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): February 16, 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 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 February 16, 2021, Celcuity Inc. (the "Company") issued a press release regarding the Company's financial results for the fourth quarter and fiscal year ended December 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 February 16, 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: February 16, 2021

CELCUITY INC.

By: /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive Officer

Exhibit 99.1

celcuity
EXPANDING TREATMENT OPTIONS

Celcuity Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

- Announced a clinical trial collaboration in December with Massachusetts General Hospital, UCLA, and Vanderbilt and Puma Biotechnology to conduct a Phase II clinical trial.

- In January, announced a clinical trial collaboration with Sarah Cannon Research Institute and Pfizer Inc. to conduct a Phase II clinical trial.

- Additional clinical trial collaborations with major pharmaceutical companies are expected to be announced in the first half of 2021.

MINNEAPOLIS, MN - February 16, 2021 - 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 fourth quarter and year ended December 31, 2020 and summarized recent business progress.

"We built momentum in our business over the past few months, signing additional clinical trial agreements to collaborate with several major cancer research centers and pharmaceutical companies while advancing additional new CELsignia tests. In December, we announced a collaboration with Massachusetts General Hospital, UCLA, Vanderbilt, and Puma Biotechnology for a Phase II trial to evaluate the safety and efficacy of Puma's drug, Nerlynx, and AstraZeneca's drug, Faslodex," said Brian Sullivan, Chairman and Chief Executive Officer of Celcuity.

"Last month, we announced another clinical trial collaboration, our fourth one, with Sarah Cannon Research Institute and Pfizer, Inc., for a Phase II trial that will evaluate the efficacy and safety of two Pfizer targeted therapies, VIZIMPRO®, a pan-HER inhibitor, and XALKORI®, a c-Met inhibitor. Both of these recent collaborations aim to address a significant unmet need for new treatment options for metastatic HER2- breast cancer patients whose disease progressed on prior therapies.

"Additional collaboration discussions with pharmaceutical companies also progressed despite the headwinds from COVID-19. We remain confident we will finalize new clinical trial collaborations in the first half of 2021. Finally, although our FACT-1 and FACT-2 trials were somewhat impacted by COVID-19 related delays in recent months, we still expect interim results from these trials in the latter half of 2021 or early 2022."

Recent Highlights and Upcoming Milestones

- Announced two new clinical trial collaborations in past two months.
- Expect to announce additional clinical trial collaborations in the first half of 2021.
- Continue to develop CELsignia RAS test for breast and ovarian cancers, and plan to report data on these new tests in the first half of 2021.
- Interim results from the FACT-1 and FACT-2 trials are expected in late 2021 or early 2022.

Fourth Quarter and Fiscal Year 2020 Financial Results
Unless otherwise stated, all comparisons are for the fourth quarter and full year ended December 31, 2020, compared with the fourth quarter and full year ended December 31, 2019.

Total operating expenses were $2.55 million for the fourth quarter of 2020, compared to $1.90 million for the fourth quarter of 2019. Operating expenses for the fiscal year 2020 were $9.56 million, compared to $7.81 million for the fiscal year 2019.

Research and development (R&D) expenses were $2.11 million for the fourth quarter of 2020, compared to $1.50 million for the fourth quarter of 2019. R&D expenses for fiscal year 2020 were $7.68 million, compared to $6.27 million for fiscal year 2019. The approximately $1.41 million increase during fiscal year 2020, compared to fiscal year 2019, resulted primarily from a $1.15 million increase in compensation related expenses, including approximately $0.49 million of non-cash stock-based compensation expense. In addition, other research and development expenses increased $0.26 million due to clinical validation and laboratory studies, and operational and business development activities.

