SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Celcuity Inc.

Form: 8-K

Date Filed: 2020-05-07

Corporate Issuer CIK: 1603454

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 7, 2020

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 as defined in [sic] 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 7, 2020, Celcuity Inc. (the "Company") issued a press release regarding the Company's financial results for the first quarter ended March 31, 2020. 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 7, 2020

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.

CELCUITY INC.

Date: May 7, 2020

By: /s/ Brian F. Sullivan

Brian F. Sullivan
Chairman and Chief Executive Officer

celcuity
EXPANDING TREATMENT OPTIONS

Celcuity Reports First Quarter 2020 Financial Results
and Recent Business Highlights

- Significant progress made in development of new, highly precise diagnostics using proprietary CELsignia platform –

- Expect to announce new clinical trial collaborations with pharmaceutical companies and trial sponsors by the end of 2020 –

- Expects to complete development of a CELsignia RAS test for breast and ovarian cancer patients by the end of 2020 –

- Potential impact of the COVID-19 pandemic on clinical sites expected to push announcement of interim data from the FACT-1 and FACT-2 trials into the second half of 2021 –

- Conference Call on Thursday, May 7th at 4:30pm (ET) -

Minneapolis, Minnesota—May 7, 2020—Celcuity Inc. (Nasdaq: CELC), a clinical stage biotechnology company translating discoveries of new cancer sub-types into pioneering diagnostics and expanded therapeutic options for cancer patients, announced financial results for the first quarter ended March 31, 2020 and provided a corporate update.

“During the first quarter, we made significant progress developing a new dynamic signaling test using our proprietary CELsignia platform that is intended to diagnose cancers driven by dysregulated RAS signaling. We expect to complete development of a CELsignia RAS test for breast and ovarian cancer patients by the end of 2020. Our current tests have the potential to diagnose oncogenic signaling activity undetectable by molecular tests in up to one in three HER2-negative breast cancer patients,” said Brian Sullivan, Chairman and Chief Executive Officer of Celcuity.

“Dysregulation of RAS signaling, which includes the RAF/ERK and PI3K/AKT pathways, is estimated to drive 30%-40% of all cancers. Our CELsignia platform is uniquely suited to untangling the complexity of dysregulated RAS signaling tumors and identifying the targeted therapy combination capable of treating it. If our efforts to develop a RAS dynamic signaling test are successful, the percentage of cancer patients who could benefit from a CELsignia test would increase significantly.

“We continue to advance our discussions with pharmaceutical companies for a number of potential clinical trial collaborations. While we still expect to close several collaborations this year, the clinical sponsors and pharmaceutical companies we hope to work with have been affected to varying degrees by the COVID-19 pandemic. These events may delay finalizing some of these potential collaborations past year end 2020. Our potential collaboration partners include many of the country’s leading cancer research centers, as well as several global pharmaceutical companies. The goal of these collaborations is to evaluate the efficacy of targeted therapies in breast cancer patients identified by CELsignia tests.

“In light of recent developments relating to the COVID-19 global pandemic, the focus of healthcare providers and hospitals on fighting the virus, and consistent with the FDA’s updated industry guidance for conducting clinical trials issued on March 18, 2020, we are experiencing delays in the enrollment of patients in our ongoing clinical trials. As a result, we now expect interim results from the FACT-1 and FACT-2 trials to be delayed until the second half of 2021 and final results approximately nine months later. We will continue to evaluate the situation and provide updates as appropriate,” concluded Sullivan.

First Quarter 2020 Financials

Unless otherwise stated, all comparisons are for the first quarter ended March 31, 2020, compared to the first quarter ended March 31, 2019.

Total operating expenses were $2.31 million for the first quarter of 2020, compared to $1.97 million for the first quarter of 2019.

Research and development (R&D) expenses were $1.85 million for the first quarter of 2020, compared to $1.59 million for the first quarter of 2019. The approximately $0.26 million increase during fiscal year 2020, compared to fiscal year 2019, resulted primarily from a $0.25 million increase in compensation related expenses, including approximately $0.19 million of non-cash stock-based compensation. In addition, other research and development expenses increased $0.01 million due to clinical validation and laboratory studies, and operational and business development activities.

General and administrative (G&A) expenses were $0.46 million for the first quarter of 2020, compared to $0.38 million for the first quarter of 2019. The approximately $0.08 million increase during fiscal year 2020, compared to fiscal year 2019, was attributable to non-cash stock-based compensation.

Net loss for the first quarter of 2020 was $2.25 million, or $0.22 per share, compared to a net loss of $1.85 million, or $0.18 per share, for the first quarter of 2019. Non-GAAP adjusted net loss for the first quarter of 2020 was $1.78 million, or $0.17 per share, compared to non-GAAP adjusted net loss of $1.66 million, or $0.16 per share, for the first quarter of 2019. 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 2020 was $1.83 million, compared to $1.59 million for the first quarter of 2019.

