ 1,766,227	$ 15,306,451	$ 3,613,641
General and administrative	573,360	447,714	1,128,787	911,113
Total operating expenses	13,643,468	2,213,941	16,435,238	4,524,754
Loss from operations	(13,643,468)	(2,213,941)	(16,435,238)	(4,524,754)
Other income (expense)				
Interest expense	(391,187)	(31)	(391,210)	(64)
Interest income	1,803	11,983	2,191	75,834
Loss on sale of fixed assets	-	-	(263)	-
Other income (expense), net	(389,384)	11,952	(389,282)	75,770
Net loss before income taxes	**(14,032,852)**	**(2,201,989)**	**(16,824,520)**	**(4,448,984)**
Income tax benefits	-	-	-	-
Net loss	**$ (14,032,852)**	**$ (2,201,989)**	**$ (16,824,520)**	**$ (4,448,984)**
Net loss per share, basic and diluted	$ (1.11)	$ (0.21)	$ (1.42)	$ (0.43)
Weighted average common shares outstanding, basic and diluted	12,610,917	10,260,234	11,845,758	10,257,111

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
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**

GAAP net loss	$ (14,032,852)	$ (2,201,989)	$ (16,824,520)	$ (4,448,984)
Adjustments:				
Stock-based compensation				
Research and development [1]	328,077	265,446	583,258	558,562
General and administrative [2]	212,240	157,747	406,157	329,280
Issuance of common stock, licensing agreement [3]	5,000,000	-	5,000,000	-
Non-cash interest expense [4]	174,968	-	174,968	-
Non-GAAP adjusted net loss	**$ (8,317,567)**	**$ (1,778,796)**	**$ (10,660,137)**	**$ (3,561,142)**
GAAP net loss per share - basic and diluted	$ (1.11)	$ (0.21)	$ (1.42)	$ (0.43)
Adjustment to net loss (as detailed above)	0.45	0.04	0.52	0.09
Non-GAAP adjusted net loss per share	**$ (0.66)**	**$ (0.17)**	**$ (0.90)**	**$ (0.34)**
Weighted average common shares outstanding, basic and diluted	12,610,917	10,260,234	11,845,758	10,257,111

[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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