

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, 2019

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
(State of incorporation)

No. 82-2863566
(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	☒

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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

On July 31, 2019 there were 10,239,165 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

Celcuity Inc.
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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, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	\$ 14,917,690	\$ 15,944,609
Investments	7,196,906	8,952,907
Deposits	22,009	22,009
Deferred transaction costs	28,743	28,743
Prepaid assets	185,532	269,940
Total current assets	22,350,880	25,218,208
Property and equipment, net	816,054	813,613
Operating lease right-of-use assets	275,483	-
Total Assets	<u>\$ 23,442,417</u>	<u>\$ 26,031,821</u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 141,216	\$ 119,811
Capital lease liabilities	5,749	5,730
Operating lease liabilities	181,330	-
Accrued expenses	557,194	536,791
Total current liabilities	885,489	662,332
Capital lease liabilities	16,999	19,878
Operating lease liabilities	146,490	-
Total Liabilities	<u>1,048,978</u>	<u>682,210</u>
Stockholders' Equity:		
Preferred stock, \$0.001 par value: 2,500,000 shares authorized as of June 30, 2019 and December 31, 2018; 0 shares issued and outstanding as of June 30, 2019 and December 31, 2018	-	-
Common stock, \$0.001 par value: 25,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 10,220,316 and 10,186,382 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	10,220	10,186
Additional paid-in capital	35,437,346	34,827,467
Accumulated deficit	(13,054,127)	(9,488,042)
Total Stockholders' Equity	<u>22,393,439</u>	<u>25,349,611</u>
Total Liabilities and Stockholders' Equity	<u>\$ 23,442,417</u>	<u>\$ 26,031,821</u>

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 1,469,731	\$ 1,546,537	\$ 3,060,689	\$ 3,092,205
General and administrative	371,988	382,646	755,533	913,286
Total operating expenses	1,841,719	1,929,183	3,816,222	4,005,491
Loss from operations	(1,841,719)	(1,929,183)	(3,816,222)	(4,005,491)
Other income (expense)				
Interest expense	(41)	-	(85)	-
Interest income	121,583	112,722	250,221	221,084
Other income (expense), net	121,542	112,722	250,136	221,084
Net loss before income taxes	(1,720,177)	(1,816,461)	(3,566,086)	(3,784,407)
Income tax benefits	-	-	-	-
Net loss	\$ (1,720,177)	\$ (1,816,461)	\$ (3,566,086)	\$ (3,784,407)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.18)	\$ (0.35)	\$ (0.37)
Weighted average common shares outstanding, basic and diluted	10,213,455	10,110,558	10,206,000	10,103,323

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	Accumulated	
	Shares	Amount	Paid-In	Deficit	Total
			Capital		
Balance at December 31, 2018	10,186,382	\$ 10,186	\$ 34,827,467	\$ (9,488,042)	\$ 25,349,611
Stock-based compensation	-	-	120,991	-	120,991
Non-employee stock-based compensation	-	-	63,654	-	63,654
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	-	-	125,633	-	125,633
Non-employee stock-based compensation	-	-	66,613	-	66,613
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)	<u>10,220,316</u>	<u>\$ 10,220</u>	<u>\$ 35,437,346</u>	<u>\$ (13,054,127)</u>	<u>\$ 22,393,439</u>

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months and Six Months Ended June 30, 2018

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balance at December 31, 2017	10,087,516	\$ 10,087	\$ 33,388,597	\$ (2,007,227)	\$ 31,391,457
Exercise of common stock warrants	19,343	20	183,739	-	183,759
Stock-based compensation			157,012	-	157,012
Non-employee stock-based compensation	-	-	179,467	-	179,467
Net loss	-	-	-	(1,967,947)	(1,967,947)
Balance at March 31, 2018 (unaudited)	10,106,859	\$ 10,107	\$ 33,908,815	\$ (3,975,174)	\$ 29,943,748
Stock-based compensation	-	-	151,347	-	151,347
Non-employee stock-based compensation	2,571	2	124,936	-	124,938
Employee stock purchases	9,882	10	79,787	-	79,797
Net loss	-	-	-	(1,816,461)	(1,816,461)
Balance at June 30, 2018 (unaudited)	<u>10,119,312</u>	<u>\$ 10,119</u>	<u>\$ 34,264,885</u>	<u>\$ (5,791,635)</u>	<u>\$ 28,483,369</u>

