



## Celcuity Inc. Reports First Quarter 2022 Financial Results and Business Updates

May 16, 2022

- **Entered into \$100 Million Private Placement Agreement**
- **Finalized pivotal Phase 3 trial design for gedatolisib**
- **Received FDA Fast Track designation for gedatolisib in HR+/HER2- advanced breast cancer**
- **Management to host webcast and conference call today, May 16, 2022, at 4:30 p.m. ET**

**MINNEAPOLIS, MN / ACCESSWIRE / May 16, 2022 /** 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 first quarter ended March 31, 2022 and other recent business progress.

"Earlier today, we entered into a definitive securities purchase agreement with a premier group of biopharmaceutical investors in a private placement that is expected to result in aggregate gross proceeds to Celcuity of \$100 million," said Brian Sullivan, CEO and Co-Founder of Celcuity. "The expected proceeds will further support the clinical development of gedatolisib, including our planned Phase 3 clinical study, VIKTORIA-1. We are very pleased to have attracted such a well-regarded group of investors in this very difficult equity capital market.

"There is an urgent unmet need for better therapeutic options for patients with HR+/HER2- metastatic breast cancer given the limited benefit currently available targeted therapies provide. This financing transaction is a testament to gedatolisib's potential to address this unmet need," Sullivan added.

### First Quarter 2022 Business Highlights and Other Recent Developments

- Today, the company announced that it has entered into a definitive securities purchase agreement with Venrock Healthcare Capital Partners, acting as the lead investor, Commodore Capital, New Enterprise Associates (NEA), RA Capital Management, Soleus Capital, and Brian Sullivan, the Company's Chief Executive Officer that is expected to result in aggregate proceeds to the Company of \$100 million, before deducting placement agent fees and other offering expenses. In this private placement, investors will purchase shares of common stock and preferred stock at a price per share of \$5.75 (on an as converted to common stock basis). For each share of common stock and each 1/10 of a share of preferred stock purchased, investors will receive a warrant initially exercisable for preferred stock equivalent to 0.40 shares of common stock on an as converted basis. The exercise price of the warrants will be at a 40% premium to the price paid by investors for the initial shares of common stock purchased in the private placement. The closing of the private placement is expected to occur shortly after the first patient enrolled in the Company's forthcoming Phase 3 clinical study (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 March, the company announced the design for its pivotal Phase 3 trial for gedatolisib, an investigational pan-PI3K/mTOR inhibitor. The pivotal Phase 3 clinical trial, which is named VIKTORIA-1, will be an open-label, randomized study to 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. This multi-center, international trial is expected to enroll subjects at clinical sites across the U.S., Europe, and Asia. Celcuity expects to initiate the clinical trial in mid-2022.
- In January, the FDA granted Fast Track designation to Celcuity's lead drug candidate, gedatolisib, for the treatment of patients with HR+/HER2- metastatic breast cancer whose disease progressed while receiving a CDK4/6 inhibitor.
- Enrollment in the trials evaluating CELsignia selected patients was impacted by COVID-19 related delays during early 2022. Hospitalizations of patients with COVID-19 increased dramatically during this period which led hospitals to reduce clinical trial related activities. The first interim results from these studies are now expected to be available in the first half of 2023.

### First Quarter 2022 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2022, compared to the first quarter ended March 31, 2021.

Total operating expenses were \$7.5 million for the first quarter of 2022, compared to \$2.8 million for the first quarter of 2021. Net cash used in operating activities for the first quarter of 2022 was \$5.9 million, compared to \$2.5 million for the first quarter of 2021. Research and development (R&D) expenses were \$6.7 million for the first quarter of 2022, compared to \$2.2 million for the first quarter of 2021. The approximately \$4.5 million increase during the first quarter of 2022, compared to the first quarter of 2021, resulted primarily from the development of gedatolisib. Employee related expenses, including consulting fees, accounted for \$1.6 million of the \$4.5 million increase, including \$0.2 million in non-cash stock-based compensation. The remaining increase of \$2.9

million of the \$4.5 million is 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 \$0.8 million for the first quarter of 2022, compared to \$0.6 million for the first quarter of 2021. The approximately \$0.2 million increase in G&A during the first quarter of 2022, compared to the first quarter of 2021, arose primarily from employee related expenses, including approximately \$0.1 million in non-cash stock-based compensation.

Net loss for the first quarter of 2022 was \$7.9 million, or \$0.53 per share, compared to a net loss of \$2.8 million, or \$0.25 per share for 2021. Non-GAAP adjusted net loss for the first quarter of 2022 was \$7.0 million, or \$0.47 per share, compared to non-GAAP adjusted net loss of \$2.3 million, or \$0.21 per share, for the first quarter of 2021. Non-GAAP adjusted net loss excludes stock-based compensation expense 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 news release.

