
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): November 9, 2020

Celcuity Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38207
(Commission
File Number)

82-2863566
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 November 9, 2020, Celcuity Inc. (the “Company”) issued a press release regarding the Company’s financial results for the third quarter ended September 30, 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
<u>99.1</u>	Press release dated November 9, 2020
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: November 9, 2020

CELCUITY INC.

By: /s/ Brian F. Sullivan

Brian F. Sullivan
Chairman and Chief Executive Officer

**Celcuity Reports Third Quarter 2020 Financial Results
and Recent Business Highlights**

- New clinical trial collaborations with pharmaceutical companies on track to close -

- Cash burn rate steady -

- Cash and cash equivalents of \$13.7 million as of September 30, 2020, which is expected to support operations through 2021 -

- Conference Call on Monday, November 9th at 4:30pm (ET) -

Minneapolis, Minnesota—November 9, 2020—Celcuity Inc. (Nasdaq: CELC), a clinical stage biotechnology company translating discoveries of new cancer sub-types into 3rd generation diagnostics and expanded therapeutic options for cancer patients, announced financial results for the third quarter ended September 30, 2020 and summarized recent business progress.

“During the third quarter, we continued to advance our collaboration discussions with pharmaceutical companies. We expect to close several pharmaceutical company collaborations over the next few months,” said Brian Sullivan, Chairman and Chief Executive Officer of Celcuity. “Each collaboration will evaluate different drug combinations in HER2-negative metastatic breast cancer patients selected with our CELsignia Multipathway Activity test. The collaborations we expect to close first will evaluate patients with either hyperactive HER2 signaling tumors or those with hyperactive c-Met and HER2 signaling tumors. Our discussions with pharmaceutical companies to evaluate PI3K inhibitors in breast or ovarian cancer patients with hyperactive PI3K signaling are also progressing. These discussions are at an earlier stage than those involving patients with hyperactive HER2 or c-Met signaling. We are also very excited about the clinical investigators we expect to partner with to field these trials. They are amongst the most respected oncology researchers and thought leaders in the country.

“We continued to make progress advancing additional new tests during the quarter. Our goal is to develop new CELsignia tests that identify RAS pathway driven cancers undetectable with molecular tests in breast and ovarian cancer. Dysregulated signaling involving RAS network nodes is responsible for a significant percentage of all cancers, which has led many pharmaceutical companies to sponsor research in this area.

“Our CELsignia platform also provides unique insights into the relative potency and efficacy of the different therapies targeting RAS nodes. This enables us to determine the relative superiority of the different RAS-node approved and investigational targeted therapies, which will help guide our collaboration activities.

“Finally, we continue to expect interim results from our FACT-1 and FACT-2 trials in the second half of 2021. However, as you would expect, we are monitoring the recent increase in COVID-19 related hospitalizations for potential impact on enrollment activities for these trials.”

Recent Highlights and Upcoming Milestones

- Multiple clinical trial collaborations amongst several major pharmaceutical companies advancing towards close.
- Data for two new CELsignia tests in two different tumor types announced during past nine months.
- Expect to complete development of a CELsignia RAS test for breast cancer patients by next quarter.
- Interim results from the FACT-1 and FACT-2 trials are expected in the second half of 2021

Third Quarter 2020 Financials

Total operating expenses were \$2.48 million for the third quarter of 2020, compared to \$2.09 million for the third quarter of 2019. Operating expenses for the first nine months of 2020 were \$7.0 million, compared to \$5.91 million for the first nine months of 2019.

Research and development (R&D) expenses were \$1.96 million for the third quarter of 2020, compared to \$1.71 million for the third quarter of 2019. R&D expenses for the first nine months of 2020 were \$5.57 million, compared to \$4.77 million for the first nine months of 2019. The approximately \$0.80 million increase during the first nine months of fiscal year 2020, compared to the first nine months of fiscal year 2019, resulted primarily from a \$0.71 million increase in compensation related expenses, including approximately \$0.45 million of non-cash stock-based compensation expense. In addition, other research and development expenses increased \$0.09 million due to clinical validation and laboratory studies, and operational and business development activities.

General and administrative (G&A) expenses were \$0.52 million for the third quarter of 2020, compared to \$0.38 million for the third quarter of 2019. G&A expenses for the first nine months of 2020 were \$1.43 million, compared to \$1.13 million for the first nine months of 2019. The approximately \$0.30 million increase during fiscal year 2020, compared to fiscal year 2019, resulted primarily from a \$0.24 million increase in compensation related expenses, including approximately \$0.21 million of non-cash stock-based compensation. In addition, other general and administrative expenses increased \$0.06 million primarily due to professional fees associated with being a public company.

