UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-38207

CELCUITY INC.

(Exact name of registrant as specified in its charter)

Delaware	**No. 82-2863566**
(State of incorporation)	(IRS Employer Identification No.)

16305 36th Avenue North; Suite 100
Minneapolis, Minnesota 55446
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (763) 392-0767

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

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As used in this report, the terms "we," "us," "our," "Celcuity," and the "Company" mean Celcuity Inc., unless the context indicates another meaning.

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Celcuity Inc.
Condensed Balance Sheets

	June 30, 2020 (unaudited)	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	232,648	274,600
Total current assets	15,875,216	19,250,354
Property and equipment, net	706,219	833,463
Operating lease right-of-use assets	121,015	196,983
Total Assets	$ 16,702,450	$ 20,280,800
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	610,508	584,319
Total current liabilities	828,883	911,327
Finance lease liabilities	11,209	14,109
Operating lease liabilities	-	57,793
Total Liabilities	840,092	983,229
Stockholders' Equity:		
Preferred stock, $0.001 par value: 2,500,000 shares authorized; 0 shares issued and outstanding as of June 30, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value: 25,000,000 shares authorized; 10,289,253 and 10,253,988 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	10,289	10,254
Additional paid-in capital	37,148,459	36,134,723
Accumulated deficit	(21,296,390)	(16,847,406)
Total Stockholders' Equity	15,862,358	19,297,571
Total Liabilities and Stockholders' Equity	$ 16,702,450	$ 20,280,800

See accompanying notes to the financial statements

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

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months and Six Months Ended June 30, 2020

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2019	10,253,988	$ 10,254	$ 36,134,723	$ (16,847,406)	$ 19,297,571
Stock-based compensation	-	-	464,649	-	464,649
Net loss	-	-	-	(2,246,995)	(2,246,995)
Balance at March 31, 2020 *(unaudited)*	10,253,988	10,254	36,599,372	(19,094,401)	17,515,225
Stock-based compensation	15,686	16	423,177	-	423,193
Employee stock purchases	4,678	4	23,893	-	23,897
Issuance of shares of common stock in an at-the-market ("ATM") offering	14,901	15	154,127	-	154,142
Issuance costs associated with ATM offering	-	-	(52,110)	-	(52,110)
Net loss	-	-	-	(2,201,989)	(2,201,989)
Balance at June 30, 2020 *(unaudited)*	10,289,253	$ 10,289	$ 37,148,459	$ (21,296,390)	$ 15,862,358

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months and Six Months Ended June 30, 2019

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2018	10,186,382	$ 10,186	$ 34,827,467	$ (9,488,042)	$ 25,349,611
Stock-based compensation	-	-	184,645	-	184,645
Exercise of common stock options	22,733	23	174,934	-	174,957
Net loss	-	-	-	(1,845,908)	(1,845,908)
Balance at March 31, 2019 *(unaudited)*	10,209,115	10,209	35,187,046	(11,333,950)	23,863,305
Stock-based compensation	-	-	192,246	-	192,246
Exercise of common stock options	-	-	-	-	-
Exercise of common stock options, net of shares withheld for exercise price	4,325	4	(4)	-	-
Employee stock purchases	6,876	7	58,058	-	58,065
Net loss	-	-	-	(1,720,177)	(1,720,177)
Balance at June 30, 2019 *(unaudited)*	10,220,316	$ 10,220	$ 35,437,346	$ (13,054,127)	$ 22,393,439

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (4,448,984)	$ (3,566,086)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	191,134	159,338
Stock-based compensation	887,842	376,891
Non-cash interest income, net of cash received	-	11,001
Changes in operating assets and liabilities:		
Prepaid assets and deposits	41,952	84,408
Accounts payable	(59,025)	44,755
Accrued expenses	26,189	84,278
Non-cash operating lease, net	(28,754)	(11,538)
Net cash used for operating activities	(3,389,646)	(2,816,953)
Cash flows from investing activities:		
Proceeds from sale of investments	-	1,745,000
Purchases of property and equipment	(66,589)	(183,828)
Net cash provided by (used for) investing activities	(66,589)	1,561,172
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	-	174,957
Proceeds from employee stock purchases	23,897	58,065
Gross proceeds from an ATM offering	154,142	-
Payments for secondary registration statement costs	(23,367)	(1,300)
Payments for finance leases	(2,880)	(2,860)
Net cash provided by financing activities	151,792	228,862
Net change in cash and cash equivalents	(3,304,443)	(1,026,919)
Cash and cash equivalents:		
Beginning of period	18,735,002	15,944,609
End of period	$ 15,430,559	$ 14,917,690
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment included in accounts payable	$ -	$ 2,005

See accompanying notes to the financial statements

CELCUITY INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)
(For the Three and Six Months Ended June 30, 2020 and 2019)

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical stage biotechnology company translating discoveries of new cancer sub-types into pioneering companion diagnostics and expanded therapeutic options for cancer patients. The Company'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. Celcuity is driven to improve outcomes for patients and to transform how pharmaceutical companies define the patient populations for their targeted therapies.The Company was co-founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota. The Company has not generated any revenues to date.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements include the accounts of the Company and have been prepared in accordance with Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, as permitted by Article 10, the unaudited financial statements do not include all of the information required by accounting principles generally accepted in the United States ("U.S. GAAP"). The balance sheet at December 31, 2019 was derived from the audited financial statements at that date and does not include all the disclosures required by U.S. GAAP. In the opinion of management, all adjustments which are of a normal recurring nature and necessary for a fair presentation have been reflected in the financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2019 and the related footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. Operating results for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

Accounting Estimates

Management uses estimates and assumptions in preparing these unaudited condensed financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could differ from those estimates and the difference could be material. Significant items subject to such estimates and assumptions include the valuation of stock-based compensation and prepaid or accrued clinical trial costs.

Risks and Uncertainties

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its diagnostic tests, ability to obtain regulatory approval of its diagnostic tests, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

Clinical Trial Costs

The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third-party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with service agreements with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its prepaid assets or accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in an adjustment to expense in future periods. Changes in these estimates that result in material changes to the Company's prepaid assets or accrued expenses could materially affect the Company's results of operations.

