UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2021

Celcuity Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-38207**	**82-2863566**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

16305 36th Avenue North; Suite 100
Minneapolis, Minnesota 55446
(Address of Principal Executive Offices and Zip Code)

(763) 392-0767
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	CELC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On May 10, 2021, Celcuity Inc. (the "Company") issued a press release regarding the Company's financial results for the first quarter ended March 31, 2021. A copy of the Company's press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 2.02, including the accompanying exhibit, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Item 2.02 shall not be incorporated by reference into any filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated May 10, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2021

CELCUITY INC.

By: /s/ Brian F. Sullivan

Brian F. Sullivan
Chairman and Chief Executive Officer

Exhibit 99.1

celcuity

EXPANDING TREATMENT OPTIONS

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

- *Entered into worldwide licensing agreement with Pfizer to develop and commercialize gedatolisib, a first-in-class PI3K/mTOR inhibitor, in clinical development for breast cancer*

- *Announced encouraging preliminary data from a Phase 1b trial of gedatolisib plus Ibrance® and endocrine therapy for patients with ER+/HER2- metastatic breast cancer, in which gedatolisib showed a potentially differentiated safety and tolerability profile*

- *Secured additional financing to strengthen cash position and provide funding for expanded clinical development activities*

- *Entered into clinical trial collaboration agreements with leading cancer research centers, Novartis, Pfizer, and Puma to evaluate the efficacy of targeted therapies in patients selected with Celcuity's CELsignia Multi-Pathway Activity Test*

- *Management to host webcast and conference call today, May 10, at 4:30 p.m. ET / 1:30 p.m. PT*

MINNEAPOLIS, May 10, 2021 — Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic (CDx) and therapeutic strategy for treating patients with cancer, today announced financial results for the first quarter ended March 31, 2021 and summarized recent business progress.

"Celcuity took a transformational strategic step in April when we entered into a global licensing agreement with Pfizer to obtain exclusive rights to develop and commercialize gedatolisib, a pan-PI3K/mTOR inhibitor, in clinical development to treat patients with ER+/HER2-negative advanced or metastatic breast cancer," said Brian Sullivan, CEO and co-founder of Celcuity. "Celcuity is planning 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 the first half of 2022. We have a highly experienced drug development team and the financial resources in place to advance the gedatolisib program and are excited by the opportunity to utilize our CELsignia cellular analysis platform to support the development of a potential first-in-class targeted cancer therapy like gedatolisib."

First Quarter 2021 Business Highlights and Other Recent Developments

- In January, Celcuity entered a collaboration with Sarah Cannon Research Institute and Pfizer Inc. to conduct an open-label Phase 2 clinical trial. This trial will evaluate the efficacy and safety of two Pfizer targeted therapies, VIZIMPRO®, a pan-HER inhibitor, and XALKORI®, a c-Met inhibitor, in patients with previously treated metastatic HER2-negative breast cancer selected with Celcuity's CELsignia Multi-Pathway Activity Test. Celcuity believes there is significant clinical interest in finding new diagnostic tests and targeted therapies for patients with metastatic HER2-negative breast cancer whose disease progressed on prior therapies. Patient enrollment is expected to begin in the second or third quarter of 2021 with interim results in the second half of 2022.

- Celcuity raised approximately $43.0 million of gross proceeds from financings in the first quarter of 2021 and April 2021.
  - In late February, Celcuity completed a successful follow-on public offering that raised gross proceeds of approximately $27.6 million.
  - 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. Celcuity will be able to draw on two additional tranches of $5.0 million each upon the achievement of certain clinical trial and financing milestones.

- In March, Celcuity entered into a clinical trial collaboration with MD Anderson, Novartis, and Puma Biotechnology to evaluate the efficacy and safety of Novartis' targeted therapy TABRECTA® and Puma's NERLYNX® in patients with metastatic HER2-negative breast cancer selected by Celcuity's CELsignia Multi-Pathway Activity Test. This is Celcuity's second clinical trial to treat patients diagnosed with hyperactive HER2 and c-Met signaling breast cancers with matching targeted therapies and Celcuity now has five clinical trial collaborations in place.

- In April, Celcuity entered a worldwide licensing agreement with Pfizer for the exclusive right to develop and commercialize gedatolisib. Gedatolisib is in Phase 1b clinical development for the treatment of patients with ER+/HER2-negative advanced or metastatic breast cancer. Celcuity announced preliminary data for the 103 patients enrolled in the expansion portion of the ongoing Phase 1b clinical trial evaluating gedatolisib, plus Ibrance and endocrine therapy. As of the January 11, 2021 data cut-off, 53 of the 88 evaluable patients (60%) had an objective response. Gedatolisib was also generally well tolerated, with the majority of treatment-related adverse events (TRAE) being Grade 1 or 2. The most common Grade 3 or 4 TRAEs related to gedatolisib were stomatitis and rash. Celcuity plans to meet with the FDA later this year to discuss its clinical development plans for gedatolisib.

- In April, Celcuity presented results of studies evaluating gedatolisib, inavolisib (a PI3K-*a* 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. Gedatolisib at one-fifth the concentration of inavolisib (30 nM vs. 150 nM), inhibited five times more signaling activity as quantified by the CELsignia test. Data also showed that synergistic cooperation between PI3K/mTOR and BCL signaling was detected, suggesting potential patient benefit of combining gedatolisib with a BCL inhibitor.

