

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Celcuity Inc.

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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): August 10, 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:

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 August 10, 2020, Celcuity Inc. (the "Company") issued a press release regarding the Company's financial results for the second quarter ended June 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**

[99.1](#) Press release dated August 10, 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.

Date: August 10, 2020

CELCUITY INC.

By: /s/ Brian F. Sullivan

Brian F. Sullivan

Chairman and Chief Executive Officer



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

- Presented data for first CELsignia Pathway Activity Test for ovarian cancer at AACR Annual Meeting -

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

- Cash burn rate steady -

- Cash and Cash Equivalents of \$15.4 million as of June 30, 2020, which is expected to support operations through 2021 -

- Conference Call on Monday, August 10th at 4:30pm (ET) -

Minneapolis, Minnesota—August 10, 2020—Celcuity Inc. (Nasdaq: CELC), a clinical stage biotechnology company translating discoveries of new cancer subtypes into 3rd generation diagnostics and expanded therapeutic options for cancer patients, announced financial results for the second quarter ended June 30, 2020 and summarized recent business progress.

“During the second quarter, we continued to advance development of additional CELsignia Pathway Activity tests. In June, we presented results from studies of our first CELsignia Pathway Activity Test for ovarian cancer at the American Association for Cancer Research (AACR) Annual Meeting. Our CELsignia test for ovarian cancer identifies a subset of ovarian cancer patients whose tumors have abnormal c-Met signaling coincident with abnormal HER2 signaling,” said Brian Sullivan, Chairman and Chief Executive Officer of Celcuity. Celcuity’s 3rd generation diagnostic platform, CELsignia, identifies the dysregulated signaling activity driving a patient’s cancer.

“We also continued to make progress advancing additional new tests and additional collaborations during the quarter. Our goal is to develop new CELsignia tests that identify RAS pathway driven cancers undetectable with molecular tests so that more cancer patients can receive the targeted therapy best suited to treat their tumors. Our collaboration discussions with pharmaceutical companies progressed despite the headwinds COVID-19 presents. We remain confident we will finalize additional collaborations before year-end. Finally, although our FACT-1 and FACT-2 trials remain somewhat impacted by COVID-19 related delays, we continue to expect interim results from these trials in the second half of 2021.”

Recent Highlights and Upcoming Milestones

- Data for two new CELsignia tests in two different tumor types announced during past nine months.
- Multiple clinical trial collaborations amongst several major pharmaceutical companies advancing towards close this year.
- Expect to complete development of a CELsignia RAS test for breast cancer patients by the end of 2020.
- Interim results from the FACT-1 and FACT-2 trials are expected in the second half of 2021

Second Quarter 2020 Financials

Unless otherwise stated, all comparisons are for the second quarter ended June 30, 2020, compared to the second quarter ended June 30, 2019.

Total operating expenses were \$2.21 million for the second quarter of 2020, compared to \$1.84 million for the second quarter of 2019. Operating expenses for the first six months of 2020 were \$4.52 million, compared to \$3.81 million for the first six months of 2019.

Research and development (R&D) expenses were \$1.77 million for the second quarter of 2020, compared to \$1.47 million for the second quarter of 2019. R&D expenses for the first six months of 2020 were \$3.61 million, compared to \$3.06 million for the first six months of 2019. The approximately \$0.55 million increase during the first half of fiscal year 2020, compared to first half of fiscal year 2019, resulted primarily from a \$0.52 million increase in compensation related expenses, including approximately \$0.36 million of non-cash stock-based compensation expense. In addition, other research and development expenses increased \$0.03 million due to clinical validation and laboratory studies, and operational and business development activities.

General and administrative (G&A) expenses were \$0.45 million for the second quarter of 2020, compared to \$0.37 million for the second quarter of 2019. G&A expenses for the first six months of 2020 were \$0.91 million, compared to \$0.75 million for the first six months of 2019. The approximately \$0.16 million increase during fiscal year 2020, compared to fiscal year 2019, was attributable to non-cash stock-based compensation expense.