At March 31, 2022, Celcuity had cash and cash equivalents of \$78.3 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 first quarter 2022 financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial (844) 825-9789 and international callers should dial (412) 317-5180 and reference conference code 10166506. A live webcast presentation can also be accessed using this weblink: [https://viaavid.webcasts.com/starthere.jsp?ei=1545538&tp\\_key=5a345444e1](https://viaavid.webcasts.com/starthere.jsp?ei=1545538&tp_key=5a345444e1). 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 strategy. The company's lead therapeutic candidate is gedatolisib, a potent, reversible dual inhibitor that selectively targets all Class I isoforms of PI3K 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 in 2022. 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](http://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, 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, and the expected timing of funding for the private placement. 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, 2021 filed with the Securities and Exchange Commission on March 23, 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.

### **Contacts:**

Celcuity Inc.  
Brian Sullivan, [bsullivan@celcuity.com](mailto:bsullivan@celcuity.com)  
Vicky Hahne, [vhahne@celcuity.com](mailto:vhahne@celcuity.com)  
763-392-0123

ICR Westwicke  
Robert Uhl, [robert.uhl@westwicke.com](mailto:robert.uhl@westwicke.com)  
619-228-5886

**Celcuity Inc.**  
**Condensed Balance Sheets**

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 78,295,426	\$ 84,286,381
Deposits	22,009	22,009
Deferred transaction costs	170,503	22,144
Payroll tax receivable	193,034	298,764
Prepaid assets	<u>762,882</u>	<u>722,677</u>
<b>Total current assets</b>	<b>79,443,854</b>	<b>85,351,975</b>
Property and equipment, net	291,076	312,444
Operating lease right-of-use assets	<u>194,925</u>	<u>241,901</u>
<b>Total Assets</b>	<b><u>\$ 79,929,855</u></b>	<b><u>\$ 85,906,320</u></b>
<b>Liabilities and Stockholders' Equity:</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 2,139,291	\$ 1,507,099
Finance lease liabilities	5,860	5,850
Operating lease liabilities	189,267	189,858
Accrued expenses	<u>1,216,392</u>	<u>802,893</u>
<b>Total current liabilities</b>	<b>3,550,810</b>	<b>2,505,700</b>
Finance lease liabilities	981	2,449
Operating lease liabilities	15,328	61,771
Note payable, non-current	<u>14,823,021</u>	<u>14,625,923</u>
<b>Total Liabilities</b>	<b><u>18,390,140</u></b>	<b><u>17,195,843</u></b>
<b>Stockholders' Equity:</b>		
Members' equity contributions	-	-
Common stock	14,920	14,919
Additional paid-in capital	125,386,089	124,622,405
Accumulated deficit	<u>(63,861,294)</u>	<u>(55,926,847)</u>
<b>Total Stockholders' Equity</b>	<b><u>61,539,715</u></b>	<b><u>68,710,477</u></b>
<b>Total Liabilities and Stockholders' Equity</b>	<b><u>\$ 79,929,855</u></b>	<b><u>\$ 85,906,320</u></b>

**Celcuity Inc.**  
**Condensed Statements of Operations**  
(unaudited)

**Three Months Ended March  
31,**

<b>2022</b>	<b>2021</b>
-------------	-------------

**Operating expenses:**

Research and development	\$ 6,696,313	\$ 2,236,342
General and administrative	811,292	555,428
Total operating expenses	7,507,605	2,791,770
Loss from operations	(7,507,605 )	(2,791,770 )
Other income (expense)		
Interest expense	(435,001 )	(24 )
Interest income	8,159	389
Loss on sale of fixed assets	-	(263 )
Other income (expense), net	(426,842 )	102
<b>Net loss before income taxes</b>	<b>(7,934,447 )</b>	<b>(2,791,668 )</b>
Income tax benefits	-	-
<b>Net loss</b>	<b>\$ (7,934,447 )</b>	<b>\$ (2,791,668 )</b>
Net loss per share, basic and diluted	\$ (0.53 )	\$ (0.25 )
Weighted average common shares outstanding, basic and diluted	14,917,187	11,072,097

### 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 March 31,	
	2022	2021
GAAP net loss	\$ (7,934,447 )	\$ (2,791,668 )
Adjustments:		
Stock-based compensation		
Research and development <sup>(1)</sup>	450,520	255,181
General and administrative <sup>(2)</sup>	305,751	193,917
Non-cash interest expense <sup>(3)</sup>	197,098	-
<b>Non-GAAP adjusted net loss</b>	<b>\$ (6,981,078 )</b>	<b>\$ (2,342,570 )</b>

GAAP net loss per share - basic and diluted	\$ (0.53 )	\$ (0.25 )
Adjustment to net loss (as detailed above)	<u>0.06</u>	<u>0.04</u>
<b>Non-GAAP adjusted net loss per share</b>	<b><u>\$ (0.47 )</u></b>	<b><u>\$ (0.21 )</u></b>
Weighted average common shares outstanding, basic and diluted	14,917,187	11,072,097

- (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.

View source version on accesswire.com:

<https://www.accesswire.com/701563/Celcuity-Inc-Reports-First-Quarter-2022-Financial-Results-and-Business-Updates>

News Provided by ACCESS Newswire via QuoteMedia