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 March 31, 2024

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	☐

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 May 8, 2024 there were 31,230,085 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

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 31,214,741	$ 30,662,774
Investments	146,447,843	149,919,974
Other current assets	9,860,535	10,007,849
Total current assets	187,523,119	190,590,597
Property and equipment, net	306,024	228,782
Operating lease right-of-use assets	351,911	400,019
Total Assets	$ 188,181,054	$ 191,219,398
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 5,276,690	$ 5,076,699
Operating lease liabilities	181,882	184,950
Accrued expenses	11,237,509	8,927,094
Total current liabilities	16,696,081	14,188,743
Operating lease liabilities	182,079	225,922
Note payable, non-current	37,566,230	37,035,411
Total Liabilities	54,444,390	51,450,076
Commitments and Contingencies (Note 5)		
Stockholders' Equity:		
Preferred stock, $0.001 par value: 2,500,000 shares authorized; 505,277 and 854,134 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	505	854
Common stock, $0.001 par value: 65,000,000 shares authorized; 30,773,895 and 25,506,012 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	30,774	25,506
Additional paid-in capital	315,393,843	299,818,965
Accumulated deficit	(181,688,458)	(160,076,003)
Total Stockholders' Equity	133,736,664	139,769,322
Total Liabilities and Stockholders' Equity	$ 188,181,054	$ 191,219,398

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended March 31, 2024	2023
Operating expenses:		
Research and development	$ 20,647,559	$ 11,278,493
General and administrative	1,846,276	1,269,044
Total operating expenses	22,493,835	12,547,537
Loss from operations	(22,493,835)	(12,547,537)
Other income (expense)		
Interest expense	(1,400,712)	(1,242,012)

Interest income	2,282,092	1,851,132
Other income, net	881,380	609,120
Net loss before income taxes	**(21,612,455)**	**(11,938,417)**
Income tax benefits	-	-
Net loss	**$ (21,612,455)**	**$ (11,938,417)**
Net loss per share, basic and diluted	$ (0.64)	$ (0.55)
Weighted average common shares outstanding, basic and diluted	33,612,054	21,680,877

See accompanying notes to the financial statements

Celcuity Inc.
Statements of Changes in Stockholders' Equity
Three Months Ended March 31, 2024

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2023	25,506,012	$ 25,506	854,134	$ 854	$299,818,965	$(160,076,003)	$139,769,322
Stock-based compensation	-	-	-	-	1,331,346	-	1,331,346
Exercise of common stock warrants, net of shares withheld for exercise price	1,742,763	1,742	-	-	14,007,409	-	14,009,151
Exercise of common stock options, net of shares withheld for exercise price	36,550	37	-	-	239,263	-	239,300
Conversion of preferred to common stock	3,488,570	3,489	(348,857)	(349)	(3,140)	-	-
Net loss	-	-	-	-	-	(21,612,455)	(21,612,455)
Balance at March 31, 2024 ***(unaudited)***	30,773,895	$ 30,774	505,277	$ 505	$315,393,843	$(181,688,458)	$133,736,664

See accompanying notes to the financial statements

Celcuity Inc.
Statements of Changes in Stockholders' Equity
Three Months Ended March 31, 2023

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2022	21,667,250	$ 21,667	1,120,873	$ 1,121	$230,045,566	$ (96,296,887)	$133,771,467
Stock-based compensation	-	-	-	-	1,273,282	-	1,273,282
Exercise of common stock options, net of shares withheld for exercise price	24,122	24	-	-	127,898	-	127,922
Conversion of preferred to common stock	250,000	250	(25,000)	(25)	(225)	-	-
Issuance costs associated with private placement offering	-	-	-	-	(7,486)	-	(7,486)
Net loss	-	-	-	-	-	(11,938,417)	(11,938,417)
Balance at March 31, 2023 ***(unaudited)***	21,941,372	$ 21,941	1,095,873	$ 1,096	$231,439,035	$(108,235,304)	$123,226,768

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (21,612,455)	$ (11,938,417)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	29,557	43,938
Stock-based compensation	1,331,346	1,273,282
Amortization of debt issuance costs and discount	65,309	57,004
PIK interest	465,510	438,184
Non-cash operating lease, net	1,197	438
Change in accrued interest income	(153,845)	(1,697,811)

Changes in operating assets and liabilities:		
Other current assets	268,849	(15,809)
Accounts payable	237,992	(8,545)
Accrued expenses	2,298,379	(1,020,102)
Net cash used for operating activities	(17,068,161)	(12,867,838)
Cash flows from investing activities:		
Purchases of investments	(121,435,343)	(3,125,462)
Proceeds from maturities of investments	125,061,320	25,000,000
Purchases of property and equipment	(89,676)	(6,987)
Net cash provided by investing activities	3,536,301	21,867,551
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	14,009,151	-
Proceeds from exercise of employee stock options	131,090	127,922
Payments for secondary registration statement costs	(56,414)	(55,789)
Payments for debt issuance costs	-	(2,716)
Payments for finance leases	-	(1,469)
Net cash provided by financing activities	14,083,827	67,948
Net change in cash and cash equivalents	551,967	9,067,661
Cash and cash equivalents:		
Beginning of period	30,662,774	24,571,557
End of period	$ 31,214,741	$ 33,639,218
Supplemental disclosure of cash flow information:		
Interest paid	$ 869,893	$ 746,824
Supplemental disclosures of non-cash investing and financing activities:		
Offering and registration statement costs included in accounts payable	$ 13,325	$ 2,402
Property and equipment included in accounts payable	18,702	-
Property and equipment included in accrued expenses	12,036	-
Exercise of stock options pending receipt of cash proceeds	108,210	-

See accompanying notes to the financial statements

CELCUITY INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)
(For the Three Months Ended March 31, 2024 and 2023)

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical-stage biotechnology company pursuing development for oncology. The Company's lead therapeutic candidate is gedatolisib, a potent pan-PI3K and mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- advanced breast cancer is currently enrolling patients. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, was initiated in the first quarter of 2024 and is currently enrolling patients. The Company's CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved 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. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements

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, 2023 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, 2023 and the related footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. Operating results for the three months ended March 31, 2024 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 clinical and commercial success of its initial drug product, gedatolisib, 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 primarily relies on a compilation of progress reports from third-party service providers, including the respective invoicing, to record actual expenses, along with determining changes to prepaid assets and accrued liabilities. To date, the Company believes utilization of third-party reports most accurately reflects expenses incurred. As the current VIKTORIA-1 Phase 3 and CELC-G-201 Phase 1b/2 trials ramp up site activation and patient enrollment, the Company's estimated expenses in future periods and actual services performed may vary from these estimates, and these estimates may become more significant. 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.

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 preferred stock, options, warrants, and restricted stock 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.

The following table summarizes the potentially-dilutive shares excluded from the diluted weighted-average shares outstanding:

	March 31,	
	2024	2023
Preferred stock on an as-if-converted to common stock basis	5,052,770	10,958,730
Options to purchase common stock	3,049,387	2,068,458
Warrants to purchase common stock	5,517,725	7,266,102
Restricted common stock	1,958	3,273
	13,621,840	20,296,563

Pre-funded warrant shares of 5,747,787 and zero are included in the computation of basic and diluted net loss per share for the periods ended March 31, 2024, and March 31, 2023, respectively, as the pre-funded warrants are exercisable for nominal consideration.

4. Investments

Debt securities for which the Company has the positive intent and ability to hold to maturity are classified as held-to-maturity and reported at historical cost adjusted for amortization of premiums and accretion of discounts. Expected credit losses, if any, are recorded through the establishment of an allowance for credit losses. All of the Company's held-to-maturity investment securities are U.S. Treasury and agencies securities that are guaranteed or otherwise supported by the United States government and have no history of credit losses. Accordingly, the Company does not expect to incur any credit losses on held-to-maturity investment securities and has no allowance for credit losses recorded for these securities.