Net loss for the second quarter of 2020 was \$2.20 million, or \$0.21 per share, compared to a net loss of \$1.72 million, or \$0.17 per share, for the second quarter of 2019. Net loss for the first six months of 2020 was \$4.45 million, or \$0.43 per share, compared to \$3.57 million, or \$0.35 per share, for the first six months of 2019. Non-GAAP adjusted net loss for the second quarter of 2020 was \$1.78 million, or \$0.17 per share, compared to non-GAAP adjusted net loss of \$1.53 million, or \$0.15 per share, for the second quarter of 2019. Non-GAAP adjusted net loss for the first six months of 2020 was \$3.56 million, or \$0.34 per share, compared to non-GAAP adjusted net loss of \$3.19 million, or \$0.31 per share, for the first six 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 second quarter of 2020 was \$1.56 million, compared to \$1.23 million for the second quarter of 2019.

At June 30, 2020, Celcuity had cash and cash equivalents of \$15.4 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 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, 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, 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.

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Celcuity Inc.
Condensed Balance Sheets

	June 30, 2020 <small>(unaudited)</small>	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 15,430,559	\$ 18,735,002
Deposits	22,009	22,009
Deferred transaction costs	-	28,743
Payroll tax receivable	190,000	190,000
Prepaid assets	<u>232,648</u>	<u>274,600</u>
Total current assets	15,875,216	19,250,354
Property and equipment, net	706,219	833,463
Operating lease right-of-use assets	<u>121,015</u>	<u>196,983</u>
Total Assets	<u>\$ 16,702,450</u>	<u>\$ 20,280,800</u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 81,048	\$ 142,773
Finance lease liabilities	5,789	5,769
Operating lease liabilities	131,538	178,466
Accrued expenses	<u>610,508</u>	<u>584,319</u>
Total current liabilities	828,883	911,327
Finance lease liabilities	11,209	14,109
Operating lease liabilities	-	57,793
Total Liabilities	<u>840,092</u>	<u>983,229</u>
Total Stockholders' Equity	<u>15,862,358</u>	<u>19,297,571</u>
Total Liabilities and Stockholders' Equity	<u>\$ 16,702,450</u>	<u>\$ 20,280,800</u>

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 1,766,227	\$ 1,469,731	\$ 3,613,641	\$ 3,060,689
General and administrative	447,714	371,988	911,113	755,533
Total operating expenses	2,213,941	1,841,719	4,524,754	3,816,222
Loss from operations	(2,213,941)	(1,841,719)	(4,524,754)	(3,816,222)
Other income (expense)				
Interest expense	(31)	(41)	(64)	(85)
Interest income	11,983	121,583	75,834	250,221
Other income, net	11,952	121,542	75,770	250,136
Net loss before income taxes	(2,201,989)	(1,720,177)	(4,448,984)	(3,566,086)
Income tax benefits	-	-	-	-
Net loss	\$ (2,201,989)	\$ (1,720,177)	\$ (4,448,984)	\$ (3,566,086)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.17)	\$ (0.43)	\$ (0.35)
Weighted average common shares outstanding, basic and diluted	10,260,234	10,213,455	10,257,111	10,206,000

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. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net loss	\$ (2,201,989)	\$ (1,720,177)	\$ (4,448,984)	\$ (3,566,086)
Adjustments:				
Stock-based compensation				
Research and development	265,446	101,303	558,562	201,560(1)
General and administrative	157,747	90,943	329,280	175,331(2)
Non-GAAP adjusted net loss	<u>\$ (1,778,796)</u>	<u>\$ (1,527,931)</u>	<u>\$ (3,561,142)</u>	<u>\$ (3,189,195)</u>
GAAP net loss per share - basic and diluted	\$ (0.21)	\$ (0.17)	\$ (0.43)	\$ (0.35)
Adjustment to net loss (as detailed above)	0.04	0.02	0.09	0.04
Non-GAAP adjusted net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.15)</u>	<u>\$ (0.34)</u>	<u>\$ (0.31)</u>
Weighted average common shares outstanding, basic and diluted	10,260,234	10,213,455	10,257,111	10,206,000

- (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.