Application of New or Revised Accounting Standards

Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Recently Adopted Accounting Pronouncements

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842),* which requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The original guidance required application on a modified retrospective basis with the earliest period presented. In August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-11, Targeted Improvements to ASC 842, which included an option to not restate comparative periods in transition and elect to use the effective date of ASC 842 as the date of initial application of transition, which the Company elected.As a result of the adoption of ASC 842 on January 1, 2019, the Company recorded both operating lease right-of-use (ROU) assets of $356,539 and lease liabilities of $404,931 and eliminated deferred rent of $63,875 and prepaid rent of $15,483. The adoption of ASC 842 had no impact on the Company's Condensed Statement of Operations and Condensed Statement of Cash Flows for the three- and six-month period ended June 30, 2020. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 4.

3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per common share are the same.

For the three and six months ended June 30, 2020 and 2019, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 723,194 and 406,518 shares of common stock, respectively, warrants to purchase 353,585 and 353,980 shares of common stock, respectively, and 15,686 and 0 shares of restricted common stock, respectively.

4. Commitments

Operating and Finance Leases

The Company leases its corporate space in Minneapolis, Minnesota. In September 2017, the Company entered into a non-cancelable operating lease agreement for building space. The new lease commenced, and the Company moved to the facility, in May 2018, in conjunction with the termination of its then existing lease. Rent expense is recorded on a straight-line basis over the lease term. The new lease agreement extends through April 2021 and provides for monthly rent, real estate taxes and operating expenses.

The lease agreement includes the option to extend the term for two periods of one year each. The option to extend is at the Company's discretion and because it has not been determined if the option to extend will be exercised, the extended lease terms are not included in the ROU assets and lease liabilities. The Company regularly evaluates the renewal options and when they are reasonably certain of exercise, the Company includes the renewal period in its lease term.
On July 28, 2020, the Company signed an amendment to exercise the option to extend the lease for a period of one year. The commencement of the extended period is May 1, 2021 and will terminate on April 30, 2022.

In May 2018, the Company entered into a non-cancelable finance lease agreement for office equipment with a five-year term. The underlying assets are included in furniture and equipment. The lease contains a bargain purchase option at the end of the lease.

When an implicit rate is not provided, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Supplemental balance sheet information consisted of the following at June 30, 2020:

Operating Lease		
Right-of-use assets	$	121,015
Operating lease liability	$	131,538
Less: short term portion		(131,538)
Long term portion	$	0
Finance Lease		
Furniture and equipment	$	28,932
Less: Accumulated depreciation		(12,055)
Net book value of property and equipment under finance lease	$	16,877
Finance lease liability	$	16,998
Less: short term portion		(5,789)
Long term portion	$	11,209

Maturity analysis under lease agreements consisted of the following as of June 30, 2020:

	Operating Leases	Finance Leases
2020	$ 81,176	$ 3,627
2021	64,940	7,255
2022	-	7,255
2023	-	3,022
Total minimum lease payments	146,116	21,159
Less: Present value discount	(14,578)	(177)
Less amount representing services	-	(3,984)
Present value of net minimum lease payments	$ 131,538	$ 16,998

Weighted Average	Remaining Lease Term	Discount Rate
Operating lease	0.8 years	5.5%
Finance lease	2.9 years	1.0%

Lease costs for the period ended June 30, 2020:

	Three-month Period	Six-month Period
Operating lease cost	$ 41,063	$ 82,126
Finance lease cost:		
Amortization	1,447	2,893
Interest	31	65
Variable lease cost	20,300	44,665
	$ 62,841	$ 129,749

Supplemental cash flow information related to leases for the period ended June 30, 2020:

	Three-month Period	Six-month Period
Cash paid for amounts included in operating and finance leases:		
Operating cash outflow from operating leases	$ 69,005	$ 163,595
Operating cash outflow from finance leases	31	65
Financing cash outflow from finance leases	1,441	2,880
	$ 70,477	$ 166,540

Clinical Research Studies

In May 2017, the Company entered into an agreement with a clinical research organization to conduct a clinical research study. The Company made payments of $50,000, $200,000 and $350,000 in 2019, 2018 and 2017, respectively. Additional payments will be due as certain milestones are met and clinical sites are added. The maximum amount of these additional payments is estimated to be approximately $2,690,000 over the course of the agreement.

In October 2018, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made payments of approximately $70,000 in 2019. Additional payments of approximately $112,000 will be due as certain milestones are met.

5. Stockholders' Equity

On June 5, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley FBR, Inc. (the "Agent"). Pursuant to the ATM Agreement, the Company may offer and sell from time to time, at its option, shares of common stock having an aggregate offering price of up to $10,000,000, par value $0.001 per share (the "Placement Shares"), through the Agent.

The Placement Shares have been registered under the Securities Act of 1933, as amended, pursuant to the Registration Statement on Form S-3 (File No. 333-227466), which was originally filed with the SEC on September 21, 2018 and declared effective by the SEC on October 4, 2018, the base prospectus contained within the Registration Statement, and a prospectus supplement that was filed on June 5, 2020. Sales of our common stock, if any, under this prospectus supplement may be made by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

During the three and six months ended June 30, 2020, the Company sold 14,901 shares of common stock pursuant to the ATM Agreement, at an average selling price of $10.34 per share.

6. Stock-Based Compensation

The following table summarizes the activity for all stock options outstanding for the six months ended June 30:

	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	585,215	$ 14.37	478,503	$ 9.73
Granted	151,231	7.14	30,216	22.42
Exercised	-	-	(28,170)	7.10
Forfeited	(13,252)	11.54	(74,031)	10.39
Balance at June 30	723,194	$ 9.71	406,518	$ 10.73
Options exercisable at June 30:	305,778	$ 9.68	267,739	$ 7.64
Weighted Average Grant Date Fair Value for options granted during the period:		$ 4.55		$ 14.94

The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2020:

Options Outstanding				Options Exercisable		
Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
723,194	8.11	$ 9.71	$ 787,728	305,778	$ 9.68	$ 301,117

The Company recognized stock-based compensation expense for stock options of $414,272 and $174,871 for the three months ended June 30, 2020 and 2019, respectively, and $864,937 and $337,700 for the six months ended June 30, 2020 and 2019, respectively. In May 2020, the Company modified the exercise price on 203,750 stock option awards to $5.10, the closing market price on the Nasdaq Capital Market on May 14, 2020. No director or officer awards were modified. The effect on stock-based compensation for the three and six months ended June 30, 2020 was approximately $51,000. The effect on stock-based compensation over the remaining service period will be approximately $168,000.