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (3,566,086)	\$ (3,784,407)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	159,338	89,704
Stock-based compensation	376,891	612,764
Non-cash interest income, net of cash received	11,001	2,705
Changes in operating assets and liabilities:		
Prepaid assets and deposits	84,408	55,706
Accounts payable	44,755	12,604
Accrued expenses	84,278	226,643
Non-cash operating lease, net	(11,538)	-
Net cash used for operating activities	<u>(2,816,953)</u>	<u>(2,784,281)</u>
Cash flows from investing activities:		
Purchases of investments	-	(3,235,000)
Proceeds from sale of investments	1,745,000	6,660,000
Purchases of property and equipment	(183,828)	(372,282)
Proceeds from sale of property and equipment	-	1,000
Net cash provided by investing activities	<u>1,561,172</u>	<u>3,053,718</u>
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	-	183,759
Proceeds from employee stock options exercised	174,957	-
Proceeds from employee stock purchases	58,065	79,797
Payments for secondary registration statement costs	(1,300)	-
Payments for capital leases	(2,860)	-
Net cash provided by financing activities	<u>228,862</u>	<u>263,556</u>
Net change in cash, cash equivalents, and restricted cash	<u>(1,026,919)</u>	<u>532,993</u>
Cash, cash equivalents, and restricted cash:		
Beginning of period	15,944,609	2,689,789
End of period	<u>\$ 14,917,690</u>	<u>\$ 3,222,782</u>

The following table shows the composition of cash, cash equivalents, and restricted cash reported within the balance sheets that sum to the same such amounts in the statements of cash flows as of June 30:

	2019	2018
Cash and cash equivalents	\$ 14,917,690	\$ 3,172,782
Restricted cash	-	50,000
Total	<u>\$ 14,917,690</u>	<u>\$ 3,222,782</u>

Supplemental disclosures of non-cash investing and financing activities:

Property and equipment included in accounts payable	\$ 2,005	\$ 64,883
Property and equipment funded by capital lease	-	28,932
Leasehold improvements funded by landlord and related deferred rent included in accrued expenses	-	75,000

See accompanying notes to the financial statements

CELCUITY INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)
(For the Three and Six Months Ended June 30, 2019 and 2018)

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the “Company”), is a cellular analysis company that is discovering new cancer sub-types and commercializing diagnostic tests designed to significantly improve the response rates of cancer patients treated with targeted therapies. The Company’s proprietary CELx diagnostic platform is currently the only commercially ready technology the Company is aware of that uses a patient’s living tumor cells to evaluate the functional status of the cell signaling pathways associated with cancer. The CELx platform identifies the abnormal signaling activity driving a patient’s cancer and quantifies how effectively a targeted therapy can treat it. This enables physicians to select the therapeutic that precisely matches and inhibits a patient’s cellular dysfunction, which significantly increases the likelihood of a positive clinical outcome. The Company was co-founded in 2012 by Brian Sullivan and Lance 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, 2018 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, 2018 and the related footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018. Operating results for the three and six months ended June 30, 2019 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. 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 are 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 the FASB 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 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, *Leases*, 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-month period ended June 30, 2019. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed us to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 5.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which amended *Statement of Cash Flows (Topic 230)* of the Accounting Standards Codification (“ASC”). The new guidance requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted this standard as of January 1, 2018 and applied it retrospectively.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Non-employee Share-Based Payment Accounting*, which expands the scope of ASC 718, *Compensation – Stock Compensation*, to include share-based payment transactions for acquiring goods and services from non-employees and to supersede the guidance in ASC 505-50. The new guidance is substantially the same as current guidance for employee awards. The Company adopted this standard as of April 1, 2018 using the modified retrospective approach. The remeasurement of open awards to non-employees was based on the fair value of such awards as of the date of adoption and resulted in no material change to accumulated deficit or additional paid-in capital.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders’ equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders’ equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of operations is required to be filed. The Company included its first presentation of changes in stockholders’ equity in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

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, 2019 and 2018, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 406,518 and 522,755 shares of common stock, respectively, warrants to purchase 353,980 shares of common stock, and 0 and 2,571 shares of restricted common stock, respectively.

