Celcuity Inc. Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

- ***Granted Breakthrough Therapy designation by the FDA for gedatolisib in HR+/HER2- advanced breast cancer***
- ***Entered into agreements for the private placement sale of $100 million of equity and to increase available debt facility from $25 million to $75 million***
- ***The Phase 3 VICTORIA-1 clinical trial remains on track to dose the first patient in the next few months***
- ***Management to host webcast and conference call today, August 11, 2022, at 4:30 p.m. ET***

MINNEAPOLIS, MN / ACCESSWIRE / August 11, 2022 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for a number of different cancers, today announced financial results for the second quarter ended June 30, 2022 and other recent business developments.

"We made progress on a variety of fronts in the second quarter of 2022. The Breakthrough Therapy Designation recently granted to gedatolisib by the FDA will facilitate close collaboration with the agency as we seek to advance this therapy to the clinic as quickly as possible. Our early phase study evaluating gedatolisib in combination with palbociclib and fulvestrant in patients with advanced breast cancer whose disease progressed on a CDK4/6 inhibitor, reported promising efficacy, with high response rates, and tolerability, with low discontinuation rates due to adverse events. We are now excited to take the next step in the development of this potential first-in-class PI3K/mTOR inhibitor. Our Phase 3 clinical trial, VIKTORIA-1, remains on track to dose the first patient in the next few months," said Brian Sullivan, CEO and Co-Founder of Celcuity.

"We also made great progress strengthening our balance sheet over the past few months to support the clinical development of gedatolisib. The $100 million private placement we signed in May and the amendment we signed just this week increasing our debt financing facility to $75 million is expected to provide the capital we need to fund operations through 2025."

Second Quarter 2022 Business Highlights and Other Recent Developments

- In May, Celcuity entered into a definitive securities purchase agreement with certain institutional and other accredited investors in a private placement for the purchase of common stock, preferred stock that may be convertible into common stock and warrants initially exercisable for preferred stock that is expected to result in aggregate proceeds to the Company of $100 million before deducting placement agent fees and other offering expenses. Investors included Venrock Healthcare Capital Partners, Commodore Capital, New Enterprise Associates (NEA), RA Capital Management, Soleus Capital, and Brian Sullivan, the Company's Chief Executive Officer. The closing of the private placement is expected to occur shortly after the first patient in VIKTORIA-1 receives their first dose of treatment at a clinical site located in the United States, provided that such date must occur on or before December 31, 2022.
- In July, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to Celcuity's lead drug product candidate gedatolisib, an investigational pan-PI3K/mTOR inhibitor, for the treatment of HR+/HER2- locally advanced, inoperable or metastatic breast cancer that has progressed after treatment with a CDK4/6 inhibitor in combination with a nonsteroidal aromatase inhibitor. This designation allows for more intensive guidance from the FDA and a potentially accelerated review time if relevant criteria are met. Gedatolisib previously received Fast Track designation from the FDA in January 2022.
- This week, Celcuity amended its existing debt financing agreement with an affiliate of Innovatus Capital Partners, LLC ("Innovatus") to provide Celcuity with up to $75 million in term loans, a $50 million increase from the original debt financing agreement. Celcuity received $15 million at the closing of the original agreement in April 2021. Celcuity will be able to draw an additional $20 million tranche following the closing of the $100 million private placement. Celcuity will be able to draw on two additional tranches of $10 million each and one additional tranche of $20 million upon achievement of certain clinical trial and financing milestones. Celcuity is entitled to make interest only payments for the 48-month period from the original agreement date or for the 60-month period from the original agreement date if certain conditions are met. The loans will mature on the sixth anniversary of the initial funding date. Innovatus has the right to convert outstanding principal into shares of Celcuity common stock until the third anniversary of the loan amendment date, with such amount limited to an aggregate of up to $6.6 million assuming all tranches are funded. The loan is secured by all of Celcuity's assets. Armentum Partners LLC acted as sole advisor to Celcuity for this transaction.
- The VIKTORIA-1 Phase 3 clinical trial remains on track to dose the first patient in the next few months. The operational activities required to initiate the clinical trial at a study site are completed. The clinical trial protocol was updated to include an additional study arm (Arm F) to evaluate gedatolisib plus fulvestrant in 50 patients who have PIK3CA mutations. This update was made in response to a recommendation from the European Medicines Agency (EMA) that the study arms for PIK3CA mutated patients mirror the same study arms for PIK3CA non-mutated patients. No changes were made to the primary endpoints. VIKTORIA-1 will evaluate the safety and efficacy of gedatolisib 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.
- Enrollment remains 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 mid-2023.