The Black-Scholes option-pricing model was used to estimate the fair value of equity-based awards with the following weighted-average assumptions for the six months ended June 30:

	2020	2019
Risk-free interest rate	0.35% - 1.66%	1.82% - 2.47%
Expected volatility	73.3% - 74.4%	78.1% - 80.0%
Expected life (years)	5.5 to 6.12	5.5 to 6.08
Expected dividend yield	0%	0%

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to the Company's initial public offering, the price per share of common stock was determined by the Company's board based on recent prices of common stock sold in private offerings. Subsequent to the initial public offering, the price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date. The risk-free interest rates are based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life is based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility is estimated based on historical volatility information of peer companies that are publicly available in combination with the Company's calculated volatility since being publicly traded.

All assumptions used to calculate the grant date fair value of non-employee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options issued in connection with the agreements would also be cancelled.

Restricted stock awards were granted to two members of the Company's board during the three months ended June 30, 2020. The Company had 15,686 and 0 shares of restricted stock outstanding as of June 30, 2020 and 2019, respectively, and 0 and 2,571 shares of restricted stock vested during the three months ended June 30, 2020 and 2019. The Company recognized stock-based compensation expense for restricted stock of $10,912 and $4,260 for the three months ended June 30, 2020 and 2019, respectively, and $10,912 and $17,047 for the six months ended June 30, 2020 and 2019, respectively.

The Company initially reserved a maximum of 750,000 shares of common stock for issuance under the 2017 Stock Incentive Plan (the "2017 Plan"). The number of shares reserved for issuance was automatically increased by 102,540 shares on January 1, 2020 and will increase automatically on January 1 of each of 2021 through 2027 by the number of shares equal to 1.0% of the aggregate number of outstanding shares of Company common stock as of the immediately preceding December 31. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for grant under the Company's 2017 Plan as of June 30, 2020 is 325,677.

Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized as follows:

2020	$ 794,868
2021	1,187,562
2022	929,554
2023	576,648
2024	105,954
Total estimated compensation cost to be recognized	$ 3,594,586

The Company recognized stock-based compensation expense related to its employee stock purchase plan of ($1,991) and $13,115 for the three months ended June 30, 2020 and 2019, respectively and $11,993 and $22,144 for the six months ended June 30, 2020 and 2019, respectively. The Company initially reserved a total of 100,000 shares for issuance under the employee stock purchase plan. The number of shares reserved for issuance was automatically increased by 51,270 shares on January 1, 2020 and will increase automatically on each subsequent January 1 by the number of shares equal to 0.5% of the total outstanding number of shares of Company common stock as of the immediately preceding December 31. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for issuance under the employee stock purchase plan as of June 30, 2020 is 119,956.

The Company recognized total stock-based compensation expense as follows for the three and six months ended June 30:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock-based compensation expense in operating expenses:				
Research and development	$ 265,446	$ 101,303	$ 558,562	$ 201,560
General and administrative	157,747	90,943	329,280	175,331
Total	$ 423,193	$ 192,246	$ 887,842	$ 376,891

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and the related notes appearing under Item 1 of Part I of this Quarterly Report on Form 10-Q (this "Quarterly Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2019 and elsewhere in this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are developing companion diagnostic tests designed to expand the eligible patient populations for targeted therapies by discovering new cancer sub-types molecular-based approaches cannot detect. Our proprietary CELsignia diagnostic platform is the only commercially ready technology we are aware of that uses a patient's living tumor cells to identify the specific abnormal cellular process driving a patient's cancer and the targeted therapy that best treats it. We believe our CELsignia platform provides two important improvements over traditional molecular diagnostics. First, molecular diagnostics can only provide a snapshot of the genetic mutations present in a patient's tumor because they analyze fixed (i.e., dead) cells. Using fixed cells prevents molecular diagnostics from analyzing the dynamic cellular activities, known as cell signaling, that regulate cell proliferation or survival. Cancer can develop when certain cell signaling activity becomes abnormal, or dysregulated. Since genetic mutations are often only weakly correlated to the dysregulated signaling activity driving a patient's cancer, a molecular diagnostic is prone to providing an incomplete diagnosis. CELsignia tests overcome this limitation by measuring dynamic cell signaling activity in a patient's living tumor cells. When a CELsignia test detects abnormal signaling activity, a more accurate diagnosis of the patient's cancer driver is obtained. Second, molecular diagnostics can only estimate the probability of a patient's potential drug response based on a statistical analysis of the drug's clinical trial results. Instead of this indirect estimate of drug response, CELsignia tests directly measure the effectiveness of a targeted therapy in a patient's living tumor cells. This enables physicians to confirm that the therapeutic matching the patient's cancer driver is functional in the patient's tumor cells before prescribing it, which significantly increases the likelihood of a positive clinical outcome.

Our first analytically validated and commercially ready test using our CELsignia platform, the CELsignia HER2 Pathway Activity Test, diagnoses two new sub-types of HER2-negative breast cancer that traditional molecular diagnostics cannot detect. Our internal studies show that approximately 15%-20% of HER2-negative breast cancer patients have abnormal HER2 signaling activity similar to levels found in HER2+ breast cancer cells. As a result, these HER2-negative patients have undiagnosed HER2-driven breast cancer and would be likely to respond to the same anti-HER2 targeted therapies only HER2+ patients receive today. We have two interventional clinical trials underway to evaluate the efficacy of HER2 targeted therapies in breast cancer patients selected with our CELsignia test.

Our second CELsignia test for breast cancer evaluates independent c-Met signaling activity and its involvement with HER family signaling in HER2-negative breast cancer tumor cells. Our internal studies show that approximately 20%-25% of HER2-negative breast cancer patients have abnormal c-Met signaling activity that is co-activated with abnormal HER family signaling. These studies suggest that this sub-group of HER2-negative breast cancer patients may best respond to treatment with a combination of HER family and c-Met inhibitors.

We completed development of our third CELsignia test for breast cancer during the fourth quarter of 2019. This new test evaluates PI3K signaling in HER2-negative breast cancer tumor cells. Our internal studies demonstrate how measurement of PI3K-node involved signaling may provide a more sensitive and specific method of identifying patients most likely to benefit from PI3K inhibitors than current genetic tests that detect PI3K mutations.