General and administrative (G&A) expenses were $0.44 million for the fourth quarter of 2020, compared to $0.40 million for the fourth quarter of 2019. G&A expenses for fiscal year 2020 were $1.87 million, compared to $1.53 million for fiscal year 2019. The approximately $0.34 million increase during fiscal year 2020, compared to fiscal year 2019, resulted primarily from a $0.28 million increase in compensation related expenses, including approximately $0.24 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 fourth quarter of 2020 was $2.55 million, or $0.25 per share, compared to a net loss of $1.81 million, or $0.18 per share, for the fourth quarter of 2019. Net loss for fiscal year 2020 was $9.47 million, or $0.92 per share, compared to $7.36 million, or $0.72 per share, for fiscal year 2019. Non-GAAP adjusted net loss for the fourth quarter of 2020 was $2.12 million, or $0.21 per share, compared to non-GAAP adjusted net loss of $1.45 million, or $0.14 per share, for the fourth quarter of 2019. Non-GAAP adjusted net loss for fiscal year 2020 was $7.71 million, or $0.75 per share, compared to non-GAAP adjusted net loss of $6.32 million, or $0.62 per share, for fiscal year 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 fourth quarter of 2020 was $2.11 million, compared to $1.70 million for the fourth quarter of 2019.

At December 31, 2020, Celcuity had cash and cash equivalents of $11.6 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 92066. 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, FACT-2, FACT-3, and FACT-4 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, 2020 filed with the Securities and Exchange Commission on February 16, 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.
Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 11,637,911	$ 18,735,002
Deposits	22,009	22,009
Deferred transaction costs	-	28,743
Payroll tax receivable	190,000	190,000
Prepaid assets	317,040	274,600
Total current assets	12,166,960	19,250,354
Property and equipment, net	558,876	833,463
Operating lease right-of-use assets	230,911	196,983
Total Assets	**$ 12,956,747**	**$ 20,280,800**
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 217,377	$ 142,773
Finance lease liabilities	5,810	5,769
Operating lease liabilities	187,518	178,466
Accrued expenses	774,612	584,319
Total current liabilities	1,185,317	911,327
Finance lease liabilities	8,299	14,109
Operating lease liabilities	60,861	57,793
Total Liabilities	1,254,477	983,229
Total Stockholders' Equity	11,702,270	19,297,571
Total Liabilities and Stockholders' Equity	**$ 12,956,747**	**$ 20,280,800**

Celcuity Inc.
Statements of Operations

	Three Months Ended December 31,		Years Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 2,107,272	$ 1,497,023	$ 7,683,522	$ 6,269,308
General and administrative	444,064	400,742	1,872,642	1,535,993
Total operating expenses	2,551,336	1,897,765	9,556,164	7,805,301
Loss from operations	(2,551,336)	(1,897,765)	(9,556,164)	(7,805,301)
Other income (expense)				
Interest expense	(26)	(36)	(120)	(159)
Interest income	469	88,776	82,109	446,096
Other income, net	443	88,740	81,989	445,937
Net loss before income taxes	(2,550,893)	(1,809,025)	(9,474,175)	(7,359,364)
Income tax benefits	-	-	-	-
Net loss	**$ (2,550,893)**	**$ (1,809,025)**	**$ (9,474,175)**	**$ (7,359,364)**
Net loss per share, basic and diluted	$ (0.25)	$ (0.18)	$ (0.92)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	10,279,535	10,251,555	10,266,884	10,226,041

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 December 31,		Years Ended December 31,	
	2020	2019	2020	2019
GAAP net loss	$ (2,550,893)	$ (1,809,025)	$ (9,474,175)	$ (7,359,364)
Adjustments:				
Stock-based compensation				
Research and development [1]	241,996	202,403	1,055,094	567,305
General and administrative [2]	185,094	158,452	708,785	473,684
Non-GAAP adjusted net loss	$ (2,123,803)	$ (1,448,170)	$ (7,710,296)	$ (6,318,375)
GAAP net loss per share - basic and diluted	$ (0.25)	$ (0.18)	$ (0.92)	$ (0.72)
Adjustment to net loss (as detailed above)	0.04	0.04	0.17	0.10
Non-GAAP adjusted net loss per share	$ (0.21)	$ (0.14)	$ (0.75)	$ (0.62)
Weighted average common shares outstanding, basic and diluted	10,279,535	10,251,555	10,266,884	10,226,041

(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.