Second Quarter 2022 Financial Results

Unless otherwise stated, all comparisons are for the second quarter ended June 30, 2022, compared to the second quarter ended June 30, 2021.

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, 2022. Total operating expenses were $9.6 million for the second quarter of 2022, compared to $13.6 million for the second quarter of 2021.

Research and development (R&D) expenses were $8.4 million for the second quarter of 2022, compared to $13.1 million for the second quarter of 2021. The approximately $4.7 million decrease during the second quarter of 2022, compared to the second quarter of 2021, reflected a $10 million reduction in gedatolisib licensing related expenses, partially offset by increases of $5.3 million in other research and development expenses. Of the $5.3 million increase in research and development expenses, $1.5 million was related to increased employee and consulting expenses, of which $0.5 million was in the form of non-cash stock-based compensation. The remaining $3.8 million increase in research and development expenses is primarily related to costs for existing clinical trials and for activities supporting the initiation of the VIKTORIA-1 pivotal trial.

General and administrative (G&A) expenses were $1.2 million for the second quarter of 2022, compared to $0.6 million for the second quarter of 2021. The approximately $0.6 million increase in G&A expenses during the second quarter of 2022, compared to the second quarter of 2021, arose primarily from approximately $0.5 million in non-cash stock-based compensation.

Net loss for the second quarter of 2022 was $10.0 million, or $0.67 loss per share, compared to a net loss of $14.0 million, or $1.11 loss per share, for the second quarter of 2021. Non-GAAP adjusted net loss for the second quarter of 2022 was $8.3 million, or $0.55 loss per share, compared to non-GAAP adjusted net loss of $8.3 million, or $0.66 loss per share, for the second quarter of 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 second quarter of 2022 was $11.3 million, compared to $7.6 million for the second quarter of 2021. At June 30, 2022, Celcuity had cash and cash equivalents of $66.9 million, compared to cash and cash equivalents of $84.3 million at December 31, 2021.

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 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 and reference conference ID: 13731012. A live webcast presentation can also be accessed using this weblink: https://viavid.webcasts.com/starthere.jsp?ei=1557419&tp_key=2043138d9a. 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 a number of different cancers. The company's lead therapeutic candidate is gedatolisib, a potent, reversible dual inhibitor that selectively targets all Class 1 PI3K isoforms and mTOR. 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. The company expects to initiate a Phase 3 study evaluating gedatolisib in patients with HR+/HER2- advanced breast cancer and expects to dose the first patient in the next few months. 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. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com.

About Innovatus Capital Partners, LLC

Innovatus Capital Partners, LLC, is an independent adviser and asset management firm with approximately $1.7B in assets under management. Innovatus adheres to an investment strategy that identifies disruptive and growth opportunities across multiple asset categories with a unifying theme of capital preservation, income generation, and upside optionality. The firm has a dedicated team of life sciences investment professionals with deep experience in healthcare, including life sciences. Innovatus and its principals have significant experience providing debt financing to medical device, diagnostics, and biotechnology companies that address unmet medical needs, improve patient outcomes, and reduce overall healthcare expenditures. To date Innovatus Life Sciences Strategy has made over $1.2B in capital commitments for debt and equity support. Further information can be found at www.innovatuscp.com.