4. Investments

The following tables summarizes the Company's held-to-maturity investment securities at amortized cost as of June 30, 2019 and December 31, 2018:

June 30, 2019				
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Certificates of Deposit	\$ 4,170,457	\$ -	\$ 7,093	\$ 4,163,364
Governmental Agency Securities	3,026,449	-	3,976	3,022,473
Total	<u>\$ 7,196,906</u>	<u>\$ -</u>	<u>\$ 11,069</u>	<u>\$ 7,185,837</u>

December 31, 2018				
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Certificates of Deposit	\$ 4,415,548	\$ -	\$ 33,526	\$ 4,382,022
Governmental Agency Securities	3,038,217	-	24,444	3,013,773
U.S. Treasury Notes	1,499,142	-	2,130	1,497,012
Total	<u>\$ 8,952,907</u>	<u>\$ -</u>	<u>\$ 60,100</u>	<u>\$ 8,892,807</u>

The Company's held-to-maturity investments of \$7,196,906 will mature in 2019.

5. 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.

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 related to leases was as follows:

	June 30, 2019
Operating Lease	
Right-of-use asset	\$ 275,483
	June 30, 2019
Operating lease liability	\$ 327,820
Less: short term portion	(181,330)
Long term portion	<u>\$ 146,490</u>
	June 30, 2019
Finance Lease	
Furniture and equipment	\$ 28,932
Less: Accumulated depreciation	(6,269)
Net book value of property and equipment under finance lease	<u>\$ 22,663</u>
	June 30, 2019
Finance lease liability	\$ 22,748
Less: short term portion	(5,749)
Long term portion	<u>\$ 16,999</u>

Maturity analysis under lease agreements was as follows:

	Operating Leases	Finance Leases
2019	\$ 95,187	\$ 3,627
2020	193,338	7,255
2021	64,940	7,255
2022	-	7,255
2023	-	3,022
Total minimum lease payments	<u>353,465</u>	<u>28,414</u>
Less: Present value discount	(25,645)	(316)
Less amount representing services	-	(5,350)
Present value of net minimum lease payments	<u>\$ 327,820</u>	<u>\$ 22,748</u>
	Remaining Lease Term	Discount Rate
Weighted Average		
Operating lease	1.8 years	5.5%
Finance lease	3.9 years	1.0%

Lease costs for the period ended June 30, 2019:

	Three-month Period	Six-month Period
Operating lease cost	\$ 41,063	\$ 82,126
Finance lease cost:		
Amortization	1,447	2,893
Interest	41	85
Variable lease cost	19,650	43,584
	<u>\$ 62,201</u>	<u>\$ 128,688</u>

Supplemental cash flow information related to leases for the period ended June 30, 2019:

	Three-month Period	Six-month Period
Cash paid for amounts included in operating and finance leases:		
Operating cash outflow from operating leases	\$ 51,037	\$ 121,082
Operating cash outflow from finance leases	383	767
Financing cash outflow from finance leases	1,431	2,860
	<u>\$ 52,851</u>	<u>\$ 124,709</u>

Clinical Research Study

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 is obligated to make a payment of approximately \$32,000 after execution of the agreement and future payments of approximately \$150,000 will be required upon certain milestones being met.

6. Stock-Based Compensation

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

	2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	478,503	\$ 9.73	501,603	\$ 7.58
Granted	30,216	22.42	21,152	18.93
Exercised	(28,170)	7.10	-	-
Forfeited	(74,031)	10.39	-	-
Balance at June 30	406,518	\$ 10.73	522,755	\$ 8.04
Options exercisable at June 30:	267,739	\$ 7.64	262,393	\$ 6.72
Weighted Average Grant Date Fair Value for options granted during the period:		\$ 14.94		\$ 14.02

The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2019:

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
406,518	7.16	\$ 10.73	\$ 5,829,873	267,739	\$ 7.64	\$ 4,647,419

The Company recognized stock-based compensation expense for stock options of \$337,700 and \$501,158 for the six months ended June 30, 2019 and 2018, respectively, and \$174,871 and \$235,060 for the three months ended June 30, 2019 and 2018, respectively.