The following tables summarize the Company's held-to-maturity investment securities at amortized cost as of March 31, 2024 and December 31, 2023:

	March 31, 2024			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
U.S. Treasury Bills	$ 146,447,843	$ -	$ (2,059)	$ 146,445,784
Total	$ 146,447,843	$ -	$ (2,059)	$ 146,445,784

	December 31, 2023			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
U.S. Treasury Bills	$ 149,919,974	$ 30,995	$ -	$ 149,950,969
Total	$ 149,919,974	$ 30,995	$ -	$ 149,950,969

The fair value of the Company's held-to-maturity debt securities is determined based upon inputs, other than the quoted prices in active markets, that are observable either directly or indirectly and are classified as level 2 fair value instruments.

5. Commitments

Operating and Finance Leases

The Company leases its corporate space in Minneapolis, Minnesota, with an operating lease in place through April 30, 2026. The lease provides for monthly rent, real estate taxes, and operating expenses. Rent expense is recorded on a straight-line basis over the lease term.

Clinical Research Studies

The Company enters into contracts in the normal course of business to conduct research and development programs internally and through third parties that include, among others, arrangements with vendors, consultants, CMO's, and CRO's. The Company currently has three Phase 2 clinical trial agreements in place to evaluate targeted therapies selected with one of our CELsignia tests. Timing of milestone payments related to the Phase 2 clinical trials are uncertain and the contracts generally provide for termination following a certain period after notice, therefore the Company believes that non-cancelable obligations under the agreements are not material. The Company also has a license agreement in place with Pfizer to research, develop, manufacture and commercialize gedatolisib. In conjunction with the license agreement, the Company continued a Phase 1b study – B2151009 related to

gedatolisib. These patients subsequently transitioned to an Expanded Access study – CELC-G-001. Contracts related to the Phase 1B and the Expanded Access studies are generally based on time and material. In addition, contracts related to the Company's Phase 3 clinical study (VIKTORIA-1) and Phase 1b/2 clinical study (CELC-G-201) are generally cancelable with reasonable notice within 120 days and the Company's obligations under these contracts are primarily based on services performed through termination dates plus certain cancelation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subjected to amendments as a result of any change orders executed by the parties. As of March 31, 2024, the Company had two material non-cancelable contractual commitments with respect to these arrangements, which totaled approximately $2.0 million.

6. Stockholders' Equity

Capital Stock

At December 31, 2023, the Company's authorized capital stock consisted of 65,000,000 shares of $.001 par value common stock, of which 25,506,012 shares were outstanding, and 2,500,000 shares of $.001 par value preferred stock, of which 854,134 shares were outstanding.

On January 15, 2024, one of the Company's preferred shareholders elected to convert 224,244 shares of Series A Convertible Preferred Stock into 2,242,440 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $5.75 per share.

On March 14, 2024, one of the Company's preferred shareholders elected to convert 50,000 shares of Series A Convertible Preferred Stock into 500,000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $5.75 per share.

On March 15, 2024, one of the Company's investors exercised 1,739,080 of common stock warrants at an exercise price of $ 8.05, which generated approximately $14 million in cash. The warrants were issued pursuant to the Securities Purchase Agreement dated May 15, 2022, that closed and was funded on December 9, 2022. Additional common stock warrants of 3,683 from several investors were exercised, which generated approximately $ 9,000 in cash in the first quarter of 2024. The 3,683 common stock warrants were net of shares withheld for exercise price.

On March 19, 2024, one of the Company's preferred shareholders elected to convert 43,913 shares of Series A Convertible Preferred Stock into 439,130 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $5.75 per share.

On March 26, 2024, one of the Company's preferred shareholders elected to convert 30,700 shares of Series A Convertible Preferred Stock into 307,000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $5.75 per share.

At March 31, 2024, the Company's authorized capital stock consisted of 65,000,000 shares of common stock, of which 30,773,895 shares were outstanding, and 2,500,000 shares of preferred stock, including 1,850,000 shares designated as Series A Preferred Stock, of which 505,277 shares were outstanding. As of March 31, 2024, no dividends have been declared on the Company's capital stock.

7. Stock-Based Compensation

The following table summarizes the activity for all stock options outstanding for the three months ended March 31:

	2024		2023	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	2,815,392	$ 7.95	1,976,586	$ 6.34
Granted	285,795	15.29	119,985	11.36
Exercised	(36,550)	6.55	(24,122)	5.30
Forfeited	(15,250)	9.05	(3,991)	6.55
Balance at March 31	3,049,387	$ 8.65	2,068,458	$ 6.65
Options exercisable at March 31:	1,569,614	$ 6.55	1,114,767	$ 5.91
Weighted Average Grant Date Fair Value for options granted during the period:		$ 10.53		$ 7.81

The following table summarizes additional information about stock options outstanding and exercisable at March 31, 2024:

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
3,049,387	7.95	$ 8.65	$ 39,506,833	1,569,614	$ 6.55	$ 23,646,843

The Company recognized stock-based compensation expense for stock options of $ 1,290,193 and $1,222,328 for the three months ended March 31, 2024 and 2023, respectively. In May 2022, the Company modified the exercise price on 776,324 stock option awards to $5.50, the closing market price on the Nasdaq Capital Market on May 17, 2022. The effect of this modification on stock-based compensation was $26,719 and $39,612 for the three months ending March 31, 2024 and 2023, respectively. The effect of this modification on stock-based compensation over the remaining service period will be approximately $137,000. In December 2021, the Company modified the exercise price on 311,000 stock option awards to $13.44, the closing market price on the Nasdaq Capital Market on December 15, 2021. No director or officer awards were modified. The effect of this modification on stock-based compensation was $15,764 and $16,924 for the three months ended March 31, 2024 and 2023, respectively. The effect of this modification on stock-based compensation over the remaining service period will be approximately $82,000. 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 of this modification on stock-based compensation was $696 and $7,108 for the three months ended March 31, 2024 and 2023, respectively. The effect of this modification on stock-based compensation over the remaining service period will be $0.

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 three months ended March 31:

	2024	2023
Risk-free interest rate	3.94% - 4.33%	3.64% - 4.14%
Expected volatility	76.1%	79.8%
Expected life (years)	5.25 to 6.08	5.25 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.

No restricted stock awards were granted during the three months ended March 31, 2024 and 2023. The Company had 1,958 and 3,273 shares of restricted stock outstanding as of March 31, 2024 and 2023, respectively, and 0 shares of restricted stock vested during the three months ended March 31, 2024 and 2023. The Company recognized stock-based compensation expense for restricted stock of $4,849 and $4,642 for the three months ended March 31, 2024 and 2023, respectively.

The Company initially reserved a maximum of 750,000 shares of common stock for issuance under the 2017 Amended and Restated Stock Incentive Plan (the "2017 Plan"). The number of shares reserved for issuance was automatically increased by 102,998, 149,189, 216,673, and 255,060 shares on January 1, 2021, 2022, 2023, and 2024, respectively, and will increase automatically on January 1 of each year from 2025 through 2028 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.

At the annual meeting held on May 12, 2021 and May 12, 2022, the stockholders approved a one-time, 500,000 increase each year for a total of 1,000,000 increase, to the number of shares reserved for issuance under the 2017 Plan. At the Annual Meeting held on May 11, 2023, the stockholders approved a one-time, 1,500,000 increase to the number of shares reserved for issuance under the 2017 Plan. The total remaining shares available for grant under the Company's 2017 Plan as of March 31, 2024 was 1,003,414.

Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized at March 31, 2024:

2024	$	3,661,229
2025		3,483,405
2026		2,496,276
2027		1,501,013
2028		48,146
Total estimated compensation cost to be recognized	$	11,190,069

The Company recognized stock-based compensation expense related to its employee stock purchase plan of $ 36,304 and $46,312 for the three months ended March 31, 2024 and 2023, 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 51,499, 74,594, 108,337, and 127,530 shares on January 1, 2021, 2022, 2023, and 2024, respectively, 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 March 31, 2024 was 394,165.

The Company recognized total stock-based compensation expense as follows for the three months ended March 31:

	Three Months Ended March 31,	
	2024	2023
Stock-based compensation expense in operating expenses:		
Research and development	$ 832,180	$ 654,471
General and administrative	499,166	618,811
Total	$ 1,331,346	$ 1,273,282

8. Debt

On April 8, 2021, the Company entered into a loan and security agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus") in its capacity as Collateral Agent and sole Lender. On August 9, 2022, the Company amended the Loan Agreement. Under the amended Loan Agreement, Innovatus, as Lender, has agreed to loan up to $75 million, a $50 million increase from the original Loan Amount. As of March 31, 2024, term loans totaling $35 million are outstanding under the Loan Agreement, including the initial Term A loan of $ 15 million which was funded on April 8, 2021, and a $20 million Term B loan which was funded on December 22, 2022. On March 29, 2024, the Company entered into a second amendment to its existing Loan Agreement to extend the date through which the Company may draw on the Term C Loan from April 1, 2024 to June 1, 2024. Other than as set forth in the second amendment, the amended Loan Agreement shall continue in full force and effect without alteration or amendment.

Long-term debt consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Note payable	$ 35,000,000	$ 35,000,000
Add: PIK interest (added to principal)	3,031,170	2,565,660
Less: unamortized debt issuance costs	(419,921)	(480,810)
Less: unamortized debt discount	(45,019)	(49,439)
Total long-term debt	$ 37,566,230	$ 37,035,411

Future principal payments, including the incurred PIK interest, are as follows:

	Years Ending December 31,
2025	$ 14,261,689
2026	19,015,585
2027	4,753,896
Total	$ 38,031,170

9. Subsequent Event

Subsequent to March 31, 2024, pursuant to an Open Market Sale Agreement SM with Jefferies LLC, as agent, the Company sold 435,414 shares of common stock at an average selling price of $ 17.55 per share, generating gross proceeds of $ 7.6 million before deducting commissions and other offering expenses of $0.2 million.

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, 2023, filed with the SEC on March 27, 2024, and the cautionary statements 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

Celcuity is a clinical-stage biotechnology company focused on the development of targeted therapies for oncology. The Company's lead therapeutic candidate is gedatolisib, a pan-PI3K/mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR alone or together. The Company initiated VIKTORIA-1, a Phase 3 study evaluating gedatolisib in patients with HR+/HER2- advanced breast cancer in 2022 and is currently enrolling patients. In addition to the Phase 3 study, the Company recently announced that it received U.S. Food and Drug Administration ("FDA") clearance for its Investigational New Drug (IND) submission for the clinical development of gedatolisib in combination with Nubeqa® (darolutamide), for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC). The Company initiated a Phase 1b/2 study, CELC-G-201, in the first quarter of 2024 and is currently enrolling patients. Its CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies.

Gedatolisib, is a potent, well-tolerated, small molecule reversible dual inhibitor, administered intravenously, that selectively targets all Class I isoforms of PI3K and mammalian target of rapamycin (mTOR). In April 2021, we obtained exclusive global development and commercialization rights to gedatolisib under a license agreement with Pfizer, Inc. We believe gedatolisib's unique mechanism of action, differentiated chemical structure, favorable pharmacokinetic properties, and intravenous formulation offer distinct advantages over currently approved and investigational therapies that target PI3K or mTOR alone or together.

- **Overcomes limitations of therapies that only inhibit a single Class I PI3K isoform or only one mTOR kinase complex.**

  Gedatolisib is a pan-class I isoform PI3K inhibitor with low nanomolar potency for the p110α, p110β, p110γ, and p110δ isoforms and mTORC1 and mTORC2 complexes. Each PI3K isoform and mTOR complex is known to preferentially affect different signal transduction events that involve tumor cell survival, depending upon the aberrations associated with the linked pathway. When a therapy only inhibits a single Class 1 isoform (e.g., alpelisib, a PI3K-α inhibitor) or only one mTOR kinase complex (e.g., everolimus, an mTORC1 inhibitor), numerous feedforward and feedback loops between the PI3K isoforms and mTOR complexes cross-activate the uninhibited sub-units. This, in turn, induces compensatory resistance that can reduce the efficacy of isoform specific PI3K or single mTOR kinase complex inhibitors. Inhibiting all four PI3K isoforms and both mTOR complexes, as gedatolisib does, thus prevents the confounding effect of isoform interaction that may occur with isoform-specific PI3K inhibitors and the confounding interaction between PI3K isoforms and mTOR.

- **Better tolerated by patients than oral PI3K and mTOR drugs.**

  Gedatolisib is administered intravenously (IV) on a four-week cycle of three weeks-on, one week-off, in contrast to the orally administered pan-PI3K or dual PI3K/mTOR inhibitors that are no longer being clinically developed. Oral pan-PI3K or PI3K/mTOR inhibitors have repeatably been found to induce significant side effects that were not well tolerated by patients. This typically leads to a high proportion of patients requiring dose reductions or treatment discontinuation. The challenging toxicity profile of these drug candidates ultimately played a significant role in the decisions to halt their development, despite showing promising efficacy. By contrast, gedatolisib stabilizes at lower concentration levels in plasma compared to orally administered PI3K inhibitors, resulting in less toxicity, while maintaining concentrations sufficient to inhibit PI3K/mTOR signaling.

  Isoform-specific PI3K inhibitors administered orally were developed to reduce toxicities in patients. While the range of toxicities associated with isoform-specific inhibitors is narrower than oral pan-PI3K or PI3K/mTOR inhibitors, administering them orally on a continuous basis still leads to challenging toxicities. The experience with an FDA approved oral p110-α specific inhibitor, Piqray, illustrates the challenge. In its Phase 3 pivotal trial Piqray was found to induce a Grade 3 or 4 adverse event (AE) related to hyperglycemia in 39% of patients evaluated. In addition, 26% of patients discontinued alpelisib due to treatment related adverse events. By contrast, in the 103-patient dose expansion portion of the Phase 1b clinical trial with gedatolisib, only 7% of patients experienced Grade 3 or 4 hyperglycemia and less than 10% discontinued treatment.

As of March 31, 2024, 492 patients with solid tumors have received gedatolisib in eight clinical trials sponsored by Pfizer. Of the 492 patients, 129 were treated with gedatolisib as a single agent in three clinical trials. The remaining 363 patients received gedatolisib in combination with other anti-cancer agents in five clinical trials. Additional patients received gedatolisib in combination with other anti-cancer agents in nine investigator sponsored clinical trials.

A Phase 1b trial (B2151009) evaluating patients with HR+/HER2- metastatic breast cancer was initiated in 2016 and subsequently enrolled 138 patients. Four patients from this study continue to receive study treatment, as of March 31, 2024, each of whom have received study treatment for more than five years. The B2151009 clinical was an open label, multiple arm Phase 1b study that evaluated gedatolisib in combination with palbociclib (CDK4/6 inhibitor) and fulvestrant or letrozole in patients with HR+/HER2- advanced breast cancer. Thirty-five patients were enrolled in two dose escalation arms to evaluate the safety and tolerability and to determine the maximum tolerated dose (MTD) of gedatolisib when used in combination with the standard doses of palbociclib and endocrine therapy (letrozole or fulvestrant). The MTD was determined to be 180 mg administered intravenously once weekly. A total of 103 patients were subsequently enrolled in one of four expansion arms (A, B, C, D).