During the first quarter of 2020, we made significant progress developing a new CELsignia test intended to diagnose cancers driven by dysregulated RAS signaling. We expect to complete development of this test for breast and ovarian cancer patients by the end of 2020. Dysregulation of RAS signaling, which includes the RAF/ERK and PI3K/AKT pathways, is estimated to drive 30%-40% of all cancers. Pharmaceutical companies have developed numerous drugs that target RAS-involved pathways. However, the number of the interactions amongst RAS-regulated pathways has made it extremely difficult to use molecular tests to identify patients with dysregulated RAS signaling tumors. The challenge of diagnosing a cancer driven by a dysregulated RAS signaling network is magnified because two or more different pathways are typically involved. Recent research has also found that RAS mutations play a much less important role in dysregulated RAS signaling than previously thought. Our CELsignia platform is uniquely suited to untangle the complexity of dysregulated RAS signaling tumors and identify the targeted therapy combination capable of treating it.

Once development of the new RAS test is completed, we intend to add it to our current CELsignia Pathway Activity test for breast cancer. This next generation CELsignia test for breast cancer would provide an analysis of HER1, HER2, HER3, c-MET, PI3K, and RAS-involved signaling activity for each patient tumor specimen received. Our current CELsignia test has the potential to diagnose oncogenic signaling activity undetectable by molecular tests in up to one in three HER2-negative breast cancer patients. 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 reported pre-clinical study results for our first CELsignia test for ovarian cancer at the 2020 Annual Meeting of the American Association for Cancer Research in late June 2020. This new test identifies a new sub-group of ovarian cancer patients with tumors that have abnormal c-Met and HER2 signaling activity. These findings suggest that a significant sub-group of ovarian cancer patients may respond to treatment with a combination of ErbB and c-Met inhibitors. Nearly 15,000 women a year die from ovarian cancer, a disease that has less than a 50% five-year survival rate and a limited range of targeted therapy options. There is thus a significant unmet need for additional therapeutic options for ovarian cancer patients. As a companion diagnostic, our CELsignia test for ovarian cancer will be intended to help pharmaceutical companies obtain new drug indications and expand treatment options for this challenging tumor type. We would expect to initiate discussions with pharmaceutical companies about collaborating on clinical trials later in 2020.

In addition to our CELsignia tests for HER2-negative breast cancer and ovarian cancer, we expect to develop CELsignia tests to diagnose nine new potential cancer sub-types we have discovered in breast, lung, colon, ovarian, kidney, and bladder cancers. Approved or investigational drugs are currently available to treat these new potential cancer sub-types. We expect to launch these additional tests on a staggered basis over the next few years while continuing our research to identify additional new cancer sub-types. Our overall commercialization strategy is to develop diagnostics that identify new cancer sub-types and to seek collaborations with pharmaceutical companies, which can vary in scope. We have two collaborations underway that rely on the CELsignia test for breast cancer to select breast cancer patients for treatment with HER2 targeted therapies. For the first one of these collaborations, we are fielding a prospective clinical trial with Genentech and NSABP (FACT-1) to evaluate the efficacy of Genentech's HER2 targeted therapies in patients with abnormal HER2 signaling. For the second of these collaborations, we are fielding a prospective clinical trial with Puma and West Cancer Center (FACT-2) to evaluate the efficacy and safety of Puma's drug, Nerlynx, and chemotherapy, in breast cancer patients selected with our CELsignia test.

For a third collaboration, we were selected by NSABP and Puma to evaluate tissue samples from a Phase II study evaluating Puma's pan-HER inhibitor, Nerlynx, Genentech's HER2 antibody, Herceptin, and Bristol-Myers Squibb's EGFR inhibitor, Erbitux, in metastatic colorectal cancer patients. This 35-patient study is expected to be completed in late 2022. Unlike the trial with NSABP and Genentech, our CELsignia test will be used solely to evaluate tissue samples after they have been enrolled in this trial. We will not receive payment for the testing we perform. We expect our CELsignia test will provide critical insight after the trial is completed about the patient characteristics most correlative to drug response.

In conjunction with the development of our CELsignia tests, we will seek collaborations with pharmaceutical companies to field clinical trials that evaluate the efficacy of various targeted therapies in combination with other targeted therapies or chemotherapy. Potential drug combinations under consideration for clinical trials include: i) pan-HER and c-Met inhibitors; 2) pan-HER inhibitors and endocrine therapy; iii) pan-HER inhibitors and chemotherapies; and iv) PI3K inhibitors and endocrine therapy. The FDA has approved three c-Met inhibitors, six HER-family inhibitors, and four PI3K inhibitors for cancer treatment. Additional c-Met, HER-family, and PI3K inhibitors are being evaluated in on-going clinical trials.

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2012. For the three months ended June 30, 2020 and 2019, we reported a net loss of approximately $2.2 million and $1.7 million, respectively, and for the six months ended June 30, 2020 and 2019, we reported a net loss of approximately $4.4 million and $3.6 million, respectively. As of June 30, 2020, we had an accumulated deficit of approximately $12.6 million under Celcuity LLC and $21.3 million under Celcuity Inc. As of June 30, 2020, we had cash and cash equivalents of approximately $15.4 million.

Impact of COVID-19 on our Business

A novel strain of coronavirus (COVID-19) was first identified in Wuhan, China in December 2019, and subsequently declared a pandemic by the World Health Organization. The impact of the COVID-19 pandemic on our business is discussed in further detail below:

Health and Safety

To help protect the health and safety of our employees, suppliers and collaborators, we took proactive, aggressive action from the earliest signs of the outbreak. We enacted rigorous safety measures in our laboratory and administrative offices, including implementing social distancing protocols, allowing working from home for those employees that do not need to be physically present in a lab to perform their work, suspending travel, implementing temperature checks at the entrances to our facilities, extensively and frequently disinfecting our workspaces and providing masks to those employees who must be physically present. We expect to continue to implement these measures until the COVID-19 pandemic is contained and we may take further actions as government authorities require or recommend or as we determine to be in the best interests of our employees, suppliers, and collaborators.

