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): November 7, 2019

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 November 7, 2019, Celcuity Inc. (the "Company") issued a press release regarding the Company's financial results for the third quarter ended September 30, 2019. 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 November 7, 2019

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: November 7, 2019

By: /s/ Brian F. Sullivan

Brian F. Sullivan
Chairman and Chief Executive Officer

Exhibit 99.1

Celcuity Reports Third Quarter 2019 Financial Results

Minneapolis, Minnesota—November 7, 2019—Celcuity Inc. (Nasdaq: CELC), a functional cellular analysis company that is discovering new cancer subtypes and commercializing diagnostic tests designed to significantly improve clinical outcomes of cancer patients treated with targeted therapies, announced financial results for the third quarter ended September 30, 2019.

Unless otherwise stated, all comparisons are for the third quarter ended September 30, 2019, compared to the third quarter ended September 30, 2018.

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FUNCTIONAL CELLULAR ANALYSIS

Celcuity reported a net loss of $1.98 million, or $0.19 per share, for the third quarter of 2019, compared to a net loss of $1.87 million, or $0.18 per share, for the third quarter of 2018. Net loss for the first nine months of 2019 was $5.55 million, or $0.54 per share, compared to $5.66 million, or $0.56 per share, for the first nine months of 2018. Non-GAAP adjusted net loss was $1.68 million, or $0.16 per share, for the third quarter of 2019, compared to non-GAAP adjusted net loss of $1.57 million, or $0.15 per share, for the third quarter of 2018. Non-GAAP adjusted net loss for the first nine months of 2019 was $4.87 million, or $0.47 per share, compared to non-GAAP adjusted net loss of $4.74 million, or $0.47 per share, for the first nine months of 2018. 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 release.

Net cash used in operating activities for the third quarter of 2019 was $1.48 million. At September 30, 2019, Celcuity had cash, cash equivalents and investments of $20.4 million, compared to cash, cash equivalents and investments of $24.9 million at December 31, 2018.

"We continued to make progress advancing development of new CELx tests to diagnose patients with new cancer sub-types and establishing collaborations with pharmaceutical companies. In December, we will report pre-clinical study results for our next cell signaling function test for breast cancer at the San Antonio Breast Cancer Conference," said Chairman and Chief Executive Officer, Brian Sullivan.

"This new test will identify a new sub-group of HER2-negative breast cancer patients with tumors that have currently undiagnosed hyperactive oncogenic signaling activity. We will incorporate this test into our CELx Multi-Pathway (MP) Signaling Function Test. With this new sub-group, we will increase the proportion of HER2-negative breast cancer patients our CELx Multi-Pathway (MP) Signaling Function test can diagnose. We would expect to initiate discussions with pharmaceutical companies about collaborating on clinical trials beginning in the early to mid-2020. Development of an additional test for breast cancer, which would be our fourth, also advanced during the quarter. We hope to complete the pre-clinical studies for this new test in 2020.

"Development of CELx tests for two new solid tumor types also progressed during the quarter. We expect to complete pre-clinical studies for a cell signaling function test in a second tumor type in the first quarter of 2020 and present the results of these studies at a cancer research conference in the second quarter. Completion of the pre-clinical data package for this second tumor type will further increase our opportunities to provide companion diagnostics that we believe will enable pharmaceutical companies to obtain new drug indications for the cancer sub-types our tests diagnose.

"We also continued to progress towards finalizing several clinical trial collaborations with pharmaceutical companies and clinical sponsors to study breast cancer patients identified by our CELx MP test. Since the collaborations we are pursuing involve Celcuity, the clinical sponsor, and in some cases two pharmaceutical companies, significant time is required to finalize the related agreements between the three or four parties. We are very confident that we will close several collaborations in the next several quarters.

"The efforts by NSABP to add new clinical sites to the FACT 1 trial continued this quarter. Six new clinical sites obtained Institutional Review Board (IRB) approval and activated the trial. We now have 26 sites who are enrollment ready and another four sites that are at various stages of obtaining IRB and other related approvals. We are hopeful that most, if not all, of the four sites that are in the midst of approval-related activities will be enrollment ready by year-end," said Chairman and Chief Executive Officer, Brian Sullivan. The FACT 1 trial is evaluating the safety and efficacy of Genentech's drugs, Herceptin® and Perjeta®, and chemotherapy, in early stage breast cancer patients selected with Celcuity's CELx HSF Test.

"The addition of these six new sites and four pending sites would double the number of activated sites enrolling patients for this trial compared to the end of 2018. Since most of the new sites only began participating recently, they have not yet had a significant impact on the patient enrollment rate for the trial. We now expect interim results will be available from this trial in mid-2020 and final results approximately nine months later.

"The FACT 2 clinical trial that is evaluating the safety and efficacy of Puma Biotechnology's pan-HER inhibitor, Nerlynx®, and chemotherapy, in early state breast cancer patients selected with Celcuity's CELx HSF Test is progressing. We expect interim results from this trial in mid-2020 and final results approximately 12 months later. The trial with NSABP and Puma Biotechnology, Inc. to evaluate tissue samples from a Phase II study evaluating Puma Biotechnology's pan-HER inhibitor, Nerlynx, Genentech's HER2 antibody, Herceptin, and Bristol-Myers Squibb's EGFR inhibitor, Erbitux®, in metastatic colorectal cancer patients also continues to progress."