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:

	2019	2018
Risk-free interest rate	1.82% - 2.47%	2.52% - 2.97%
Expected volatility	78.1% - 80.0%	76.0%
Expected life (years)	5.5 to 6.08	6.25 to 10.00
Expected dividend yield	0%	0%

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to the Company's IPO, the price per share of common stock was determined by the Company's board based on recent prices of shares of common stock sold in private offerings. Subsequent to the IPO, the price per share of common stock is determined by using the quoted price 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.

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. Unvested non-employee options were marked-to-market as of April 1, 2018, the date that the Company adopted ASU No. 2018-07, *Improvements to Non-employee Share-Based Payment Accounting*.

A restricted stock award of 2,571 shares was granted to a member of the Company's board in 2018. The Company had 0 and 2,571 shares of restricted stock outstanding as of June 30, 2019 and 2018, respectively, and 2,571 and 5,250 shares of restricted stock vested during the six months ended June 30, 2019 or 2018. The Company recognized stock-based compensation expense for restricted stock of \$17,047 and \$64,719 for the six months ended June 30, 2019 and 2018, respectively, and \$4,260 and \$22,431 for the three months ended June 30, 2019 and 2018, respectively.

The total remaining shares available for grant under the 2017 Plan is 603,468.

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

2019	\$ 370,773
2020	461,576
2021	287,659
2022	126,068
2023	9,027
Total estimated compensation cost to be recognized	<u>\$ 1,255,103</u>

The Company recognized stock-based compensation expense related to the ESPP of \$22,144 and \$46,887 for the six months ended June 30, 2019 and 2018, respectively, and \$13,115 and \$18,793 for the three months ended June 30, 2019 and 2018, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock-based compensation expense in operating expenses:				
Research and development	\$ 101,303	\$ 175,864	\$ 201,560	\$ 337,535
General and administrative	90,943	100,420	175,331	275,229
Total	<u>\$ 192,246</u>	<u>\$ 276,284</u>	<u>\$ 376,891</u>	<u>\$ 612,764</u>

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, 2018 filed with the Securities and Exchange Commission on March 1, 2019 and elsewhere in this Quarterly Report on Form 10-Q 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 a cellular analysis company that is discovering new cancer sub-types and commercializing diagnostic tests designed to significantly improve the clinical outcomes of cancer patients treated with targeted therapies. Our proprietary CELx 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 CELx 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 dead cells. Using dead cells prevents molecular diagnostics from analyzing in real-time the dynamic cellular activities, known as cell signaling, that regulate cell proliferation or survival. Cancer can develop when certain cell signaling activity becomes abnormal. Since genetic mutations are often only weakly correlated to the cell signaling activity driving a patient's cancer, a molecular diagnostic is prone to providing an incomplete diagnosis. CELx tests overcome this limitation by measuring real-time cell signaling activity in a patient's living tumor cells. When a CELx 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, CELx 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 CELx platform, the CELx HSF 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 CELx HSF Test.

We completed development of our second CELx test for breast cancer during the first quarter of 2018. This new test 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 intend to combine this c-Met signaling function test with our current HER2 signaling function test to create the CELx Multi-Pathway Signaling Function (MP) Test, or CELx MP Test. With this next generation CELx test, we plan to provide an analysis of HER1, HER2, HER3, and c-MET signaling activity with a single patient tumor specimen.

In addition to the two new breast cancer sub-types our CELx MP Test diagnoses, we are developing CELx tests to diagnose 12 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 CELx HSF Test to select breast cancer patients for treatment with HER2 targeted therapies. For the first of these collaborations, we are fielding a prospective clinical trial with Genentech and the NSABP to evaluate the efficacy of Genentech's HER2 targeted therapies in patients with abnormal HER2 signaling. We expect interim results from this trial in early to mid-2020 and final results approximately nine months later. For the second of these collaborations, we are fielding a prospective clinical trial with Puma Biotechnology, Inc. ("Puma") and West Cancer Center to evaluate the efficacy and safety of Puma's drug, Nerlynx, and chemotherapy, in breast cancer patients selected with our CELx HSF Test. The trial was activated in early 2019 and we expect to obtain interim results in early to mid-2020 and final results approximately 12 months later.