Clinical Trials and Collaborations

As a result of the COVID-19 pandemic, governmental authorities have implemented and are continuing to implement numerous and constantly evolving measures to try to contain the virus, such as travel bans and restrictions, limits on gatherings, quarantines, shelter-in-place orders, and business shutdowns. As we continue to advance our clinical trial collaborations, we are in close contact with our current clinical sponsors, and principal investigators, as well as prospective pharmaceutical company and clinical collaborators, to assess the impact of COVID-19 on our trial enrollment timelines and collaboration discussions. 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. 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. As the impact of COVID-19 on our industry becomes clearer, we may need to reassess the timing of our anticipated clinical milestones. Prospective clinical trial collaborations with pharmaceutical companies and sponsors may also be delayed but the impact on the timing of finalizing agreements is not yet known.

Research and Development

While our facility currently remains operational, the evolving measures to try to contain the virus have impacted and may further impact our workforce and operations, as well as those of our vendors and suppliers. Our laboratory remains operational as of this date, but, in response to the COVID-19 pandemic, we have implemented protective policies that reduce the number of research and development staff operating in our laboratory at any one time. While governmental measures may be modified or extended, we expect that our research and development and clinical laboratory will remain operational. However, in light of the focus of healthcare providers and hospitals on fighting the virus, several of the clinical sites that provide us tumor tissue for research have halted this service, reducing the number of new tumor tissue specimens we would typically expect to receive. These various constraints may slow or diminish our research and development activities. In addition, cancer research-related industry meetings, such as the American Association for Cancer Research (AACR), were delayed for several months. Our submissions to present research results at these meetings were accepted, but the release of the results were postponed in conjunction with the delayed meeting schedules.

Liquidity

Although there is uncertainty related to the anticipated impact of the recent COVID-19 outbreak on our future results, we believe our existing balance of cash and cash equivalents will be sufficient to meet our cash needs arising in the ordinary course of business for at least the next twelve months. We continue to monitor the rapidly evolving situation and guidance from federal, state and local public health authorities and may take additional actions based on their recommendations. In these circumstances, there may be developments outside our control requiring us to adjust our operating plan. In addition, see Item 1A of Part II of this Quarterly Report for additional information on risks associated with pandemics in general and COVID-19 specifically and how those risks may impact our business and operations.

Results of Operations

Components of Operating Results

Revenue

To date, we have not generated any revenue. Initially, our ability to generate revenue will depend primarily upon our ability to obtain partnership agreements with pharmaceutical companies to provide companion diagnostics for such pharmaceutical partners' existing or investigational targeted therapies. We expect these partnerships to generate significant revenue from the sale of tests to identify patients eligible for clinical trials, from milestone payments, and, potentially, from royalties on the incremental drug revenues our tests enable. Once a new drug indication is received that requires use of our companion diagnostic to identify eligible patients, we expect to generate revenues from sales of tests to treating physicians.

Research and Development

Since our inception, we have primarily focused on research and development of our CELsignia platform, development and validation of our CELsignia tests, and research related to the discovery of new cancer sub-types. Research and development expenses primarily include:

- employee-related expenses related to our research and development activities, including salaries, benefits, recruiting, travel and stock-based compensation expenses;
- laboratory supplies;
- consulting fees paid to third parties;
- clinical trial costs;
- facilities expenses; and
- legal costs associated with patent applications.

Internal and external research and development costs are expensed as they are incurred. As we initiate clinical trials to evaluate efficacy of targeted therapies in cancer patients selected with one of our CELsignia tests, the proportion of research and development expenses allocated to external spending will grow at a faster rate than expenses allocated to internal expenses.

General and Administrative

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation related to our executive, finance and support functions. Other general and administrative expenses include professional fees for auditing, tax, and legal services associated with being a public company, director and officer insurance and travel expenses for our general and administrative personnel.

Sales and Marketing

Sales and marketing expenses consist primarily of professional and consulting fees related to these functions. To date, we have incurred immaterial sales and marketing expenses as we continue to focus primarily on the development of our CELsignia platform and corresponding CELsignia tests. We expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first CELsignia tests. These increased expenses are expected to include payroll-related costs as we add employees in the commercial departments, costs related to the initiation and operation of our sales and distribution network and marketing related costs.

Interest Expense

Interest expense is the result of finance lease obligations.

Interest Income

Interest income consists of interest income earned on our cash, cash equivalents, and investment balances.

Results of Operations

Statements of Operations Data:	Three Months Ended June 30, 2020 (unaudited)	2019 (unaudited)	Increase(Decrease) $	Percent Change
Operating expenses:				
Research and development	$ 1,766,227	$ 1,469,731	$ 296,496	20%
General and administrative	447,714	371,988	75,726	20
Total operating expenses	2,213,941	1,841,719	372,222	20
Loss from operations	(2,213,941)	(1,841,719)	(372,222)	20
Other income (expense)				
Interest expense	(31)	(41)	10	n/a
Interest income	11,983	121,583	(109,600)	(90)
Other income, net	11,952	121,542	(109,590)	(90)
Net loss before income taxes	(2,201,989)	(1,720,177)	(481,812)	28
Income tax benefits	-	-	-	-
Net loss	$ (2,201,989)	$ (1,720,177)	$ (481,812)	28%

Statements of Operations Data:	Six Months Ended June 30, 2020 (unaudited)	2019 (unaudited)	Increase(Decrease) $	Percent Change
Operating expenses:				
Research and development	$ 3,613,641	$ 3,060,689	$ 552,952	18%
General and administrative	911,113	755,533	155,580	21
Total operating expenses	4,524,754	3,816,222	708,532	19
Loss from operations	(4,524,754)	(3,816,222)	(708,532)	19
Other income (expense)				
Interest expense	(64)	(85)	21	n/a
Interest income	75,834	250,221	(174,387)	(70)
Other income, net	75,770	250,136	(174,366)	(70)
Net loss before income taxes	(4,448,984)	(3,566,086)	(882,898)	25
Income tax benefits	-	-	-	-
Net loss	$ (4,448,984)	$ (3,566,086)	$ (882,898)	25%

Research and Development

Our research and development expenses for the three months ended June 30, 2020 were approximately $1.77 million, representing an increase of approximately $0.30 million, or 20%, compared to the same period in 2019. The increase primarily resulted from a $0.28 million increase in compensation related expenses, including approximately $0.16 million of non-cash stock-based compensation, to support development of our CELsignia platform. In addition, other research and development expenses increased $0.02 million due to clinical validation and laboratory studies, and operational and business development activities.