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 clinical trials and receiving results from such trials, including without limitation, Celcuity's planned Phase 3 clinical trial (VIKTORIA-1), the costs and expected results from any ongoing or planned clinical trials, expectations with respect to planned clinical collaborations, the expected timing of funding for our private placement and additional tranches under our debt financing agreement, and expectations with respect to available cash to fund operations. 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, 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 Quarterly Report for the period ended March 31, 2022 filed with the Securities and Exchange Commission on May 16, 2022. 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, 2022	December 31, 2021
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 66,910,824	$ 84,286,381
Deposits	22,009	22,009
Deferred transaction costs	332,824	22,144
Payroll tax receivable	95,300	298,764
Prepaid assets	4,601,874	722,677
Total current assets	71,962,831	85,351,975
Property and equipment, net	238,629	312,444
Operating lease right-of-use assets	148,727	241,901
Total Assets	**$ 72,350,187**	**$ 85,906,320**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 2,304,543	$ 1,507,099
Finance lease liabilities	5,379	5,850
Operating lease liabilities	156,769	189,858
Accrued expenses	1,683,305	802,893
Total current liabilities	4,149,996	2,505,700
Finance lease liabilities	-	2,449
Operating lease liabilities	-	61,771

Note payable, non-current	15,011,460	14,625,923
Total Liabilities	19,161,456	17,195,843
Total Stockholders' Equity	53,188,731	68,710,477
Total Liabilities and Stockholders' Equity	**$ 72,350,187**	**$ 85,906,320**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 8,367,687	$ 13,070,108	$ 15,064,000	$ 15,306,451
General and administrative	1,233,040	573,360	2,044,332	1,128,787
Total operating expenses	9,600,727	13,643,468	17,108,332	16,435,238
Loss from operations	(9,600,727)	(13,643,468)	(17,108,332)	(16,435,238)
Other income (expense)				
Interest expense	(455,445)	(391,187)	(890,446)	(391,210)
Interest income	95,646	1,803	103,805	2,191
Loss on sale of fixed assets	-	-	-	(263)
Other income (expense), net	(359,799)	(389,384)	(786,641)	(389,282)
Net loss before income taxes	**(9,960,526)**	**(14,032,852)**	**(17,894,973)**	**(16,824,520)**
Income tax benefits	-	-	-	-
Net loss	**$ (9,960,526)**	**$ (14,032,852)**	**$ (17,894,973)**	**$ (16,824,520)**
Net loss per share, basic and diluted	$ (0.67)	$ (1.11)	$ (1.20)	$ (1.42)
Weighted average common shares outstanding, basic and diluted	14,930,538	12,610,917	14,923,900	11,845,758

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,	
	2022	2021	2022	2021
GAAP net loss	$ (9,960,526)	$ (14,032,852)	$ (17,894,973)	$ (16,824,520)
Adjustments:				
Stock-based compensation				
Research and development [1]	810,664	328,077	1,261,183	583,258
General and administrative [2]	708,795	212,240	1,014,547	406,157
Issuance of common stock, licensing agreement [3]	-	5,000,000	-	5,000,000
Non-cash interest expense [4]	188,439	174,968	385,537	174,968
Non-GAAP adjusted net loss	**$ (8,252,627)**	**$ (8,317,566)**	**$ (15,233,706)**	**$ (10,660,137)**
GAAP net loss per share - basic and diluted	$ (0.67)	$ (1.11)	$ (1.20)	$ (1.42)
Adjustment to net loss (as detailed above)	0.12	0.45	0.18	0.52
Non-GAAP adjusted net loss per share	**$ (0.55)**	**$ (0.66)**	**$ (1.02)**	**$ (0.90)**
Weighted average common shares outstanding, basic and diluted	14,930,538	12,610,917	14,923,900	11,845,758

(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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https://www.accesswire.com/711772/Celcuity-Inc-Reports-Second-Quarter-2022-Financial-Results-and-Provides-Corporate-Update