High objective overall response rates (ORR) were observed in all four expansion arms and were comparable in each arm for PIK3CA WT and PIK3CA MT patients. As of the data cut-off date, March 16, 2023, for treatment- naïve patients in Escalation Arm A and Expansion Arm A (n=41), median progression free survival (mPFS) was 48.6 months, median duration of response (mDOR) was 46.9 months, and ORR was 79%, respectively. This data compares favorably to published data for current first-line standard-of-care treatments for patients with HR+/HER2-advanced breast cancer. In patients who received prior hormonal therapy alone or in combination with a CDK4/6 inhibitor (Arms B, C, and D), ORR (including unconfirmed partial responses) ranged from 36% to 77%. Each arm achieved its primary endpoint target, which was reporting higher ORR in the study arm than ORR from either the PALOMA-2 (ORR=55%) study that evaluated palbociclib plus letrozole for Arm A or the PALOMA-3 study (ORR=25%) that evaluated palbociclib plus fulvestrant for Arms B, C, and D. For all enrolled patients, a clinical benefit rate (CBR) of ≥ 79% was observed. Median progression-free survival (PFS)was 12.9 months for patients who received a prior CDK4/6 inhibitor and were treated in the study with the Phase 3 dosing schedule (Arm D).

Gedatolisib combined with palbociclib and endocrine therapy demonstrated a favorable safety profile with manageable toxicity. The majority of treatment emergent adverse events were Grade 1 and 2. The most frequently observed adverse events included stomatitis/mucosal inflammation, the majority of which were Grade 1 and 2. The most common Grade 4 AEs were neutropenia and neutrophil count decrease, which were assessed as related to treatment with palbociclib. No grade 5 events were reported in this study.

We are currently enrolling patients in a Phase 3, open-label, randomized clinical trial (VIKTORIA-1) to evaluate the efficacy and safety of two regimens in adults with HR+/HER2- advanced breast cancer whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor: 1) gedatolisib in combination with palbociclib and fulvestrant; and 2) gedatolisib in combination with fulvestrant. Approximately two hundred clinical sites in North America, Europe, South America, Asia, and Australia have been selected to participate in the study. The first clinical site was activated in the third quarter of 2022, and the first patient was dosed in December 2022.

The VIKTORIA-1 clinical trial will enable separate evaluation of subjects according to their PIK3CA status. Subjects who meet eligibility criteria and are PIK3CA WT will be randomly assigned (1:1:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm A), gedatolisib and fulvestrant (Arm B), or fulvestrant (Arm C). Subjects who meet eligibility criteria and are PIK3CA MT will be randomly assigned (3:3:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm D) or alpelisib and fulvestrant (Arm E), or gedatolisib and fulvestrant (Arm F).

We received approval from the FDA in mid-2023 to proceed with the clinical development of gedatolisib in combination with Nubeqa® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC. We have since initiated a Phase 1b/2 study (CELC-G-201) that will enroll up to 54 participants with mCRPC who progressed after treatment with an androgen receptor inhibitor. We dosed our first patient in this trial in February 2024.

In the Phase 1b portion of the study, Celcuity expects that 36 participants will be randomly assigned to receive 600 mg darolutamide combined with either 120 mg gedatolisib in Arm 1 or 180 mg gedatolisib in Arm 2. An additional 12 participants will then be enrolled in the Phase 2 portion of the study at the recommended phase 2 dose (RP2D) level to enable evaluation of 30 participants treated with the RP2D of gedatolisib.

The primary objectives of the Phase 1b portion of the trial include assessment of the safety and tolerability of gedatolisib in combination with darolutamide and determination of the recommended Phase 2 dose of gedatolisib. The primary objective of the Phase 2 portion of the trial is to assess the radiographic progression-free survival (rPFS) at six months of patients who received the RP2D.

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. This enables us to identify patients whose tumors may respond to a targeted therapy, even though they lack a previously associated molecular mutation. By identifying cancer patients whose tumors lack an associated genetic mutation but have abnormal cellular activity a matching targeted therapeutic is designed to inhibit, CELsignia CDx can expand the markets for a number of already approved targeted therapies. Our current CDx identifies breast and ovarian cancer patients whose tumors have cancer drivers potentially responsive to treatment with human epidermal growth factor receptor 2-negative (HER2), mesenchymal-epithelial transition factor (c-MET), or phosphatidylinositol 3-kinases (PI3K) targeted therapeutics. While FDA approval or clearance is not currently required for CELsignia tests offered as a stand-alone laboratory developed test, if we are partnered with a drug company to launch a CELsignia test as a companion diagnostic for a new drug indication, we would be required to obtain premarket approval, or PMA, in conjunction with the pharmaceutical company seeking a new drug approval for the matching therapy.

We are supporting the advancement of new potential indications for three different targeted therapies, controlled by other pharmaceutical companies, that would rely on a CELsignia CDx to select patients. Three Phase 2 trials are underway to evaluate the efficacy and safety of these therapies in CELsignia selected patients. These patients are not currently eligible to receive these drugs and are not identifiable with a molecular test.

Supporting the development of a potential first-in-class targeted therapy for breast cancer, like gedatolisib, with our CELsignia platform is a natural extension of our strategy to use our CELsignia CDx to enable new indications for other companies' targeted therapies. By combining companion diagnostics designed to enable proprietary new drug indications with targeted therapies that treat signaling dysregulation our CDx identifies, we believe we are uniquely positioned to improve the standard-of-care for many early and late-stage breast cancer patients. Our goal is to play a key role in the multiple treatment approaches required to treat breast cancer patients at various stages of their disease. With each program, we are:

- Leveraging the proprietary insights CELsignia provides into live patient tumor cell function
- Using a CELsignia CDx to identify new patients likely to respond to the paired targeted therapy
- Developing a new targeted therapeutic option for breast cancer patients
- Maximizing the probability of getting regulatory approval to market the targeted therapy indication

Recent Developments

On February 22, 2024, the Company announced that the first patient has been dosed in its Phase 1b/2 study (CELC-G-201) evaluating gedatolisib in combination with Nubeqa® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC.

Results of Operations

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 March 31, 2024 and 2023, we reported a net loss of approximately $21.6 million and $11.9 million, respectively. As of March 31, 2024, we had an accumulated deficit of approximately $181.7 million. As of March 31, 2024, we had cash and cash equivalents and short-term investments of approximately $177.7 million.

Components of Operating Results

Revenue

To date, we have not generated any revenue. With the execution of the Pfizer license agreement in April 2021, whereby we acquired exclusive world-wide licensing rights to develop and commercialize gedatolisib, we initiated a Phase 3 clinical trial, VIKTORIA-1, in 2022 to support potential regulatory approval to market gedatolisib. In August 2023, we announced plans to proceed with the clinical development of gedatolisib in combination with Nubeqa® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC. If we obtain regulatory approvals to market gedatolisib, we expect to initially generate revenue from sales of the drug for the treatment of breast cancer patients. Additionally, we will seek to generate revenue from partnership agreements with pharmaceutical companies to provide companion diagnostics for such pharmaceutical partners' existing or investigational targeted therapies. If 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 gedatolisib, a PI3K/mTOR targeted therapy and our CELsignia platform and corresponding tests. 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;
- validation costs for gedatolisib;
- facilities expenses; and
- legal costs associated with patent applications.

Internal and external research and development costs are expensed as they are incurred. As we continue development of gedatolisib and manage studies and clinical trials, including the VIKTORIA-1 Phase 3 trial, the CELC-G-201 Phase 1b/2 trial, and other clinical trials to evaluate the 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, investor relations 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 first drug, gedatolisib, managing the VIKTORIA-1 Phase 3 and CELC-G-201 Phase 1b/2 trials, and developing our CELsignia platform and corresponding CELsignia tests. We would expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first drug, gedatolisib, and CELsignia tests. These increased expenses are expected to include employee-related and consulting costs.