At March 31, 2020, Celcuity had cash and cash equivalents of $16.9 million, compared to cash and cash equivalents of $18.7 million at December 31, 2019.

Conference Call
Management will host a conference call at 4:30 PM Eastern Time today to discuss the results. Anyone interested in participating should dial 1-866-342-8588 and use passcode 52638. Participants are asked to dial in 5 to 10 minutes prior to the start of the call.

About Celcuity
Celcuity is a clinical stage biotechnology company translating discoveries of new cancer sub-types into pioneering companion diagnostics and expanded therapeutic options for cancer patients. Celcuity's proprietary CELsignia diagnostic platform analyzes living tumor cells to untangle the complexity of the cellular activity driving a patient's cancer. This allows Celcuity to discover new cancer sub-types molecular diagnostics cannot detect. We are driven to improve outcomes for patients and to transform how pharmaceutical companies define the patient populations for their targeted therapies. Celcuity is headquartered in Minneapolis, MN. 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 in this release include, without limitation, expectations with respect to commercializing diagnostic tests, the use of cash, the discovery of additional cancer sub-types, the development of additional CELsignia tests, the uses and breadth of application of CELsignia tests, collaboration with pharmaceutical companies and the outcomes of such collaboration, the outcome of the FACT 1 and FACT 2 clinical trials, clinical trial patient enrollment and timing of results, anticipated benefits that Celcuity's tests may provide to pharmaceutical companies and to the clinical outcomes of cancer patients, expectations regarding the impact that the COVID-19 pandemic and related economic effects will have on our business and results of operations, and plans to expand research and development and operational processes. 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 our 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, 2019 filed with the Securities and Exchange Commission on March 13, 2020. 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 release, except as required by law.

Contacts:
Celcuity Inc.
Brian Sullivan, bsullivan@celcuity.com
Vicky Hahne, vhahne@celcuity.com
763-392-0123

LifeSci Advisors, LLC
Jeremy Feffer,
Jeremy@LifeSciAdvisors.com
(212) 915-2568

Celcuity Inc.
Condensed Balance Sheets

	March 31, 2020 (unaudited)	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,854,359	$ 18,735,002
Deposits	22,009	22,009
Deferred transaction costs	34,870	28,743
Payroll tax receivable	190,000	190,000
Prepaid assets	337,251	274,600
Total current assets	17,438,489	19,250,354
Property and equipment, net	795,676	833,463
Operating lease right-of-use assets	158,666	196,983
Total Assets	**$ 18,392,831**	**$ 20,280,800**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 68,104	$ 142,773
Finance lease liabilities	5,780	5,769
Operating lease liabilities	176,600	178,466
Accrued expenses	614,462	584,319
Total current liabilities	864,946	911,327
Finance lease liabilities	12,660	14,109
Operating lease liabilities	-	57,793
Total Liabilities	877,606	983,229
Total Stockholders' Equity	17,515,225	19,297,571
Total Liabilities and Stockholders' Equity	**$ 18,392,831**	**$ 20,280,800**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,847,414	$ 1,590,958
General and administrative	463,399	383,545
Total operating expenses	2,310,813	1,974,503
Loss from operations	(2,310,813)	(1,974,503)
Other income (expense)		
Interest expense	(33)	(43)
Interest income	63,851	128,638
Other income (expense), net	63,818	128,595
Net loss before income taxes	(2,246,995)	(1,845,908)
Income tax benefits	-	-
Net loss	$ (2,246,995)	$ (1,845,908)
Net loss per share, basic and diluted	$ (0.22)	$ (0.18)
Weighted average common shares outstanding, basic and diluted	10,253,988	10,198,461

Cautionary Statement Regarding Non-GAAP Financial Measures

This news 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. Therefore, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may not be comparable to similar 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. 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 and, accordingly, may not be comparable to similarly titled measures used by other companies.

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,	
	2020	2019
GAAP net loss	$ (2,246,995)	$ (1,845,908)
Adjustments:		
Stock-based compensation		
Research and development	293,116	100,257(1)
General and administrative	171,533	84,388(2)
Non-GAAP adjusted net loss	$ (1,782,346)	$ (1,661,263)
GAAP net loss per share - basic and diluted	$ (0.22)	$ (0.18)
Adjustment to net loss (as detailed above)	0.05	0.02
Non-GAAP adjusted net loss per share	$ (0.17)	$ (0.16)
Weighted average common shares outstanding, basic and diluted	10,253,988	10,198,461

(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.