Our research and development expenses for the six months ended June 30, 2020 were approximately $3.61 million, representing an increase of approximately $0.55 million, or 18%, compared to the same period in 2019. The increase primarily resulted from a $0.52 million increase in compensation related expenses, including approximately $0.36 million of non-cash stock-based compensation, to support development of our CELsignia platform. In addition, other research and development expenses increased $0.03 million due to clinical validation and laboratory studies, and operational and business development activities.

Conducting a significant amount of research and development is central to our business model. We plan to increase our research and development expenses for the foreseeable future as we seek to discover new cancer sub-types and to develop and validate additional CELsignia tests to diagnose such sub-types. We also expect to incur increased expenses to support companion diagnostic business development activities with pharmaceutical companies as we develop additional CELsignia tests.

General and Administrative

Our general and administrative expenses for the three months ended June 30, 2020 were approximately $0.45 million, representing an increase of approximately $0.08 million, or 20%, compared to the same period in 2019. The increase was attributable to an increase in non-cash stock-based compensation.

Our general and administrative expenses for the six months ended June 30, 2020 were approximately $0.91 million, representing an increase of approximately $0.16 million, or 21%, compared to the same period in 2019. The increase was attributable to an increase in non-cash stock-based compensation.

We anticipate that our general and administrative expenses will increase in future periods, reflecting both increased costs in connection with the potential future commercialization of CELsignia tests, an expanding infrastructure, and increased professional fees associated with being a public company.

Interest Expense

Interest expense for the three and six months ended June 30, 2020 is related to finance lease liabilities.

Interest Income

Interest income for the three months ended June 30, 2020 was approximately $0.01 million, representing a decrease of approximately 90% compared to the same period in 2019. This decrease was primarily the result of lower market interest rates.

Interest income for the six months ended June 30, 2020 was approximately $0.08 million, representing a decrease of approximately 70% compared to the same period in 2019. This decrease was primarily the result of lower market interest rates.

Liquidity and Capital Resources

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through June 30, 2020, we have raised capital of approximately $13.7 million and $7.5 million through private placements of common equity and unsecured convertible notes, respectively. On September 22, 2017, we closed on the initial public offering of our common stock, which generated approximately $23.3 million of additional cash after taking into account underwriting discounts and commissions and offering expenses. On June 5, 2020, we entered into an At Market Issuance Sales Agreement with B. Riley, FBR, Inc (the “ATM Agreement”). The ATM Agreement allows us to sell shares of common stock up to an aggregate offering price of $10.0 million. Through June 30, 2020 we generated approximately $0.1 million of additional cash through sales pursuant to the ATM Agreement, after taking into account commissions and offering expenses. Cash from these capital raising activities has been our primary source of funds for our operations since inception. As of June 30, 2020, our cash and cash equivalents were approximately $15.4 million, and we had an accumulated deficit of approximately $12.6 million under Celcuity LLC and approximately $21.3 million under Celcuity Inc.

We expect that our research and development and general and administrative expenses will increase as we continue to develop our CELsignia platform and additional CELsignia tests, conduct research related to the discovery of new cancer sub-types, conduct clinical trials, and pursue other business development activities. We will also start to incur sales and marketing expenses as we commercialize our CELsignia tests. We expect to use cash on hand to fund our research and development expenses, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses, as well as for the increased costs associated with being a public company.

Based on our current business plan, we believe that our current cash on hand will provide sufficient cash to finance operations and pay obligations when due for at least the next twelve months.

We may seek to raise additional capital to expand our business, pursue strategic investments, and take advantage of financing or other opportunities that we believe to be in the best interests of the Company and our stockholders. Additional capital may be raised through the sale of common or preferred equity or convertible debt securities, entry into debt facilities or other third-party funding arrangements. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. Agreements entered into in connection with such capital raising activities could contain covenants that would restrict our operations or require us to relinquish certain rights. Additional capital may not be available on reasonable terms, or at all.

Cash Flows

	Six Months Ended June 30,	
	2020	**2019**
	(unaudited)	
Net cash provided by (used in):		
Operating activities	$ (3,389,646)	$ (2,816,953)
Investing activities	(66,589)	1,561,172
Financing activities	151,792	228,862
Net decrease in cash and cash equivalents	$ (3,304,443)	$ (1,026,919)

Operating Activities

Net cash used in operating activities was approximately $3.39 million for the six months ended June 30, 2020 and consisted primarily of a net loss of approximately $4.45 million and working capital changes of approximately $0.02 million, offset by non-cash expense items of approximately $1.08 million. Non-cash expense items of approximately $1.08 million primarily consisted of depreciation expense of $0.19 million and $0.89 million of stock-based compensation expense. The net cash used in operating activities was approximately $2.82 million for the six months ended June 30, 2019 and consisted primarily of a net loss of approximately $3.57 million, adjusted for working capital changes of approximately $0.21 million and non-cash expense items of approximately $0.54 million. The approximately $0.21 million of working capital changes was primarily due to decreases in prepaid assets and increases in accounts payable and accrued expenses. Non-cash expense items of approximately $0.54 million primarily consisted of depreciation expense of $0.16 million and stock-based compensation expense of approximately $0.38 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2020 was approximately $0.07 million and consisted of purchases of property and equipment. Net cash provided by investing activities for the six months ended June 30, 2019 was approximately $1.56 million and consisted primarily of net proceeds from the sale of investments of approximately $1.74 million, offset by approximately $0.18 million for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 was approximately $0.15 million and primarily reflects net proceeds from the sale of shares of our common stock through the ATM Agreement and employee stock purchases. The net cash provided by financing activities for the six months ended June 30, 2019 was approximately $0.23 million and primarily reflects the proceeds from the exercise of common stock options and employee stock purchases.

Off-Balance Sheet Arrangements

We do not currently have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

From time to time new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed in Note 2 to our unaudited condensed financial statements included in Item 1 of Part I of this Quarterly Report, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates.

Our significant accounting policies are more fully described in Note 2 to our unaudited condensed financial statements included in Item 1 of Part I of this Quarterly Report.