Interest Expense

Interest expense is primarily due to a Loan Agreement and finance lease obligations.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

	Three Months Ended March 31,		Increase (Decrease)	
	2024	2023	$	Percent Change
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 20,647,559	$ 11,278,493	$ 9,369,066	83%
General and administrative	1,846,276	1,269,044	577,232	45
Total operating expenses	22,493,835	12,547,537	9,946,298	79

Loss from operations	(22,493,835)	(12,547,537)	(9,946,298)	79
Other income (expense)				
Interest expense	(1,400,712)	(1,242,012)	(158,700)	13
Interest income	2,282,092	1,851,132	430,960	23
Other income (expense), net	881,380	609,120	272,260	45
Net loss before income taxes	(21,612,455)	(11,938,417)	(9,674,038)	81
Income tax benefits	-	-	-	-
Net loss	$ (21,612,455)	$ (11,938,417)	$ (9,674,038)	81%

Research and Development

Our research and development expenses for the three months ended March 31, 2024 were approximately $20.7 million, representing an increase of approximately $9.4 million, or 83%, compared to the same period in 2023. Of the $9.4 million increase in research and development expense, $1.5 million was related to increased employee and consulting expenses. The remaining $7.9 million increase of research and development costs are primarily related to costs supporting activities for the VIKTORIA-1 and CELC-G-201 pivotal trials.

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 develop gedatolisib, manage the VIKTORIA-1 Phase 3 and the CELC-G-201 Phase 1b/2 trials, discover new cancer sub-types, and 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 and manage the clinical trials for gedatolisib.

General and Administrative

Our general and administrative expenses for the three months ended March 31, 2024 were approximately $1.8 million, representing an increase of approximately $0.5 million, or 45%, compared to the same period in 2023. Of the $0.5 million increase in general and administrative expense, $0.3 million was related to increased employee and consulting expenses. The remaining $0.2 million of the $0.5 million increase resulted from professional fees and other administrative expenses.

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 gedatolisib and CELsignia tests, an expanding infrastructure, and increased professional fees associated with public company regulatory developments and other compliance matters.

Interest Expense

Interest expense for the three months ended March 31, 2024 was $1.4 million and represents an increase of $0.2 million compared to the same period in 2023. Interest expense is the result of a Loan Agreement that was executed in April 2021 and amended in August 2022 and March 2024. The increase is due to the increase in prime interest rates. The $1.4 million of interest expense includes $0.5 million of non-cash interest expense.

Interest Income

Interest income for the three months ended March 31, 2024 was $2.3 million and represents an increase of $0.4 million compared to the same period in 2023. The increase was primarily the result of higher market interest rates and the closing of additional financing activities, leading to higher cash, cash equivalents and short-term investment balances.

Liquidity and Capital Resources

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through March 31, 2024, we have funded our operations primarily through private placements and registered offerings of our equity securities and unsecured convertible notes, and borrowings under loan agreements. From inception through March 31, 2024, we raised an aggregate of approximately $303.7 million of net proceeds through sales of our securities, and as of March 31, 2024 had $35.0 million of borrowings under loan agreements. In March 2024, an investor exercised 1,739,080 warrants at an exercise price of $8.05, which generated approximately $14 million in cash. The warrants were issued pursuant to a previously reported private placement that closed and was funded on December 9, 2022. Subsequent to March 31, 2024, pursuant to an Open Market Sale Agreement℠ with Jefferies LLC, as agent, the Company sold 435,414 shares of common stock at an average selling price of $ 17.55 per share, generating gross proceeds of $7.6 million before deducting commissions and other offering expenses of $0.2 million. As of March 31, 2024, our cash and cash equivalents and short-term investments were approximately $31.2 million and $146.5 million, respectively, and we had an accumulated deficit of approximately $181.7 million.

Private Placement. On December 9, 2022, we issued 6,182,574 shares of common stock, 1,120,873 shares of Series A Preferred Stock and warrants exercisable for 6,956,450 shares of common stock to certain institutional and other accredited investors pursuant to a securities purchase agreement entered into on May 15, 2022. Pursuant to the securities purchase agreement, the closing (funding) of the private placement occurred following dosage of the first patient in the Company's Phase 3 study, VIKTORIA-1. Investors purchased shares of common stock and Series A Preferred Stock at a price of $5.75 per share (on an as converted to common stock basis), with forty percent (40%) warrant coverage (on an as converted to common stock basis) and customary resale registration rights. The warrants have an exercise price of $8.05 per share. The private placement generated gross proceeds of approximately $100 million before deducting placement agent fees and other offering expenses of $4.3 million.

Pre-funded Warrants On October 18, 2023, the Company entered into a securities purchase agreement to sell pre-funded warrants at a price of $8.70 per warrant, to purchase up to 5,747,787 shares of the Company's common stock in a private placement. The closing of the private placement occurred on October 20, 2023, and resulted in gross proceeds of approximately $50 million, before deducting offering expenses of approximately $0.1 million.

Open Market Sale Agreement℠. On February 4, 2022, we entered into an Open Market Sale Agreement ℠ with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $50,000,000. On December 1, 2023, pursuant to this agreement, the Company sold 1,034,500 shares of common stock in a single transaction at a price of $14.50 per share, generating gross proceeds of $15 million ($14.4 million net of commissions and offering expenses). At March 31, 2024, $29.8 million of common stock remains available for sale under the Jefferies agreement.

Innovatus Loan Agreement. On April 8, 2021, we entered into a Loan Agreement with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), under which Innovatus agreed to loan up to $25 million in three tranches consisting of (i) a $15.0 million non-contingent Term A loan that was funded on April 8, 2021, (ii) a $5 million Term B loan with a deadline of March 31, 2022, and (iii) a $5 million Term C loan to be funded upon our request, subject to

our ability to achieve certain milestones, no later than March 31, 2023. On August 9, 2022, the Company amended the Loan Agreement with Innovatus to provide for up to $75 million in term loans. As of March 31, 2024, term loans totaling $35 million are outstanding under the Loan Agreement, including the initial Term A loan of $15 million which was funded on April 8, 2021, and a $20 million Term B loan which was funded on December 22, 2022 following the closing of the $100 million private placement described above. Additionally, the Company will be able to draw on two additional tranches of $10 million and one additional tranche of $20 million upon achievement of certain clinical trial milestones and satisfaction of certain financial covenants determined on a pro forma as-funded basis. Funding of these additional tranches is also subject to other customary conditions and limits on when the Company can request funding for such tranches. On March 29, 2024, the Company entered into a Second Amendment to Loan Agreement with Innovatus in order to extend the date through which the Company may draw on the Term C loan from April 1, 2024 to June 1, 2024. Other than as set forth in the Second Amendment to Loan Agreement, the amended Loan Agreement shall continue in full force and effect without alteration or amendment.

We expect that our research and development and general and administrative expenses will increase as we continue to develop gedatolisib, manage the VIKTORIA-1 Phase 3 and CELC-G-201 Phase 1b/2 trials, conduct research related to the discovery of new cancer sub-types, conduct other studies and clinical trials, and pursue other business development activities. We would also expect to incur sales and marketing expenses as we commercialize gedatolisib and our CELsignia tests. We expect to use cash on hand, together with the funds to be received under the debt and equity financings described above, to fund our research and development expenses, clinical trial costs, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses.

Based on our current business plan, we believe that our current cash, cash equivalents and short-term investments together with available borrowings under the Innovatus Loan Agreement will provide sufficient cash to finance our operations and pay obligations when due through at least 2025.

Our expectations as to how long our current capital resources will be sufficient to fund our operations are based on assumptions that may not be accurate, and we could use our current capital resources sooner than we currently expect. In addition, we may seek to raise additional capital to finance capital expenditures and operating expenses over the next several years as we launch our integrated therapeutic and companion diagnostic strategy and expand our infrastructure, commercial operations and research and development activities, and to 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 not at all.