Operating Expenses

Total operating expenses were $2.09 million for the third quarter of 2019, compared to $1.98 million for the third quarter of 2018. Operating expenses for the first nine months of 2019 were $5.91 million, compared to $5.98 million for the first nine months of 2018.

Research and Development Expenses:

Research and development (R&D) expenses were $1.71 million for the third quarter of 2019, compared to $1.60 million for the third quarter of 2018. R&D expenses for the first nine months of 2019 were $4.77 million, compared to $4.69 million for the first nine months of 2018. The approximately $0.08 million increase during the first nine months of fiscal year 2019, compared to the first nine months of fiscal year 2018, resulted primarily from a $0.37 million increase in clinical validation and laboratory studies, legal expenses related to patent costs and operational and business development activities. This increase was offset by a decrease of $0.19 million in non-cash stock-based compensation and a $0.10 million decrease in payroll taxes primarily resulting from utilization of research and development tax credits as authorized by the Path Act Tax Provision.

General and Administrative Expenses:

General and administrative (G&A) expenses were $0.38 million for the third quarter of 2019, compared to $0.38 million for the third quarter of 2018. G&A expenses for the first nine months of 2019 were $1.14 million, compared to $1.29 million for the first nine months of 2018. The approximately $0.15 million decrease during the first nine months of 2019, compared to the first nine months of 2018, primarily resulted from a decrease in non-cash stock-based compensation and professional fees associated with being a public company.

Conference Call

Management will host a teleconference call at 4:30 PM Eastern Time today to discuss the results. Anyone interested in participating should dial 1-877-876-9173 referencing confirmation code "Celcuity." Participants are asked to dial in 5 to 10 minutes prior to the start of the call and inform the operator you would like to join the "Celcuity Conference Call."

About Celcuity

Celcuity Inc. is a cellular analysis company that is discovering new cancer sub-types and commercializing diagnostic tests designed to significantly improve the clinical outcomes of cancer patients treated with targeted therapies. Celcuity's proprietary CELx diagnostic platform uses a patient's living tumor cells to identify the specific abnormal cellular activity driving a patient's cancer and the targeted therapy that can best treat that patient's disease. 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 CELx signaling function tests, the uses and breadth of application of CELx signaling function tests, whether alone or in collaboration with other tests, collaboration with pharmaceutical companies and the outcomes of such collaboration, the outcome of the FACT 1 clinical trial with NSABP Foundation and Genentech, the outcome of the FACT 2 clinical trial with Puma Biotechnology, Inc. and the West Cancer Center , the outcome of the clinical trial Puma Biotechnology and the NSABP Foundation are fielding and of which Celcuity is providing services, clinical trial site approval activities and the timing of such activities, 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 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, those set forth in the Risk Factors section in Celcuity’s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 1, 2019. 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:

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Celcuity Inc.
Condensed Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,269,595	$ 15,944,609
Investments	4,178,825	8,952,907
Deposits	22,009	22,009
Deferred transaction costs	28,743	28,743
Prepaid assets	109,713	269,940
Total current assets	20,608,885	25,218,208
Property and equipment, net	897,110	813,613
Operating lease right-of-use assets	235,919	-
Total Assets	**$ 21,741,914**	**$ 26,031,821**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 198,183	$ 119,811
Finance lease liabilities	5,759	5,730
Operating lease liabilities	164,664	-
Accrued expenses	543,486	536,791
Total current liabilities	912,092	662,332
Finance lease liabilities	15,555	19,878
Operating lease liabilities	101,838	-
Total Liabilities	1,029,485	682,210
Total Stockholders' Equity	20,712,429	25,349,611
Total Liabilities and Stockholders' Equity	**$ 21,741,914**	**$ 26,031,821**

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 1,711,597	$ 1,599,045	$ 4,772,286	$ 4,691,250
General and administrative	379,718	376,796	1,135,251	1,290,082
Total operating expenses	2,091,315	1,975,841	5,907,537	5,981,332
Loss from operations	(2,091,315)	(1,975,841)	(5,907,537)	(5,981,332)
Other income (expense)				
Interest expense	(39)	(65)	(123)	(65)
Interest income	107,100	104,799	357,321	325,883
Other income (expense), net	107,061	104,734	357,198	325,818
Net loss before income taxes	(1,984,254)	(1,871,107)	(5,550,339)	(5,655,514)
Income tax benefits	-	-	-	-
Net loss	$ (1,984,254)	$ (1,871,107)	$ (5,550,339)	$ (5,655,514)
Net loss per share, basic and diluted	$ (0.19)	$ (0.18)	$ (0.54)	$ (0.56)
Weighted average common shares outstanding, basic and diluted	10,239,957	10,128,606	10,217,443	10,111,843

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
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net loss	$ (1,984,254)	$ (1,871,107)	$ (5,550,339)	$ (5,655,514)
Adjustments:				
Stock-based compensation				
Research and development	163,342	217,499	364,902	555,034(1)
General and administrative	139,901	82,777	315,232	358,006(2)
Non-GAAP adjusted net loss	$ (1,681,011)	$ (1,570,831)	$ (4,870,205)	$ (4,742,474)
GAAP net loss per share - basic and diluted	$ (0.19)	$ (0.18)	$ (0.54)	$ (0.56)
Adjustment to net loss (as detailed above)	0.03	0.03	0.07	0.09
Non-GAAP adjusted net loss per share	$ (0.16)	$ (0.15)	$ (0.47)	$ (0.47)
Weighted average common shares outstanding, basic and diluted	10,239,957	10,128,606	10,217,443	10,111,843

(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.