Net loss for the third quarter of 2020 was \$2.47 million, or \$0.24 per share, compared to a net loss of \$1.98 million, or \$0.19 per share, for the third quarter of 2019. Net loss for the first nine months of 2020 was \$6.92 million, or \$0.67 per share, compared to \$5.55 million, or \$0.54 per share, for the first nine months of 2019. Non-GAAP adjusted net loss for the third quarter of 2020 was \$2.03 million, or \$0.20 per share, compared to non-GAAP adjusted net loss of \$1.68 million, or \$0.16 per share, for the third quarter of 2019. Non-GAAP adjusted net loss for the first nine months of 2020 was \$5.59 million, or \$0.54 per share, compared to non-GAAP adjusted net loss of \$4.87 million, or \$0.47 per share, for the first nine months 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 third quarter of 2020 was \$1.65 million, compared to \$1.48 million for the third quarter of 2019.

At September 30, 2020, Celcuity had cash and cash equivalents of \$13.7 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 1-866-831-8616 and use passcode 33954. 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 3rd generation diagnostic platform, CELsignia, 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. Celcuity is 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 press release include, without limitation, expectations with respect to new clinical trial collaborations and the timing or outcomes of such collaborations, 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, 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, and expectations regarding the impact that the COVID-19 pandemic and related economic effects will have on Celcuity's business and results of operations. 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, 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 press release, except as required by law.

Contacts:

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763-392-0123

Celcuity Inc.
Condensed Balance Sheets

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 13,696,387	\$ 18,735,002
Deposits	22,009	22,009
Deferred transaction costs	-	28,743
Payroll tax receivable	190,000	190,000
Prepaid assets	103,610	274,600
Total current assets	14,012,006	19,250,354
Property and equipment, net	626,271	833,463
Operating lease right-of-use assets	275,696	196,983
Total Assets	\$ 14,913,973	\$ 20,280,800
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 83,130	\$ 142,773
Finance lease liabilities	5,799	5,769
Operating lease liabilities	189,400	178,466
Accrued expenses	756,873	584,319
Total current liabilities	1,035,202	911,327
Finance lease liabilities	9,756	14,109
Operating lease liabilities	107,040	57,793
Total Liabilities	1,151,998	983,229
Total Stockholders' Equity	13,761,975	19,297,571
Total Liabilities and Stockholders' Equity	\$ 14,913,973	\$ 20,280,800

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 1,962,610	\$ 1,711,597	\$ 5,576,250	\$ 4,772,286
General and administrative	517,465	379,718	1,428,578	1,135,251
Total operating expenses	2,480,075	2,091,315	7,004,828	5,907,537
Loss from operations	(2,480,075)	(2,091,315)	(7,004,828)	(5,907,537)
Other income (expense)				
Interest expense	(28)	(39)	(93)	(123)
Interest income	5,805	107,100	81,639	357,321
Other income, net	5,777	107,061	81,546	357,198
Net loss before income taxes	(2,474,298)	(1,984,254)	(6,923,282)	(5,550,339)
Income tax benefits	-	-	-	-
Net loss	\$ (2,474,298)	\$ (1,984,254)	\$ (6,923,282)	\$ (5,550,339)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.19)	\$ (0.67)	\$ (0.54)
Weighted average common shares outstanding, basic and diluted	10,273,567	10,239,957	10,262,636	10,217,443

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP net loss	\$ (2,474,298)	\$ (1,984,254)	\$ (6,923,282)	\$ (5,550,339)
Adjustments:				
Stock-based compensation				
Research and development(1)	254,537	163,343	813,099	364,902
General and administrative(2)	194,410	139,901	523,690	315,232
Non-GAAP adjusted net loss	<u>\$ (2,025,351)</u>	<u>\$ (1,681,010)</u>	<u>\$ (5,586,493)</u>	<u>\$ (4,870,205)</u>
GAAP net loss per share - basic and diluted	\$ (0.24)	\$ (0.19)	\$ (0.67)	\$ (0.54)
Adjustment to net loss (as detailed above)	0.04	0.03	0.13	0.07
Non-GAAP adjusted net loss per share	<u>\$ (0.20)</u>	<u>\$ (0.16)</u>	<u>\$ (0.54)</u>	<u>\$ (0.47)</u>
Weighted average common shares outstanding, basic and diluted	10,273,567	10,239,957	10,262,636	10,217,443

(1) Reflects a non-cash charge to operating expense for Research and Development stock-based compensation.

(2) Reflects a non-cash charge to operating expense for General and Administrative stock-based compensation.