Cash Flows

The following table sets forth the primary sources and uses of cash for the three months ended March 31:

	2024	2023
Net cash provided by (used in):		
Operating activities	$ (17,068,161)	$ (12,867,838)
Investing activities	3,536,301	21,867,551
Financing activities	14,083,827	67,948
Net increase (decrease) in cash and cash equivalents	$ 551,967	$ 9,067,661

Operating Activities

Net cash used in operating activities was approximately $17.1 million for the three months ended March 31, 2024 and consisted primarily of a net loss of approximately $21.6 million, offset by working capital changes of $2.8 million and non-cash expense items of approximately $1.7 million. Non-cash expense items of approximately $1.7 million primarily consisted of $1.3 million of stock-based compensation expense and net non-cash interest of $0.4 million. The approximately $2.8 million of working capital changes was primarily due to increases in accrued expenses and accounts payable and a decrease in other current assets. The net cash used in operating activities was approximately $12.9 million for the three months ended March 31, 2023 and consisted primarily of a net loss of approximately $11.9 million and working capital changes of $1.0 million, offset by non-cash expense items of $0.1 million. Non-cash expense items of approximately $0.1 million primarily consisted of $1.3 million of stock-based compensation expense and non-cash interest expense of $0.5 million, offset by $1.7 million of non-cash interest income. The approximately $1.0 million of working capital changes was primarily due to a decrease in accrued expenses.

Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2024 was approximately $3.5 million and consisted primarily of net proceeds from maturities of short-term investments in government securities (U.S. Treasury Bills), partially offset by $0.1 million purchases of property and equipment. Net cash provided by investing activities for the three months ended March 31, 2023 was approximately $21.9 million and consisted of net proceeds from maturities of short-term investments in government securities (U.S. Treasury Bills and U.S. government securities) and minimal purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 was approximately $14.1 million and primarily consisted of proceeds from the exercise of common stock warrants and the exercise of employee stock options, slightly offset by payments for secondary registration costs. The net cash provided by financing activities for the three months ended March 31, 2023 was minimal and primarily consisted of the exercise of employee stock options offset by payments for secondary registration and debt issuance costs.

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 our competitive advantages, including the potential efficacy of gedatolisib in various patient types alone or in combination with other treatments; (iii) our expectations regarding the timeline of patient enrollment and results from clinical trials, including our existing Phase 3 VIKTORIA-1 clinical trial and Phase 1b/2 study and clinical trial for gedatolisib; (iv) our expectations regarding our ability to obtain FDA approval to commercialize gedatolisib; (v) our expectations with respect to the development, validation, required approvals, costs and timelines of gedatolisib and our CELsignia tests; (vi) our plans with respect to research and development and related expenses for the foreseeable future; (vii) our beliefs about our ability to capitalize on the exclusive global development and commercialization rights obtained from our license agreement with Pfizer with respect to gedatolisib; (viii) the future payments that may be owed to Pfizer under the license agreement; (ix) our beliefs related to the perceived advantages of our CELsignia tests compared to traditional molecular or other diagnostic tests; (x) our revenue expectations; (xi) our expectations regarding business development activities, including collaborations with pharmaceutical companies; (xii) our expectations as to the use of proceeds from our recent financing activities; (xiii) 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 (xiv) our plans with respect to potentially raising capital.

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; our potential inability to develop, validate and commercialize gedatolisib on a timely basis or at all; the uncertainties and costs associated with clinical studies and with developing and commercializing biopharmaceuticals; the complexity and difficulty of demonstrating the safety and sufficient magnitude of benefit to support regulatory approval of gedatolisib and other products we may develop; 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; tightening credit markets and limitations on access to capital; 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, 2023 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 March 31, 2024. 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 March 31, 2024 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, 2023, 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.

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

Recent Unregistered Sales of Equity Securities

During the three months ended March 31, 2024, we issued 3,683 shares of common stock upon the exercise of previously issued warrants as follows:

- 1,006 shares were issued pursuant to the exercise of warrants at an exercise price of $9.50 per share, resulting in cash proceeds of approximately $9,000; and
- 2,677 shares were issued pursuant to the exercise of 5,922 warrants in a cashless exercise whereby 3,245 shares with a value of $17.34 per share were used to settle the exercise price and the remaining 2,677 shares were issued to the warrant holders.

The shares were issued pursuant to exemption from registration under Section 4(a)(2) of the Securities Act.

Issuer Purchases of Equity Securities

None

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

None.

ITEM 5. Other Information

During the three months ended March 31, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

ITEM 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of the Company, as amended, including the Certifications of Designations of Preferences, Rights, and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K/A filed with the SEC on April 7, 2023).
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).
4.2	Form of Warrant to Purchase Units of Membership Interest issued by Celcuity LLC to Cedar Point Capital, LLC, as placement agent of membership units and unsecured convertible promissory notes of Celcuity LLC (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
4.3*	Form of Amendment to Placement Agent's Warrants, dated February 13, 2024.
4.4	Form of Warrant to Purchase Shares of Common Stock issued by Celcuity Inc. in connection with the conversion of 1.25% Unsecured Convertible Promissory Notes (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 25, 2017).
4.5*	Form of Amendment to Warrants to Purchase Shares of Common Stock, dated February 13, 2024.
4.6	Representative's Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 25, 2017).
4.7	First Amendment to Representative's Warrant, dated September 13, 2022, between Celcuity Inc. and Craig-Hallum Capital Group LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 14, 2022).

4.8	Form of Warrant issued by Celcuity Inc. to Innovatus Life Sciences Lending Fund I, LP in connection with the Loan and Security Agreement dated April 8, 2021(incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021).
4.9	Equity Grant Agreement, dated April 8, 2021, between the Company and Pfizer, Inc., (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021).
4.10	Form of Warrant issued by Celcuity Inc. in connection with the Securities Purchase Agreement, dated May 15, 2022 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2022).
4.11	Form of Pre-Funded Warrant issued by Celcuity Inc. in connection with the Securities Purchase Agreement, dated October 18, 2023(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 23, 2023).
10.1*+	Amendment to Form of Stock Option Agreement pursuant to Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan..
10.2*+	Form of Non-Qualified Stock Option Transfer Agreement pursuant to Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan..
10.3	Second Amendment to Loan and Security Agreement, dated March 29, 2024 by and among the Company and Innovatus Life Sciences Lending Fund I, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 29, 2024.
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 March 31, 2024, 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.
\+ Management contract or compensatory plan.

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: May 15, 2024

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 4.3

CELCUITY INC.

AMENDMENT TO
PLACEMENT AGENT'S WARRANTS

THIS AMENDMENT, dated February ___, 2024, is made by Celcuity Inc., a Delaware corporation (the "Company") to amend those certain Warrants ("Warrants") originally issued as of _____, 201_,[1] to Cedar Point Capital, LLC, as placement agent, granting the Holder named therein, or its registered assigns, the right to subscribe for and purchase from the Company, at any time after the date thereof up to and including 5:00 p.m. Minneapolis, Minnesota time on _____, 202_, (the "Expiration Date"), the number of fully paid and non-assessable Warrant Shares set forth in the applicable Warrant at the Warrant Exercise Price of $___ per share, all subject to the terms and conditions set forth in the Warrants. Capitalized terms used in this Amendment, but not otherwise defined herein, shall have the meanings given to them in the Warrants.

A. The Company desires to amend the Warrants to provide the Holders thereof the option to exercise the Warrants on a "cashless" basis.