Private Securities Litigation Reform Act

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Such forward-looking information is included in this Quarterly Report and in other materials filed or to be filed by us with the SEC (as well as information included in oral statements or other written statements made or to be made by us). Forward-looking statements include all statements based on future expectations. This Quarterly Report contains forward-looking statements that involve risks and uncertainties including, but not limited to, (i) our clinical trial plans and the estimated costs for such trials; (ii) our expectations with respect to costs and timelines to develop, validate and launch CELsignia tests; (iii) our beliefs related to the perceived advantages of our CELsignia tests compared to traditional molecular or other diagnostic tests; (iv) our expectations regarding the timeline of patient enrollment and results from clinical trials; (v) our expectations regarding partnering with pharmaceutical companies and other third parties; (vi) our expectations regarding revenue from sales of CELsignia tests and revenue from milestone or other payment sources; (vii) our plans with respect to research and development and related expenses for the foreseeable future; (viii) our expectations regarding business development activities, including companion diagnostic related activities with pharmaceutical companies, expanding our sales and marketing functions and the costs associated with such activities; (ix) our expectations with respect to the CELsignia tests and the analytical capabilities of such tests; (x) our beliefs regarding the ability of our cash on hand to fund our research and development expenses, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses, as well as the increased costs associated with being a public company; and (xi) our expectations regarding the impact that the COVID-19 pandemic and related economic effects will have on our business and results of operations.

In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management's beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Certain risks, uncertainties and other factors include, but are not limited to, our limited operating history; the unknown impact of the COVID-19 pandemic on our business; our initial success being heavily dependent on the success of our CELsignia HER2 Pathway Activity Test; our inability to determine whether our CELsignia tests are currently commercially viable; challenges we may face in developing and maintaining relationships with pharmaceutical company partners; the complexity and timeline for development of CELsignia tests; the uncertainty and costs associated with clinical trials; the uncertainty regarding market acceptance by physicians, patients, third-party payors and others in the medical community, and with the size of market opportunities available to us; the pricing of molecular and other diagnostic products and services that compete with us; uncertainty with insurance coverage and reimbursement for our CELsignia tests; difficulties we may face in managing growth, such as hiring and retaining a qualified sales force and attracting and retaining key personnel; changes in government regulations; and obtaining and maintaining intellectual property protection for our technology and time and expense associated with defending third-party claims of intellectual property infringement, investigations or litigation threatened or initiated against us. These and additional risks, uncertainties and other factors are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2019 and elsewhere in this Quarterly Report. Copies of filings made with the SEC are available through the SEC's electronic data gathering analysis and retrieval system (EDGAR) at www.sec.gov.

You should read the cautionary statements made in this Quarterly Report as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report. We cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Quarterly Report completely. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of June 30, 2020. Based on that review and evaluation, the Certifying Officers have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures, as designed and implemented, are effective and provide reasonable assurance that information required to be disclosed by us in the periodic and current reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the periods specified by the SEC's rules and forms.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. — OTHER INFORMATION

ITEM 1. Legal Proceedings

From time to time we may be involved in disputes or litigation relating to claims arising out of our operations. We are not currently a party to any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition and results of operations.

ITEM 1A. Risk Factors

As a smaller reporting company, we are not required to provide disclosure pursuant to this item. However, in addition to other information set forth in this Quarterly Report, including the important information in the section entitled "Private Securities Litigation Reform Act," you should carefully consider the "Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2019 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Quarterly Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results. You should also consider the following risk factor:

The COVID-19 pandemic may materially and adversely impact our business, including ongoing clinical trials.

The outbreak of COVID-19 and government measures taken in response have had a significant impact on the global economy, with healthcare systems particularly affected. In response to the COVID-19 outbreak, public health measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, and partners. Due to these public health measures, we are allowing employees who do not need to be physically present in the lab to perform their work at home. Our increased reliance on employees working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

As a result of the COVID-19 outbreak and related public health measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in clinical trials and obtaining the results of completed clinical trials;
- increased rates of patients withdrawing from clinical trials following enrollment as a result of quarantine or concerns about COVID-19;
- diversion of healthcare resources away from the conduct of clinical trials;
- delays in prospective clinical trial collaborations with pharmaceutical companies and sponsors.
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and
- limitations on employee resources that would otherwise be focused on the conduct of clinical trials and research as a result of focus addressing COVID-19 mitigation and loss of productivity from remote work.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the magnitude of the pandemic, the duration of social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Beyond the direct effect of the pandemic, mitigation efforts have had broad economic effects. The extent of the scope and duration of these economic effects cannot currently be predicted, although they are likely to be significant for the near future. The economic impact of COVID-19 will affect us in a variety of ways, including without limitation making our stock price more volatile, making it more difficult to raise additional capital through offerings of equity or debt securities, and reducing the availability of bank loans. As a result, we may face difficulties raising capital and capital raising efforts may be on terms than are less favorable than would have been previously available.

All of the effects of COVID-19 described herein are expected to apply to any future recurrences of COVID-19 and any other pandemics that may occur in the future.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Initial Public Offering of Common Stock

On September 22, 2017, we completed our initial public offering of 2,760,000 shares of our common stock at a price to the public of $9.50 per share. The total number of shares of common stock sold in the offering includes the exercise of an overallotment we granted to Craig-Hallum Capital Group LLC, the sole managing underwriter of the offering, to purchase 360,000 shares of common stock. The shares of common stock were registered for sale pursuant to Registration Statements on Form S-1 (Registration Nos. 333-220128 and 333-220527), filed with the SEC and declared effective on September 19, 2017 (the "Effective Date"). The aggregate offering price for the registered shares of common stock was approximately $26.2 million. The offering commenced on September 20, 2017 and did not terminate before all of the shares of common stock that were registered were sold.

The aggregate offering price for the shares of common stock sold in the offering was approximately $26.2 million. We received net proceeds of approximately $23.3 million from the offering, after deducting underwriting discounts and commissions of approximately $1.8 million and offering expenses of approximately $1.1 million. No payments for the foregoing expenses were made by us to any of our officers, directors or persons owning ten percent or more of our common stock, or to the associates of any of the foregoing, or to its affiliates, other than payments in the ordinary course of business to our officers for salaries and bonuses.