First Quarter 2021 Financial Results

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2021, compared to the first quarter ended March 31, 2020.

Total operating expenses were $2.79 million for the first quarter of 2021, compared to $2.31 million for the first quarter of 2020.

Research and development (R&D) expenses were $2.24 million for the first quarter of 2021, compared to $1.85 million for the first quarter of 2020. The approximately $0.39 million increase during the first three months of fiscal year 2021, compared to the first three months of fiscal year 2020, resulted from a $0.06 million increase in compensation related expenses, which included a decrease of approximately $0.04 million of non-cash stock-based compensation expense. In addition, other research and development expenses increased $0.33 million due to clinical validation and laboratory studies, and operational and business development activities.

General and administrative (G&A) expenses were $0.56 million for the first quarter of 2021, compared to $0.46 million for the first quarter of 2020. The approximately $0.09 million increase during the first three months of fiscal year 2021, compared to the first three months of fiscal year 2020, resulted primarily from a $0.08 million increase in professional fees associated with being a public company and director and officer insurance.

Net loss for the first quarter of 2021 was $2.79 million, or $0.25 per share, compared to a net loss of $2.25 million, or $0.22 per share, for the first quarter of 2020. Non-GAAP adjusted net loss for the first quarter of 2021 was $2.34 million, or $0.21 per share, compared to non-GAAP adjusted net loss of $1.78 million, or $0.17 per share, for the first quarter of 2020. Non-GAAP adjusted net loss excludes stock-based compensation expense. Because this item has 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 first quarter of 2021 was $2.52 million, compared to $1.83 million for the first quarter of 2020.

At March 31, 2021, Celcuity had cash and cash equivalents of $34.9 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 $14.5 million of net proceeds from a debt financing agreement. Taking into account these two events subsequent to the end of the first quarter, Celcuity has approximately $44.0 million of cash-on-hand.

Anticipated Milestones

Celcuity expects to do the following over the next twelve months:

- Announce additional clinical trial collaborations in the first half of 2021 utilizing the CELsignia platform.
- Initiate Phase 2/3 clinical trial for gedatolisib in breast cancer in the first half of 2022 pending discussions with the FDA regarding the clinical development pathway.
- 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 first quarter financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial 1-877-407-8035 and international callers should dial 201-689-8035. A live webcast presentation can also be accessed using this weblink: https://www.webcaster4.com/Webcast/Page/2678/40988. 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. Our CELsignia companion diagnostic (CDx) platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from targeted therapies. This enables our CELsignia CDx platform to support advancement of new indications for already approved targeted therapies. Our therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver our companion diagnostics can identify. By pursuing an integrated companion diagnostic and therapeutic strategy, we believe we are uniquely positioned to achieve our goal of helping cancer patients receive the therapeutic best suited to treat their cancer driver. 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." 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

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 34,936,902	$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	13,719	-
Payroll tax receivable	190,000	190,000
Prepaid assets	551,345	317,040
Total current assets	35,713,975	12,166,960
Property and equipment, net	466,484	558,876
Operating lease right-of-use assets	186,602	230,911
Total Assets	**$ 36,367,061**	**$ 12,956,747**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 318,213	$ 217,377
Finance lease liabilities	5,819	5,810
Operating lease liabilities	185,656	187,518
Accrued expenses	660,849	774,612
Total current liabilities	1,170,537	1,185,317
Finance lease liabilities	6,841	8,299
Operating lease liabilities	15,139	60,861
Total Liabilities	1,192,517	1,254,477
Total Stockholders' Equity	35,174,544	11,702,270
Total Liabilities and Stockholders' Equity	**$ 36,367,061**	**$ 12,956,747**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 2,236,342	$ 1,847,414
General and administrative	555,428	463,399
Total operating expenses	2,791,770	2,310,813
Loss from operations	(2,791,770)	(2,310,813)
Other income (expense)		
Interest expense	(24)	(33)
Interest income	388	63,851
Loss on sale of fixed assets	(263)	-
Other income, net	101	63,818
Net loss before income taxes	(2,791,668)	(2,246,995)
Income tax benefits	-	-
Net loss	$ (2,791,668)	$ (2,246,995)
Net loss per share, basic and diluted	$ (0.25)	$ (0.22)
Weighted average common shares outstanding, basic and diluted	11,072,097	10,253,988

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 from net loss and net loss per share. Management excludes this item because it does 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,	
	2021	2020
GAAP net loss	$ (2,791,668)	$ (2,246,995)
Adjustments:		
Stock-based compensation		
Research and development [1]	255,181	293,116
General and administrative [2]	193,917	171,533
Non-GAAP adjusted net loss	$ (2,342,570)	$ (1,782,346)
GAAP net loss per share - basic and diluted	$ (0.25)	$ (0.22)
Adjustment to net loss (as detailed above)	0.04	0.05
Non-GAAP adjusted net loss per share	$ (0.21)	$ (0.17)
Weighted average common shares outstanding, basic and diluted	11,072,097	10,253,988

(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.