B. Pursuant to Section 9(c) of the Warrants, the Warrants or any term hereof may be changed, waived, discharged or terminated by an instrument in writing signed by the party against which enforcement of the change, waiver, discharge or termination is sought.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Company agrees as follows:

1. Amendment to Warrants. The first paragraph of Section 2(a) of the Warrants is hereby amended and restated in its entirety to read as follows:

"(a) Exercise. Subject to the provisions of Section 2(a)(ii) hereof, the rights represented by this Warrant may be exercised by the Holder hereof, in whole or in part (but not as to a fractional Warrant Share), by written notice of exercise (in the form attached hereto) delivered to the Company at its principal office prior to the Expiration Date and accompanied or preceded by the surrender of this Warrant and payment of the aggregate Warrant Exercise Price for the Warrant Shares purchased upon such exercise. Payment of the aggregate Warrant Exercise Price shall be made, at the option of the Holder, by the following methods:

(x) by delivery to the Company of a check payable to the order of the Company or by wire transfer of immediately available funds to an account designated in writing by the Company, in the amount of such aggregate Warrant Exercise Price; or

(y) through a "cashless exercise", without payment of any cash consideration or other immediately available funds, in which event the Company shall issue to the Holder the number of Warrant Shares computed using the following formula:

[1] Agent's Warrants issued 01/14/2016, Expiration Date 01/14/2026, Warrant Exercise Price $7.5628 per share;
Agent's Warrants issued 05/02/2016, Expiration Date 05/02/2026, Warrant Exercise Price $7.5628 per share;
Agent's Warrants issued 04/28/2017, Expiration Date 04/28/2027, Warrant Exercise Price $8.4208 per share;
Agent's Warrants issued 05/17/2017, Expiration Date 05/17/2027, Warrant Exercise Price $8.4208 per share.

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised (inclusive of the Warrant Shares surrendered to the Company in payment of the aggregate Warrant Price);

"A" equals the last reported sale price of a share of Common Stock during the regular daily trading session on the Nasdaq Capital Market on the trading day immediately preceding the date on which the Holder delivers a valid notice of exercise (the "Fair Market Value"); and

"B" equals the Warrant Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act of 1933, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the U.S. Securities and Exchange Commission continues to take the position that such treatment is proper at the time of such exercise)."

2. Form of Notice of Exercise. A Holder electing to exercise a Warrant on a cashless basis may use the form of notice of exercise attached hereto as Exhibit A.

3. No Other Amendments. Other than as specifically set forth herein, all other terms and provisions of the Warrants shall remain unaffected by the terms of this Amendment and shall continue in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be duly executed as of the date first above written.

CELCUITY, INC.

By: */s/ Brian F. Sullivan*
Brian F. Sullivan
Chief Executive Officer

Exhibit A

NOTICE OF EXERCISE OF WARRANT

To be signed by the registered Holder in order to exercise the Warrant

TO: CELCUITY INC.

The undersigned Holder hereby irrevocably elects to exercise the attached Warrant with respect to _____ of the Warrant Shares issuable upon the exercise of such Warrant. Payment of the Warrant Exercise Price for such Warrant Shares shall take the form of [*check the applicable box below*]:

☐ Check payable to the order of the Company or wire transfer of immediately available funds to an account designated in writing by the Company; or

☐ Cancellation of such number of Warrant Shares that have an aggregate Fair Market Value as of the date of this notice of exercise that satisfies the aggregate Warrant Exercise Price for the total number of Warrant Shares set forth above (which is inclusive of the Warrant Shares surrendered to the Company in payment of the aggregate Warrant Price), in accordance with the formula set forth in Section 2(a)(y) of the Warrant.*

Please issue such Warrant Shares in book entry form (together with a new Warrant to purchase the number of Warrant Shares, if any, with respect to which the attached Warrant is not exercised) in the name of the following person:

Name in which Shares shall be registered

_____
(please print)

Social security or tax identification number: _____

Address: _____

_____

_____

Dated: _____

_____
Signature of Holder**

_____
Name of Holder (please print)

_____
Title of signatory (if signing for an entity)

* The number of Warrant Shares issued will be the number of Warrant Shares with respect to which the Warrant is exercised, minus the number of Warrant Shares cancelled to satisfy the Warrant Exercise Price.

** The signature on this Notice of Exercise of Warrant must correspond to the name as written upon the face of the Warrant in every particular without alteration or enlargement or any change whatsoever. When signing on behalf of a corporation, partnership, trust or other entity, please indicate your position(s) and title(s) with such entity.

Exhibit 4.5

CELCUITY INC.

AMENDMENT TO
WARRANTS TO PURCHASE SHARES OF COMMON STOCK

THIS AMENDMENT, dated February 13,2024, is made by Celcuity Inc., a Delaware corporation (the "Company") to amend those certain Warrants to Purchase Shares of Common Stock ("Warrants") originally issued as of September 22, 2017, granting the Holder named therein, or its registered assigns, the right to subscribe for and purchase from the Company, at any time after the date thereof up to and including 5:00 p.m. Minneapolis, Minnesota time on September 22, 2024 (the "Expiration Date"), the number of fully paid and non-assessable Warrant Shares set forth in the applicable Warrant at the Warrant Exercise Price of $9.50 per share, all subject to the terms and conditions set forth in the Warrants. Capitalized terms used in this Amendment, but not otherwise defined herein, shall have the meanings given to them in the Warrants.

A. The Company desires to amend the Warrants to provide the Holders thereof the option to exercise the Warrants on a "cashless" basis.

B. Pursuant to Section 9(c) of the Warrants, the Warrants or any term hereof may be changed, waived, discharged or terminated by an instrument in writing signed by the party against which enforcement of the change, waiver, discharge or termination is sought.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Company agrees as follows:

1. Amendment to Warrants. The first paragraph of Section 2 of the Warrants is hereby amended and restated in its entirety to read as follows:

"2. Exercise. Subject to the provisions of Section 2(b) hereof, the rights represented by this Warrant may be exercised by the Holder hereof, in whole or in part (but not as to a fractional Warrant Share), by written notice of exercise (in the form attached hereto) delivered to the Company at its principal office prior to the Expiration Date and accompanied or preceded by the surrender of this Warrant and payment of the aggregate Warrant Exercise Price for the Warrant Shares purchased upon such exercise. Payment of the aggregate Warrant Exercise Price shall be made, at the option of the Holder, by the following methods:

(i) by delivery to the Company of a check payable to the order of the Company or by wire transfer of immediately available funds to an account designated in writing by the Company, in the amount of such aggregate Warrant Exercise Price; or

(ii) through a "cashless exercise", without payment of any cash consideration or other immediately available funds, in which event the Company shall issue to the Holder the number of Warrant Shares computed using the following formula:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised (inclusive of the Warrant Shares surrendered to the Company in payment of the aggregate Warrant Price);

"A" equals the last reported sale price of a share of Common Stock during the regular daily trading session on the Nasdaq Capital Market on the trading day immediately preceding the date on which the Holder delivers a valid notice of exercise (the "Fair Market Value"); and

"B" equals the Warrant Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act of 1933, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the U.S. Securities and Exchange Commission continues to take the position that such treatment is proper at the time of such exercise)."

2. Form of Notice of Exercise. A Holder electing to exercise a Warrant on a cashless basis may use the form of notice of exercise attached hereto as Exhibit A.

3. No Other Amendments. Other than as specifically set forth herein, all other terms and provisions of the Warrants shall remain unaffected by the terms of this Amendment and shall continue in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be duly executed as of the date first above written.

CELCUITY, INC.

By: */s/ Brian F. Sullivan*
Brian F. Sullivan
Chief Executive Officer

Exhibit A

NOTICE OF EXERCISE OF WARRANT

To be signed by the registered Holder in order to exercise the Warrant

TO: CELCUITY INC.