There has been no material change in the planned use of proceeds as described in our Prospectus filed with the SEC on September 20, 2017. From the Effective Date through June 30, 2020, we have used approximately $8.5 million in furtherance of our planned use of proceeds, which includes funding additional research and development for discovery of new cancer sub-types and development and validation of new CELsignia tests; clinical trials to support clinical claims; development of operational processes and capital expenditures; and working capital and other general corporate purposes.

Recent Unregistered Sales of Equity Securities

None

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation filed September 15, 2017, as amended by the Certificate of Amendment of Certificate of Incorporation, filed May 11, 2018, incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018.
3.2	Bylaws, incorporated by reference from Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2017.
4.1	Specimen Certificate representing shares of common stock of Celcuity Inc., incorporated by reference from Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed September 12, 2017.
10.1	Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan, incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 14, 2020.
10.2	At Market Issuance Sales Agreement, dated June 5, 2020, between Celcuity Inc. and B. Riley FBR, Inc., incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 5, 2020.
10.3*	Commercial Lease, First Amendment to Lease, dated July 28, 2020, between West Glen Development I, LLC and Celcuity Inc.
31.1*	Certification of Chairman and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chairman and Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2020, formatted in Inline XBRL: (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Changes in Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) the Notes to Condensed Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

_____

* Filed herewith.

** Furnished herewith.

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 thereunto duly authorized.

Dated: August 10, 2020

CELCUITY INC.

By /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive Officer
(Principal Executive Officer)

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian F. Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celcuity Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 10, 2020

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

EXHIBIT 31.2

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vicky Hahne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celcuity Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 10, 2020

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (the "Report") by Celcuity Inc. ("Registrant"), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 10, 2020

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (the "Report") by Celcuity Inc. ("Registrant"), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 10, 2020

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer

FIRST AMENDMENT TO LEASE

This First Amendment to Lease ("Amendment"), dated this 28th day of July, 2020, is by and between **West Glen Development I, LLC**, a Minnesota limited liability company ("Landlord") and **Celcuity, Inc.,** a Delaware corporation ("Tenant"), and amends that certain Commercial Lease agreement dated the 28th day of September, 2017, (the "**Lease Agreement**") by and between Landlord and Tenant with respect to that certain building located at 16305 – 36th Avenue North, the City of Plymouth, Hennepin County, Minnesota. Unless otherwise indicated, the terms defined in the Lease Agreement shall have the same meanings when used herein.

WHEREAS, the parties agreed to extend the Term of the Lease Agreement pursuant to Section 45 of the Lease Agreement, except for the Base Rent adjustment as provided herein.

NOW, THEREFORE, in consideration of the foregoing, the parties hereby agree that:

1. **TERM.** The Term of the Lease commenced May 15, 2018 and will be extended for one (1) year to terminate on April 30, 2022, unless sooner terminated in accordance with the provisions of the Lease Agreement.

2. **BASE RENT.** The monthly installments of Base Rent payable for the Premises during the Term are as follows:

Months	Price Per Square Foot	Monthly
May 1, 2021- April 30, 2022	$11.95	$16,235.07

3. **SECTION 45 OF LEASE AGREEMENT.** Section 45 of the Lease Agreement, Option to Extend Term, shall be deleted and replaced with the following:

A. Subject to the provisions of Article 45B below and provided this Lease Agreement or Tenant's right of possession hereunder has not been earlier terminated, Tenant shall have the right to extend the Term of the Lease Agreement as to all, but not less than all, of the Premises then being leased hereunder, for one additional period of one (1) year beginning immediately following the end of the Term (the "**Extended Term**") subject to the following terms and conditions:

(i) Tenant shall give written notice to Landlord of the exercise of Tenant's right to extend the Term of this Lease Agreement no later than nine (9) months prior to the commencement of the Extended Term, time being of the essence (the "**Renewal Notice**"). If no such Renewal Notice is timely given, this Lease Agreement shall terminate as of the end of the initial Term;
(ii) Tenant shall not be in default under this Lease Agreement beyond the passage of any applicable period of cure, grace or notice at the time of giving the Renewal Notice or at any time thereafter to and including the commencement of the Extended Term; and
(iii) The extension of the Term hereunder for the Extended Term shall be on the same terms and conditions as are applicable to the initial Term;

provided, however, (i) Tenant shall have no further right to extend the Term of this Lease Agreement, and (ii) the Base Rent payable by Tenant to Landlord in monthly installments during the Extended Term shall be as follows:

Months	Price Per Square Foot	Monthly
May1, 2022 to April 30, 2023	$12.52	$17,019.89

B. It is acknowledged and agreed by the parties that the right of Tenant (hereafter the "**Original Tenant**") to extend the Term of this Lease Agreement under Article 45A above is personal to Original Tenant. and should said Original Tenant either assign this Lease Agreement or sublet all or any part of the Premises to any person or entity other than to an Affiliate of said Original Tenant, Article 45A above shall automatically become null and void and of no further force or effect.

4. **POSSESSION.** Tenant acknowledges and agrees that the Premises and Tenant Improvements have been delivered to Tenant by Landlord in the condition required by the Lease Agreement and Tenant has accepted possession of the Premises in such condition.

5. **"AS IS."** Tenant accepts the Premises as is, where is, and without any warranty or representation, express or implied, or arising by operation of law, including, but in no way limited to, any warranty of quantity, quality, condition, habitability, merchantability, suitability or fitness for a particular purpose.

6. **Brokerage.** With regard to Section 41 of the Lease, each of the parties represents and warrants that there are no Leasing Commissions due in connection with this Amendment, and agrees to indemnify the other party against, and hold it harmless from all liabilities arising from any claim for Leasing Commissions asserted by a broker, agent or other person or entity claiming through the indemnifying party, including without limitation, reasonable attorneys fees incurred in connection therewith.

Except as otherwise stated herein, all of the remaining terms and conditions of the Lease Agreement shall continue to be unchanged, in full force and effect.

Landlord:

West Glen Development I, LLC
A Minnesota limited liability company

Date: _____

By: _____
Bradley L. Moen, Vice President

Date: 7/29/2020

By: _____
Michael J. Leuer, Governor

Tenant:

Celcuity, Inc.
A Delaware corporation

Date: 7-27-2020

By: _____
Name: BRIAN SULLIVAN
Its: CEO

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