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 2020. Unlike the trial with NSABP and Genentech, our 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 CELx 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 the CELx MP Test, we will seek collaborations with pharmaceutical companies to field clinical trials that evaluate the efficacy of combining HER family inhibitors and c-Met inhibitors in breast cancer patients who have abnormal c-Met and abnormal HER1 pathway activity. The FDA has approved two c-Met inhibitors and six HER-family inhibitors for cancer treatment. Additional c-Met and HER-family inhibitors are being evaluated in on-going clinical trials. Several pharmaceutical companies possess both a c-Met and a HER family inhibitor.

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 six months ended June 30, 2019 and 2018, we reported a net loss of approximately \$3.6 million and \$3.8 million, respectively, and for the three months ended June 30, 2019 and 2018, we reported a net loss of approximately \$1.7 million and \$1.8 million, respectively. As of June 30, 2019, we had a combined accumulated deficit of approximately \$12.6 million under Celcuity LLC and \$13.1 million under Celcuity Inc. As of June 30, 2019, we had cash, cash equivalents, and investments of approximately \$22.1 million.

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 CELx platform, development and validation of our CELx 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, 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 CELx 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 travel expenses for our general and administrative personnel, professional fees for auditing, tax, and legal services associated with being a public company and director and officer insurance.

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 CELx platform and corresponding CELx tests. We expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first CELx 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

	Three Months Ended June 30,		Increase (Decrease)	
	2019	2018	\$	Percent Change
	(unaudited)			
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 1,469,731	\$ 1,546,537	\$ (76,806)	-5%
General and administrative	371,988	382,646	(10,658)	(3)
Total operating expenses	1,841,719	1,929,183	(87,464)	(5)
Loss from operations	(1,841,719)	(1,929,183)	87,464	(5)
Other income (expense)				
Interest expense	(41)	-	(41)	n/a
Interest income	121,583	112,722	8,861	8
Other income (expense), net	121,542	112,722	8,820	8
Net loss before income taxes	(1,720,177)	(1,816,461)	96,284	(5)
Income tax benefits	-	-	-	-
Net loss	\$ (1,720,177)	\$ (1,816,461)	\$ 96,284	-5%

	Six Months Ended June 30,		Increase (Decrease)	
	2019	2018	\$	Percent Change
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 3,060,689	\$ 3,092,205	\$ (31,516)	-1%
General and administrative	755,533	913,286	(157,753)	(17)
Total operating expenses	3,816,222	4,005,491	(189,269)	(5)
Loss from operations	(3,816,222)	(4,005,491)	189,269	(5)
Other income (expense)				
Interest expense	(85)	-	(85)	n/a
Interest income	250,221	221,084	29,137	13
Other income (expense), net	250,136	221,084	29,052	13
Net loss before income taxes	(3,566,086)	(3,784,407)	218,321	(6)
Income tax benefits	-	-	-	-
Net loss	\$ (3,566,086)	\$ (3,784,407)	\$ 218,321	-6%

Research and Development

Our research and development expenses for the three months ended June 30, 2019 were approximately \$1.47 million, representing a decrease of approximately \$0.08 million, or 5%, compared to the same period in 2018. The decrease primarily resulted from a \$0.08 million decrease in non-cash stock-based compensation.

Our research and development expenses for the six months ended June 30, 2019 were approximately \$3.06 million, representing a decrease of approximately \$0.03 million, or 1%, compared to the same period in 2018. The decrease primarily resulted from a \$0.1 million decrease in non-cash stock-based compensation, offset by a \$0.07 million increase in 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 CELx 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 CELx tests.

General and Administrative

Our general and administrative expenses for the three months ended June 30, 2019 were approximately \$0.37 million representing a decrease of approximately \$0.01 million, or 3%, compared to the same period in 2018. The decrease primarily resulted from a decrease in non-cash stock-based compensation.

Our general and administrative expenses for the six months ended June 30, 2019 were approximately \$0.76 million representing a decrease of approximately \$0.16 million, or 17%, compared to the same period in 2018. The decrease primarily resulted from a decrease 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 CELx 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, 2019 is related to finance lease liabilities.

Interest Income

Interest income for the three months ended June 30, 2019 was approximately \$0.12 million, representing an increase of approximately \$0.01 million, or 8%. The increase resulted from higher market interest rates.