The undersigned Holder hereby irrevocably elects to exercise the attached Warrant with respect to _____ of the Warrant Shares issuable upon the exercise of such Warrant. Payment of the Warrant Exercise Price for such Warrant Shares shall take the form of [*check the applicable box below*]:

☐ Check payable to the order of the Company or wire transfer of immediately available funds to an account designated in writing by the Company; or

☐ Cancellation of such number of Warrant Shares that have an aggregate Fair Market Value as of the date of this notice of exercise that satisfies the aggregate Warrant Exercise Price for the total number of Warrant Shares set forth above (which is inclusive of the Warrant Shares surrendered to the Company in payment of the aggregate Warrant Price), in accordance with the formula set forth in Section 2(ii) of the Warrant.*

Please issue such Warrant Shares in book entry form (together with a new Warrant to purchase the number of Warrant Shares, if any, with respect to which the attached Warrant is not exercised) in the name of the following person:

Name in which Shares shall be registered

_____
(please print)

Social security or tax identification number: _____

Address: _____

_____

_____

Dated: _____

_____
Signature of Holder**

_____
Name of Holder (please print)

_____
Title of signatory (if signing for an entity)

* The number of Warrant Shares issued will be the number of Warrant Shares with respect to which the Warrant is exercised, minus the number of Warrant Shares cancelled to satisfy the Warrant Exercise Price.

** The signature on this Notice of Exercise of Warrant must correspond to the name as written upon the face of the Warrant in every particular without alteration or enlargement or any change whatsoever. When signing on behalf of a corporation, partnership, trust or other entity, please indicate your position(s) and title(s) with such entity.

Exhibit 10.1

Amended Agreement

Celcuity Inc.
Amended and Restated 2017 Stock Incentive Plan

Amendment to Stock Option Agreement

Section 7 of the Celcuity Inc. Form of Stock Option Agreement is hereby amended and restated as follows:

7. Non-Transferability of Option. This Option may not be transferred in any manner otherwise than by will or by the laws of descent or distribution and may be exercised during the lifetime of the Optionee only by the Optionee, unless this Option is a non-statutory stock option and such transfer is otherwise approved by the Committee in its sole discretion. The terms of the Plan and this Option Agreement will be binding upon the executors, administrators, heirs, successors and assigns of the Optionee.

Exhibit 10.2

CELCUITY INC.

NON-QUALIFIED STOCK OPTION TRANSFER AGREEMENT

This Non-Qualified Stock Option Transfer Agreement (this " Agreement") is entered into as of _____ __, 202_ (the " Effective Date"), by and among Celcuity Inc., a Delaware corporation (the "Company"), [_____] (the "Transferor") and [_____] (the "Transferee"). The Company, the Transferor and the Transferee are each sometimes referred to herein as a "Party," and collectively sometimes referred to herein as the "Parties."

RECITALS

WHEREAS, on [OPTION GRANT DATE], the Company granted to the Transferor an option (the " Granted Option") to purchase [___] shares of common stock, par value $0.001 per share of the Company, subject to the terms and conditions of the Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan attached hereto as Exhibit A (as amended, the "Plan") and a Non-Qualified Stock Option Agreement thereunder by and between the Company and the Transferor attached hereto as Exhibit B (as amended, the "Stock Option Agreement");

WHEREAS, the Company has adopted that certain Policy for the Transfer of Non-Statutory Stock Options by Directors and Executive Officers Under the Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (the "Permitted Transfer Policy") pursuant to which directors and executive officers may, subject to certain conditions, transfer all or any portion of any vested non-statutory stock options to certain Permitted Recipients (as defined in the Permitted Transfer Policy); and

WHEREAS, the Transferor desires to transfer the Granted Option with respect to [___] vested shares (the " Option") to the Transferee and the Company desires to consent to such transfer, all in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing recitals, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Company, the Transferor and the Transferee agree as follows:

AGREEMENT

1. Transfer of the Option.

(a) As of the Effective Date, the Transferor hereby transfers to the Transferee the Option (the " Transfer") and the Transferee hereby accepts the transfer of the Option by the Transferor.

(b) The Transferee and the Transferor acknowledge and agree that the Transferee shall be bound by all of the terms and conditions of the Plan and the Stock Option Agreement as if the Transferee were the Grantee (as named in the Stock Option Agreement) and as if the Transferee had accepted the Stock Option Agreement; provided, however, that references in the Plan and the Stock Option Agreement to (A) the service of the Optionee or (B) the termination of service of the Optionee shall be deemed to continue to be references to (X) the service of the Transferor or (Y) the termination of service of the Transferor, as applicable, and the Transferor shall remain responsible for any withholding taxes that may be due in connection with the exercise or other disposition of the Option.

(c) The Company consents to the Transfer in accordance with Section 15.3 of the Plan and the section of the Stock Option Agreement entitled "Non-Transferability of Option". Except as expressly set forth in this Section 1(c), nothing in this Agreement shall be deemed a waiver of any of the Company's rights under the Plan or the Stock Option Agreement, including with respect to the Company's rights to withhold consent, in its discretion, to future transfers.

---

2. Representations and Warranties by the Transferor and Transferee . The Transferor and the Transferee hereby represent and warrant to the Company, jointly and severally, that:

(a) The Transferee qualifies as a Permitted Recipient within the meaning of the Permitted Transfer Policy, and the Transferor has delivered to the Company a true and complete copy of the instrument creating the Transferee (including all amendments thereto).

(b) The Transferor has been informed and acknowledges that the Transferor may be subject to certain federal and state tax liability in connection with the Transfer of the Option and/or the exercise of the Option. The Transferor and the Transferee have consulted their applicable individual tax advisor(s) regarding the specific tax consequences of the Transfer and are not relying on any statements or representations by the Company or its advisors with respect thereto. The Transferor hereby covenants and agrees that the Transferor will be responsible for paying to the Company or its designated subsidiary any amount of any applicable withholding taxes required to be withheld with respect to the exercise or other disposition of the Option.

(c) The Transferor and the Transferee each have the full legal right, power and capacity to execute and deliver this Agreement and to perform their respective obligations hereunder, and that this Agreement has been duly authorized, executed and delivered on behalf of the Transferor and Transferee.

3. Notices. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery, upon deposit in the United States mail by certified mail, with postage and fees prepaid, or delivered via electronic mail to the respective Parties at their address as set forth on the signature page hereto.

4. Further Instruments. The Parties agree to execute such further instruments and to take such further action as may be reasonably necessary to carry out the purposes and intent of this Agreement.

5. Entire Agreement. The terms of the Plan and the Stock Option Agreement are incorporated herein by reference. This Agreement, together with the Plan and the Stock Option Agreement, constitutes the entire agreement of the Parties and supersedes in its entirety all prior undertakings and agreements of the Parties with respect to the subject matter hereof.

6. Governing Law. The validity and construction of this Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive laws of any other jurisdiction.

7. Severability. Should any provision of this Agreement be determined by a court of law to be illegal or unenforceable, the other provisions shall nevertheless remain effective and shall remain enforceable.

8. Binding Effect. The provisions of this Agreement shall be binding upon and accrue to the benefit of the Parties hereto and their respective heirs, legal representatives, successors and permitted assigns.

9. Amendment. This Agreement may be amended only by a written instrument signed by the Parties hereto.

10. Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which together shall constitute one document.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

TRANSFEROR

Signed: _____

_____
Name of Transferor (please print)

_____
Address

_____
Email

CELCUITY INC.

Signed: _____

_____
Name

_____
Title

_____
Address

_____
Email

TRANSFEREE

Signed: _____

_____
Name of Transferee (please print)

_____
Name and Title of Signatory (if signing for an entity)

_____
Address

_____
Email:

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: May 15, 2024

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: May 15, 2024

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 March 31, 2024 (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: May 15, 2024

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 March 31, 2024 (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: May 15, 2024

By*/s/ Vicky Hahne*
Vicky Hahne
Chief Financial Officer