Interest income for the six months ended June 30, 2019 was approximately \$0.25 million, representing an increase of approximately \$0.03 million, or 13%. The increase resulted from higher market interest rates.

Liquidity and Capital Resources

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through June 30, 2019, 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. Cash from these capital raising activities has been our primary source of funds for our operations since inception. As of June 30, 2019, our cash, cash equivalents, and investments were approximately \$22.1 million, and we had a combined accumulated deficit of approximately \$12.6 million under Celcuity LLC and approximately \$13.1 million under Celcuity Inc.

We expect that our research and development and general and administrative expenses will increase as we continue to develop our CELx platform and additional CELx 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 CELx 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 during at least the next 24 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,	
	2019	2018
	(unaudited)	
Net cash provided by (used in):		
Operating activities	\$ (2,816,953)	\$ (2,784,281)
Investing activities	1,561,172	3,053,718
Financing activities	228,862	263,556
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (1,026,919)</u>	<u>\$ 532,993</u>

Operating Activities

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 \$0.38 million of stock-based compensation expense. The net cash used in operating activities was approximately \$2.78 million for the six months ended June 30, 2018 and consisted primarily of a net loss of approximately \$3.78 million, adjusted for working capital changes of approximately \$0.3 million and for non-cash items of approximately \$0.7 million. The approximately \$0.3 million of working capital changes was primarily due to increases in accounts payable and accrued expenses. Non-cash expense items of approximately \$0.7 million primarily consisted of depreciation expense of \$0.09 million and \$0.61 million of stock-based compensation expense.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2019 was approximately \$1.56 million and consisted of net proceeds from the sale of investments of \$1.74 million, adjusted for approximately \$0.18 million of purchases of property and equipment. Net cash provided by investing activities for the six months ended June 30, 2018 was approximately \$3.05 million and consisted of approximately \$3.42 million of net proceeds from the sale and purchase of investments, adjusted for approximately \$0.37 million of purchases of property and equipment.

Financing Activities

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 stock options and employee stock purchases. The net cash provided by financing activities for the six months ended June 30, 2018 was approximately \$0.26 million and reflects the proceeds from the exercise of common stock warrants 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 FASB, 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 or elsewhere in 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 accounting principles generally accepted in the United States, or Generally Accepted Accounting Principles ("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 Securities and Exchange Commission (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 CELx tests; (iii) our beliefs related to the perceived advantages of our CELx 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 CELx 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 CELx MP Test and the analytical capabilities of such test; and (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.

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 risk, uncertainties and other factors include, but are not limited to, our limited operating history; our initial success being heavily dependent on the success of our CELx HSF Test; our inability to determine whether our CELx 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 CELx 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 CELx 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, 2018. 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 these risk factors and the other 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 (the “Exchange Act”)) as of June 30, 2019. As previously disclosed under “Item 9A – Controls and Procedures” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, we concluded that our internal control over financial reporting was not effective due to limited segregation of duties. Based on that assessment, the Certifying Officers have concluded that, as of the end of the period covered by this Report, our disclosure controls and procedures, as designed and implemented, were not effective. Nevertheless, we believe that the unaudited condensed financial statements in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

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, 2019 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 on Form 10-Q, 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, 2018, and elsewhere in this Quarterly Report on Form 10-Q, 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. 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.

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 IPO 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 IPO includes the exercise of an overallotment we granted to Craig-Hallum Capital Group LLC, the sole managing underwriter of the IPO (“Craig-Hallum”), 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 in the Registration Statement were sold.

The aggregate offering price for the shares 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, 2019, we did not use any material portion of the offering proceeds.

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
<u>3.1</u>	<u>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.</u>
<u>3.2</u>	<u>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.</u>
<u>4.1</u>	<u>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.</u>
<u>31.1*</u>	<u>Certification of Chairman and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2*</u>	<u>Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.1**</u>	<u>Certification of Chairman and Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.2**</u>	<u>Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2019, formatted in 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.

* 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 8, 2019

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)

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 8, 2019

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

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 8, 2019

By /s/ Vicky Hahne
 Vicky Hahne
 Chief Financial Officer

**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, 2019 (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 8, 2019

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

**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, 2019 (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 8, 2019

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer
