# 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 September 30, 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 November 8, 2024 there were 37,129,556 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**

| | September 30, 2024 (unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 12,603,289 | $ 30,662,774 |
| Investments | 251,455,468 | 149,919,974 |
| Other current assets | 8,379,682 | 10,007,849 |
| **Total current assets** | 272,438,439 | 190,590,597 |
| Property and equipment, net | 338,787 | 228,782 |
| Operating lease right-of-use assets | 259,744 | 400,019 |
| **Total Assets** | $ 273,036,970 | $ 191,219,398 |
| **Liabilities and Stockholders' Equity:** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 9,158,778 | $ 5,076,699 |
| Operating lease liabilities | 175,226 | 184,950 |
| Accrued expenses | 16,974,725 | 8,927,094 |
| **Total current liabilities** | 26,308,729 | 14,188,743 |
| Operating lease liabilities | 95,699 | 225,922 |
| Note payable, non-current | 96,923,914 | 37,035,411 |
| **Total Liabilities** | 123,328,342 | 51,450,076 |
| **Commitments and Contingencies (Note 5)** | | |
| **Stockholders' Equity:** | | |
| Preferred stock, $0.001 par value: 2,500,000 shares authorized; 317,577 and 854,134 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 318 | 854 |
| Common stock, $0.001 par value: 65,000,000 shares authorized; 37,116,267 and 25,506,012 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 37,116 | 25,506 |
| Additional paid-in capital | 384,873,261 | 299,818,965 |
| Accumulated deficit | (235,202,067) | (160,076,003) |
| **Total Stockholders' Equity** | 149,708,628 | 139,769,322 |
| **Total Liabilities and Stockholders' Equity** | $ 273,036,970 | $ 191,219,398 |

*See accompanying notes to the condensed financial statements*



**Celcuity Inc.**
**Condensed Statements of Operations**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Operating expenses:** | | | | |
| Research and development | $ 27,587,483 | $ 17,488,236 | $ 70,732,017 | $ 42,512,811 |
| General and administrative | 2,472,416 | 1,409,801 | 6,104,803 | 3,988,248 |
| Total operating expenses | 30,059,899 | 18,898,037 | 76,836,820 | 46,501,059 |
| Loss from operations | (30,059,899) | (18,898,037) | (76,836,820) | (46,501,059) |
| Other (expense) income | | | | |
| Interest expense | (3,343,989) | (1,372,132) | (7,005,284) | (3,929,140) |

| | | | | |
|---|---|---|---|---|
| Interest income | 3,612,099 | 1,865,629 | 8,716,040 | 5,499,555 |
| Other income, net | 268,110 | 493,497 | 1,710,756 | 1,570,415 |
| **Net loss before income taxes** | **(29,791,789)** | **(18,404,540)** | **(75,126,064)** | **(44,930,644)** |
| Income tax benefits | - | - | - | - |
| **Net loss** | **$ (29,791,789)** | **$ (18,404,540)** | **$ (75,126,064)** | **$ (44,930,644)** |
| | | | | |
| Net loss per share, basic and diluted | $ (0.70) | $ (0.83) | $ (1.96) | $ (2.05) |
| | | | | |
| Weighted average common shares outstanding, basic and diluted | 42,793,047 | 22,117,626 | 38,299,548 | 21,920,147 |

*See accompanying notes to the condensed financial statements*



**Celcuity Inc.**
**Condensed Statements of Changes in Stockholders' Equity**
**Three and Nine Months Ended September 30, 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 |
| Stock-based compensation | 1,429 | 1 | - | - | 1,410,512 | - | 1,410,513 |
| Employee stock purchases | 20,426 | 20 | | | 131,226 | | 131,246 |
| Conversion of preferred to common stock | 1,877,000 | 1,878 | (187,700) | (187) | (1,691) | - | - |
| Exercise of common stock warrants, net of shares withheld for exercise price | 19,390 | 19 | - | - | 172,967 | - | 172,986 |
| Exercise of common stock options, net of shares withheld for exercise price | 16,197 | 17 | - | - | 95,694 | - | 95,711 |
| Issuance of common stock in an ATM offering | 435,414 | 435 | - | - | 7,641,765 | - | 7,642,200 |
| Issuance costs associated with an ATM offering | - | - | - | - | (263,727) | - | (263,727) |
| Issuance of common stock upon closing of follow-on offering, net of underwriting discounts and offering costs | 3,871,000 | 3,871 | - | - | 56,248,237 | - | 56,252,108 |
| Issuance of common stock warrants, note payable | - | - | - | - | 1,228,911 | - | 1,228,911 |
| Net loss | - | - | - | - | - | (23,721,820) | (23,721,820) |
| **Balance at June 30, 2024 *(unaudited)*** | 37,014,751 | $ 37,015 | 317,577 | $ 318 | $382,057,737 | $(205,410,278) | $176,684,792 |
| Stock-based compensation | - | - | - | - | 1,931,201 | - | 1,931,201 |
| Exercise of common stock warrants, net of shares withheld for exercise price | 65,204 | 65 | - | - | 553,615 | - | 553,680 |
| Exercise of common stock options, net of shares withheld for exercise price | 36,312 | 36 | - | - | 330,708 | - | 330,744 |
| Net loss | - | - | - | - | - | (29,791,789) | (29,791,789) |
| **Balance at September 30, 2024 *(unaudited)*** | 37,116,267 | $ 37,116 | 317,577 | $ 318 | $384,873,261 | $(235,202,067) | $149,708,628 |

*See accompanying notes to the condensed financial statements*



**Celcuity Inc.**
**Condensed Statements of Changes in Stockholders' Equity**
**Three and Nine Months Ended September 30, 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 |
| Stock-based compensation | 1,958 | 2 | - | - | 1,276,980 | - | 1,276,982 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Employee stock purchases | 17,477 | 17 | - | - | 102,621 | - | 102,638 |
| Conversion of preferred to common stock | 100,000 | 100 | (10,000) | (10) | (90) | - | - |
| Exercise of common stock options, net of shares withheld for exercise price | 21,086 | 22 | - | - | 113,618 | - | 113,640 |
| Net loss | - | - | - | - | - | (14,587,687) | (14,587,687) |
| **Balance at June 30, 2023 *(unaudited)*** | 22,081,893 | $ 22,082 | 1,085,873 | $ 1,086 | $232,932,164 | $(122,822,991) | $110,132,341 |
| Stock-based compensation | - | - | - | - | 1,108,637 | - | 1,108,637 |
| Conversion of preferred to common stock | 250,000 | 250 | (25,000) | (25) | (225) | - | - |
| Exercise of common stock options, net of shares withheld for exercise price | 37,500 | 37 | - | - | 59,965 | - | 60,002 |
| Net loss | - | - | - | - | - | (18,404,540) | (18,404,540) |
| **Balance at September 30, 2023 *(unaudited)*** | 22,369,393 | $ 22,369 | 1,060,873 | $ 1,061 | $234,100,541 | $(141,227,531) | $ 92,896,440 |

*See accompanying notes to the condensed financial statements*



**Celcuity Inc.**
**Condensed Statements of Cash Flows**
**(unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (75,126,064) | $ (44,930,644) |
| Adjustments to reconcile net loss to net cash and cash equivalents used for operations: | | |
| Depreciation | 94,693 | 114,824 |
| Stock-based compensation | 4,673,059 | 3,658,902 |
| Amortization of debt issuance costs and discount | 780,555 | 177,939 |
| Payment-in-kind interest | 1,110,584 | 1,345,760 |
| Non-cash operating lease, net | 326 | 3,171 |
| Change in accrued interest income | (1,112,420) | (439,331) |
| Changes in operating assets and liabilities: | | |
| Other current assets | 1,740,973 | (1,065,732) |
| Accounts payable | 4,093,903 | 3,031,923 |
| Accrued expenses | 8,047,631 | 2,826,856 |
| Net cash used for operating activities | (55,696,760) | (35,276,332) |
| | | |
| **Cash flows from investing activities:** | | |
| Proceeds from maturities of investments | 415,134,729 | 221,054,402 |
| Purchases of investments | (515,557,800) | (184,779,534) |
| Purchases of property and equipment | (204,729) | (64,945) |
| Net cash (used for) provided by investing activities | (100,627,800) | 36,209,923 |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of common stock warrants | 14,735,816 | - |
| Proceeds from exercise of employee stock options | 665,758 | 285,564 |
| Proceeds from employee stock purchases | 131,246 | 102,638 |
| Proceeds from follow-on offering, net of underwriting discounts and offering costs | 56,252,109 | - |
| Proceeds from note payable, net of debt issuance costs and discount of $ 2,437,644 | 59,226,276 | - |
| Proceeds from an ATM offering, net of issuance costs | 7,356,107 | - |
| Payments for secondary registration statement costs | (102,237) | (128,298) |
| Payments for debt issuance costs | - | (2,716) |
| Payments for finance leases | - | (2,449) |
| Net cash provided by financing activities | 138,265,075 | 254,739 |
| Net change in cash and cash equivalents | (18,059,485) | 1,188,330 |
| | | |
| **Cash and cash equivalents:** | | |
| Beginning of period | 30,662,774 | 24,571,557 |
| End of period | $ 12,603,289 | $ 25,759,887 |
| | | |
| **Supplemental disclosure of cash flow information:** | | |
| Interest paid | $ 5,114,145 | $ 2,405,441 |
| **Supplemental disclosures of non-cash investing and financing activities:** | | |
| Offering and registration statement costs included in accounts payable | $ 44,621 | $ 13,865 |
| Property and equipment included in accounts payable | $ 13,584 | $ 12,961 |
| Common stock warrants issued with note payable transaction | $ 1,228,911 | $ - |

*See accompanying notes to the condensed financial statements*



**CELCUITY INC.**
**NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)**
**(For the Three and Nine Months Ended September 30, 2024 and 2023)**

## 1. Organization

**Nature of Business**

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical-stage biotechnology company focused on development of targeted therapies for treatment of multiple solid tumor indications. 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. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer is expected to begin enrolling patients in the second quarter of 2025. 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 condensed 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 condensed 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 and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected during the remainder of the current year or for any other 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, the clinical and commercial success of its initial drug product, gedatolisib, the regulatory approval of 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, the CELC-G-201 Phase 1b/2 and the VIKTORIA-2 Phase 3 clinical 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 and financial position.



**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:

| | September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Preferred stock on an as-if-converted to common stock basis | 3,175,770 | 10,608,730 |
| Options to purchase common stock | 4,212,102 | 2,702,629 |
| Warrants to purchase common stock | 5,521,152 | 7,266,102 |
| Restricted common stock | 1,079 | 1,958 |
| Total | 12,910,103 | 20,579,419 |

Pre-funded warrant shares of 5,747,787 are included in the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2024, 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 September 30, 2024 and December 31, 2023:

| | September 30, 2024 |
|---|---|

| | Amortized Cost, as Adjusted | Gross Unrealized Holding Gains | Gross Unrealized Holding Losses | Estimated Fair Value |
|---|---|---|---|---|
| U.S. Treasury Bills | $ 251,455,468 | $ 196,920 | $ - | $ 251,652,388 |
| Total | $ 251,455,468 | $ 196,920 | $ - | $ 251,652,388 |

| | 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, contract manufacturing organizations ("CMOs") and contract research organizations ("CROs"). The Company currently has two 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 September 30, 2024, the Company had two material non-cancelable contractual commitments with respect to these arrangements, which totaled approximately $1.6 million.

**Software**

In August 2024, the Company entered into two software license agreements. These agreements will expire in August 2026. As of September 30, 2024, the Company had non-cancelable contractual commitments with respect to these arrangements, which totaled approximately $0.2 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 common stock warrants at an exercise price of $8.05 per share, which generated approximately $14.0 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.

On May 31, 2024, one of the Company's preferred shareholders elected to convert 100,000 shares of Series A Convertible Preferred Stock into 1,000,000 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 June 26, 2024, one of the Company's preferred shareholders elected to convert 87,700 shares of Series A Convertible Preferred Stock into 877,000 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.

Common stock warrants of 19,390 from several investors were exercised, which generated approximately $ 173,000 in cash in the second quarter of 2024. The 19,390 common stock warrants were net of shares withheld for exercise price.

Common stock warrants of 65,204 from several investors were exercised, which generated approximately $ 554,000 in cash in the third quarter of 2024. The 65,204 common stock warrants were net of shares withheld for exercise price.

At September 30, 2024, the Company's authorized capital stock consisted of 65,000,000 shares of common stock, of which 37,116,267 shares were outstanding, and 2,500,000 shares of preferred stock, including 1,850,000 shares designated as Series A Preferred Stock, of which 317,577 shares were outstanding. As of September 30, 2024, no dividends have been declared on the Company's capital stock.

*Sale and Issuance of Stock*

On April 22, 2024, pursuant to an Open Market Sale Agreement $^{SM}$ with Jefferies LLC, as agent, the Company sold 285,714 shares of common stock in a single transaction at a price of $17.50 per share, generating gross proceeds of $ 5.0 million.

On May 8, 2024, pursuant to an Open Market Sale Agreement with Jefferies LLC, as agent, the Company sold 149,700 shares of common stock in a single transaction at a price of $17.65 per share, generating gross proceeds of $ 2.6 million.



Commissions and other offering expenses related to the Open Market Sale Agreement transactions in April and May 2024 were $ 0.3 million.

On May 30, 2024, the Company entered into an underwriting agreement with Leerink Partners LLC, TD Securities (USA) LLC and Stifel, Nicolaus & Company, Incorporated as representatives of the several underwriters relating to the issuance and sale of 3,871,000 shares of Common Stock, at a price to the public of $15.50, generating gross proceeds of approximately $ 60.0 million. The offering closed on May 31, 2024 and resulted in net proceeds to the Company of approximately $56.3 million after deducting underwriting discounts and other offering expenses payable by the Company. The Company intends to use the net proceeds from the offering for working capital and general corporate purposes, which may include capital expenditures, research and development expenditures, clinical trial expenditures, expansion of business development activities and other general corporate purposes.

**7. Stock-Based Compensation**

The following table summarizes the activity for all stock options outstanding for the nine months ended September 30:

| | 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 | 1,557,479 | 16.37 | 874,548 | 10.13 |
| Exercised | (89,059) | 7.48 | (82,708) | 3.65 |
| Forfeited | (71,710) | 9.95 | (65,797) | 7.45 |
| Balance at September 30 | 4,212,102 | $ 11.04 | 2,702,629 | $ 7.63 |
| Options exercisable at September 30: | 1,891,297 | $ 7.11 | 1,440,231 | $ 6.26 |
| Weighted Average Grant Date Fair Value for options granted during the period: | | $ 11.38 | | $ 7.09 |

The following table summarizes additional information about stock options outstanding and exercisable at September 30, 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 |
| 4,212,102 | 8.16 | $ 11.04 | $ 18,651,440 | 1,891,297 | $ 7.11 | $ 14,838,086 |

The Company recognized stock-based compensation expense for stock options of $ 1,843,424 and $1,065,567 for the three months ended September 30, 2024 and 2023, respectively and $4,463,423 and $3,516,180 for the nine months ended September 30, 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 $26,652 and $30,188 for the three months ended September 30, 2024 and 2023, respectively, and $80,063 and $107,490 for the nine months ended September 30, 2024 and 2023, respectively. The effect of this modification on stock-based compensation over the remaining service period will be approximately $83,000. 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 $15,773 and $15,773 for the three months ended September 30, 2024 and 2023, respectively and $47,300 and $49,617 for the nine months ended September 30, 2024 and 2023, respectively. The effect of this modification on stock-based compensation over the remaining service period will be approximately $51,000. 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 $0 and $3,041 for the three months ended September 30, 2024 and 2023, respectively and $696 and $16,975 for the nine months ended September 30, 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 and the Monte Carlo simulation model was used to estimate the fair value of the performance-based awards, with the following weighted-average assumptions for the nine months ended September 30:

| | 2024 | 2023 |
|---|---|---|
| Risk-free interest rate | 3.48% - 4.71% | 3.41% - 4.61% |
| Expected volatility | 71.2 to 76.10% | 78.0 to 79.8% |
| Expected life (years) | 5.25 to 10.00 | 5.25 to 6.08 |
| Expected dividend yield | 0% | 0% |

The inputs for the Black-Scholes valuation model and the Monte Carlo simulation 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 for the time-based awards and the life of the option for the performance-based awards, 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 for the time-based awards. For the performance-based awards, the Company's full historical volatility was used to value the options.

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.

The Company had 1,079 and 1,958 shares of restricted stock outstanding as of September 30, 2024 and 2023, respectively, and no shares of restricted stock vested during the three months ended September 30, 2024 and 2023. The Company recognized stock-based compensation expense for restricted stock of $4,448 and $4,903 for the three months ended September 30, 2024 and 2023, respectively and $ 17,773 and $13,597 for the nine months ended September 30, 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 2027 by the number of shares equal to 1.0% of the aggregate number of outstanding shares of Company common stock as of the immediately preceding December 31. However, the Company's board may reduce the amount of the increase in any particular year.

At the Annual Meetings held on May 12, 2021 and May 12, 2022, the stockholders approved one-time, 500,000 increases each year for a total increase of 1,000,000, to the number of shares reserved for issuance under the 2017 Plan. At the Annual Meetings held on May 11, 2023 and May 9, 2024, the stockholders approved one-time, 1,500,000 increases each year for a total increase of 3,000,000, 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 September 30, 2024 was 1,286,511.



Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized at September 30, 2024:

| | |
|---|---|
| 2024 | $ 2,158,997 |
| 2025 | 7,470,910 |
| 2026 | 6,066,260 |
| 2027 | 4,918,768 |
| 2028 | 1,740,835 |
| **Total estimated compensation cost to be recognized** | $ 22,355,770 |

The Company recognized stock-based compensation expense related to its employee stock purchase plan of $ 83,329 and $38,167 for the three months ended September 30, 2024 and 2023, respectively and $191,863 and $129,125 for the nine months ended September 30, 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 September 30, 2024 was 373,739.

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

| | Three Months Ended September | | Nine Months Ended September | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Stock-based compensation expense in operating expenses: | | | | |
| Research and development | $ 1,190,424 | $ 660,706 | $ 3,000,641 | $ 1,954,689 |
| General and administrative | 740,777 | 447,931 | 1,672,418 | 1,704,213 |
| Total | $ 1,931,201 | $ 1,108,637 | $ 4,673,059 | $ 3,658,902 |

**8. Debt**

On May 30, 2024, the Company entered into an Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), as collateral agent, and the Lenders including Innovatus in its capacity as a Lender and Oxford Finance LLC ("Oxford"), pursuant to which Innovatus and Oxford, as Lenders, have agreed to make certain term loans ("Term Loans") to the Company in the aggregate principal amount of up to $180 million. The A&R Loan Agreement amends and restates, in its entirety, that certain Loan and Security Agreement, dated April 8, 2021, as amended, between the Company and Innovatus, as collateral agent, and the Lenders named therein.

Funding of the first $100 million under the A&R Loan Agreement occurred on May 30, 2024, including tranche payments of $ 16.8 million (the "Term A Loan") and $21.5 million (the "Term B Loan") reflecting repayment of the principal amount of loans under the Prior Loan Agreement plus accrued payment-in-kind interest, in addition to $61.7 million of new borrowings (the "Term C Loan"). The Company will be eligible to draw on a fourth tranche of $30 million (the "Term D Loan") and fifth tranche of $ 50 million (the "Term E Loan"), in each case upon achievement of certain clinical trial milestones and satisfaction of certain financial covenants determined on a pro forma as-funded basis. The Lenders may, in their sole discretion upon the Company's request, make additional term loans to the Company of $45 million (the "Term F Loan"). Funding of these additional tranches is also subject to other customary conditions and limits on when the Company can request funding for such tranches. Costs associated with the new borrowings was

approximately $2.4 million.



The Company is entitled to make interest-only payments for thirty-six months, or up to forty-eight months if certain conditions are met. The Term Loans will mature on May 1, 2029 and will bear interest at a rate equal to the sum of (a) the greater of (i) the Prime Rate (as defined in the A&R Loan Agreement) or (ii) 7.75%, plus (b) 2.85%, provided that 1.0% of such interest will be payable in-kind by adding an amount equal to such 1.0% of the outstanding principal amount to the then outstanding principal balance on a monthly basis through May 31, 2027. The A&R Loan Agreement is secured by all assets of the Company. Proceeds will be used for working capital purposes and to fund the Company's general business requirements, including the Phase 3 VIKTORIA-2 clinical trial. The A&R Loan Agreement contains customary representations and warranties and covenants, subject to customary carve-outs, and includes financial covenants related to liquidity and other financial measures. Innovatus has the right, at its election and until August 9, 2025, to convert up to 20% of the outstanding principal of the Term A Loan into shares of the Company's common stock at a price per share of $10.00 (the "Conversion Right"). Innovatus will continue to have the right to exercise a previously disclosed warrant granted to it under the Prior Loan Agreement to purchase 26,042 shares of common stock at a price per share of $ 14.40 through April 8, 2031.

The A&R Loan Agreement contains a Final Fee, which is equal to 4.5% of the initial funding of the agreement and is due on the earliest to occur of (a) the Maturity Date, (b) the acceleration of any Term Loan, and (c) the prepayment of the Term Loans. There is also a contingent non-utilization fee for both the Term D and Term E loans. If the Company achieves the Term D Milestone and (i) fails to draw the full amount of the Term D Loan during the Term D Draw Period and (ii) fails to notify Collateral Agent, at any time before the date that is four weeks after the Company's achievement of the Term D Milestone, of the Company's intent not to draw the full amount of the Term D Loan, a non-utilization fee of $900,000, with respect to the Term D Loan shall become due and payable on the earliest of (i) the termination of the Term D Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. If the Company achieves the Term E Milestone and (i) fails to draw the full amount of the Term E Loan during the Term E Draw Period and (ii) fails to notify Collateral Agent, at any time before the date that is four weeks after the Company's achievement of the Term E Milestone, of the Company's intent not to draw the full amount of the Term E Loan, a non-utilization fee of $ 1,500,000, with respect to the Term E Loan shall become due and payable on the earliest of (i) the termination of the Term E Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. After the 18-month anniversary of the Effective Date, the Company shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under the A&R Loan Agreement, provided the Company (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least seven Business Days prior to such prepayment, and (ii) pays to Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Fee, plus (D) all other outstanding Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. At May 30, 2024, the Company recognized the Final Fee of $4.5 million as additional debt principal and a corresponding debt discount to be amortized over the life of the loan.

In connection with the funding of each of the Term C Loan, the Term D Loan, the Term E Loan and the Term F Loan, the Company agreed to issue to Innovatus and Oxford warrants to purchase that number of shares of the Company's common stock equal to 2.5% of the principal amount of the applicable Term Loan divided by the exercise price, which shall, with respect to the Term C Loan, be equal to the lower of (i) the volume weighted average closing price of the Company's common stock for the five-trading day period ending on the last trading day immediately preceding the execution of the A&R Loan Agreement or (ii) the closing price on the last trading day immediately preceding the execution of the A&R Loan Agreement. Accordingly, on May 30, 2024, the Company issued 103,876 warrants with an exercise price of $14.84 per share. The relative fair value of the warrants was approximately $1.2 million. For the additional Term Loans, the exercise price will be based on the lower of (i) the exercise price for the Warrants issued pursuant to the Term C Loan or (ii) the volume weighted average closing price of the Company's common stock for the five-trading day period ending on the last trading day immediately preceding the applicable Term Loan funding. The Warrants may be exercised on a cashless basis and are exercisable through the tenth anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant.

The Company evaluated the change of terms under ASC 470-50, "Debt – Modification and Extinguishment", and concluded the change in terms did not result in significant and consequential changes to the economic substance of the debt and thus resulted in a modification of the debt and not an extinguishment of the debt.



Long-term debt consisted of the following at September 30, 2024 and December 31, 2023:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Note payable | $ 100,000,000 | $ 35,000,000 |
| Add: Final fee | 4,500,000 | - |
| Add: PIK interest (added to principal) | 340,164 | 2,565,660 |
| Less: unamortized debt issuance costs | (1,856,880) | (480,810) |
| Less: unamortized debt discount | (6,059,370) | (49,439) |
| Total long-term debt | $ 96,923,914 | $ 37,035,411 |

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

| | Years Ending December 31, |
|---|---|
| 2027 | $ 30,538,311 |
| 2028 | 52,351,390 |
| 2029 | 21,950,463 |
| Total | $ 104,840,164 |

**9. Subsequent Event**

On October 7, 2024, the Company held a Special Meeting of Stockholders at which the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the authorized number of shares of the Company's Common Stock from 65,000,000 to 95,000,000 (the "Authorized Share Increase"). The Authorized Share Increase had previously been approved, subject to stockholder approval, by the Company's Board of Directors. On October 7, 2024, the Company filed a certificate of amendment to the Certificate of Incorporation with the Delaware Secretary of State to effect the Authorized Share Increase, which became effective immediately upon its filing.

**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 treatment of multiple solid tumor indications. 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. In 2022, the Company began enrolling patients in VIKTORIA-1, a Phase 3 study evaluating gedatolisib and fulvestrant with and without Ibrance® (palbociclib) as second line treatment for patients with HR+, HER2- advanced breast cancer. In early 2024, the Company began enrolling patients in CELC-G-201, a Phase 1b/2 study evaluating gedatolisib combined with Nubeqa® (darolutamide) in patients with metastatic castration resistant prostate cancer (mCRPC). In May 2024, the Company announced plans to initiate VIKTORIA-2, a Phase 3 trial evaluating gedatolisib combined with fulvestrant plus a CDK 4/6 inhibitor as first-line treatment for patients with HR+, HER2- advanced breast cancer. The first patient is expected to be enrolled in the second quarter of 2025. 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.

Gedatolisib is a potent, well-tolerated, reversible, ATP-competitive, pan-PI3K/mTOR inhibitor 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 I 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 AEs. 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 9% discontinued treatment.



As of September 30, 2024, 492 patients with solid tumors have received gedatolisib in eight completed clinical trials. 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 September 30, 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 wild-type ("WT") and PIK3CA mutant ("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 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 AEs were Grade 1 and 2. The most frequently observed AEs 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 AEs 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). Enrollment of the PIK3CA WT cohort is 100% enrolled and enrollment in the PIK3CA MT cohort is on plan. The PIK3CA WT cohort represents approximately 60% of the total patients enrolled to date in VIKTORIA-1. Based on our current forecast of reaching the event thresholds that will trigger primary analysis in both the PIKCA WT and MT cohorts, we expect to report topline data for the PIK3CA WT cohort sometime in late Q1 2025 or during Q2 2025 and to report topline data for the PIK3CA MT cohort in the second half of 2025. If the results from the PIK3CA wild-type patient cohort are positive, we would expect to file a new drug application, or NDA, with this data and follow-up with a supplemental NDA for the PIK3CA mutant cohort if those results are positive. If gedatolisib ultimately does receive FDA approval for both the PIK3CA wild-type and mutant populations, we estimate the peak revenue potential for this second-line indication could exceed $2 billion.



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. We expect to report preliminary data in Q2 of 2025.

The Phase 3 VIKTORIA-2 clinical trial, an open-label, randomized study to evaluate the efficacy and safety of gedatolisib combined with fulvestrant plus a CDK4/6 inhibitor in comparison to fulvestrant plus a CDK4/6 inhibitor as first-line treatment for patients with HR+/HER2- advanced breast cancer who are endocrine therapy resistant is on track to enroll its first Patient in Q2 2025. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. The safety profile of gedatolisib combined with fulvestrant and palbociclib is well described, but the investigational combination of gedatolisib with ribociclib has not yet been clinically tested. Therefore, a safety run-in of approximately 12-36 subjects will evaluate the safety profile of gedatolisib combined with ribociclib and fulvestrant. The safety run-in will be completed, and gedatolisib's Phase 3 dose confirmed, before enrolling patients in the Phase 3 portion of the study.

For the Phase 3 study, approximately 638 subjects who meet the eligibility criteria will be assigned to a cohort based on their PIK3CA mutation status. After the investigator selects the CDK4/6 inhibitor for a subject, the subject will then be randomly assigned on a 1:1 basis to either Arm A (gedatolisib, fulvestrant, and Investigator's choice of ribociclib or palbociclib) or Arm B (fulvestrant and Investigator's choice of ribociclib or palbociclib).

The clinical trial primary endpoints are progression free survival (PFS), per RECIST 1.1 criteria, as assessed by blinded independent central review. The primary PFS endpoints will be evaluated separately in subjects who are PI3KCA WT and PI3KCA MT.

The study's design was reviewed and discussed with the U.S. Food and Drug Administration (FDA) during a Type C meeting. This global trial is expected to enroll subjects at up to 200 clinical sites across North America, Europe, Latin America, and Asia. Site qualification activities to support activation for the 200 sites is on track.

**Recent Developments**

Enrollment in our VIKTORIA-1 study remains robust and on-track. The PIK3CA WT cohort is 100% enrolled, and enrollment in the PIK3CA MT cohort is on plan. Based on our current forecast of reaching the event thresholds that will trigger primary analysis in both the PIK3CA WT and MT cohorts, we expect to report topline data for the PIK3CA WT cohort sometime in late Q1 2025 or during Q2 2025 and to report topline data for the PIK3CA MT cohort in the second half of 2025.

The Phase 1b/2 clinical trial, evaluating gedatolisib in combination with darolutamide for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC), is ongoing and expected to report preliminary data in Q2 2025

The VIKTORIA-2 Phase 3 clinical trial remains on track to enroll its first patient in Q2 2025. Site qualification activities to support activation of up to 200 sites across North America, Europe, Latin America, and Asia are on track.

Overall survival data from the B2151009 Phase 1b clinical trial will be presented at the San Antonio Breast Cancer Symposium (SABCS), taking place December 10-13, 2024.

Additional nonclinical data further characterizing the mechanism of action of gedatolisib and its effect on breast cancer cell metabolic functions will also be presented at the SABCS.

In October, Cancers published results of nonclinical studies in gynecological cancer cell line models highlighting the differences between single-node inhibitors of the PI3K/AKT/mTOR pathway and gedatolisib. The published manuscript is available online and on the publications section of Celcuity's website.

**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 September 30, 2024 and 2023, we reported a net loss of approximately $29.8 million and $18.4 million, respectively, and for the nine months ended September 30, 2024, we reported a net loss of approximately $75.1 million and $44.9 million, respectively. As of September 30,

2024, we had an accumulated deficit of approximately $235.2 million. As of September 30, 2024, we had cash and cash equivalents and short-term investments of approximately $264.1 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 as a second line treatment for HR+, HER2- advanced breast cancer. 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. In May 2024, we announced plans to initiate a Phase 3 clinical trial, VIKTORIA-2, to evaluate gedatolisib plus a CDK4/6 inhibitor and fulvestrant as a first-line treatment for patients with HR+, HER2-, advanced breast cancer who are endocrine therapy resistant. 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.

*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 clinical trial, the CELC-G-201 Phase 1b/2 clinical trial, and the VIKTORIA-2 Phase 3 clinical 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 clinical trial, the CELC-G-201 Phase 1b/2 clinical trial, and the VIKTORIA-2 Phase 3 clinical trial. We would expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first drug, gedatolisib. These increased expenses are expected to include employee-related, consulting costs and professional fees.



*Interest Expense*

Interest expense is primarily due to a Loan Agreement.

*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 September 30, 2024 and 2023***

| | Three Months Ended September 30, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2024 | 2023 | $ | Percent Change |
| **Statements of Operations Data:** | | | | |
| Operating expenses: | | | | |
| Research and development | $ 27,587,483 | $ 17,488,236 | $ 10,099,247 | 58% |
| General and administrative | 2,472,416 | 1,409,801 | 1,062,615 | 75 |
| Total operating expenses | 30,059,899 | 18,898,037 | 11,161,862 | 59 |
| Loss from operations | (30,059,899) | (18,898,037) | (11,161,862) | 59 |
| Other (expense) income | | | | |
| Interest expense | (3,343,989) | (1,372,132) | (1,971,857) | 144 |
| Interest income | 3,612,099 | 1,865,629 | 1,746,470 | 94 |
| Other income, net | 268,110 | 493,497 | (225,387) | (46) |
| **Net loss before income taxes** | **(29,791,789)** | **(18,404,540)** | **(11,387,249)** | **62** |

| | | | | |
|---|---|---|---|---|
| Income tax benefits | - | - | - | - |
| **Net loss** | **$ (29,791,789)** | **$ (18,404,540)** | **$ (11,387,249)** | **62%** |



***Comparison of the Nine Months Ended September 30, 2024 and 2023***

| | Nine Months Ended September 30, | | Increase (Decrease) | |
|---|---|---|---|---|
| | **2024** | **2023** | **$** | **Percent Change** |
| **Statements of Operations Data:** | | | | |
| Operating expenses: | | | | |
| Research and development | $ 70,732,017 | $ 42,512,811 | $ 28,219,206 | 66% |
| General and administrative | 6,104,803 | 3,988,248 | 2,116,555 | 53 |
| Total operating expenses | 76,836,820 | 46,501,059 | 30,335,761 | 65 |
| Loss from operations | (76,836,820) | (46,501,059) | (30,335,761) | 65 |
| Other (expense) income | | | | |
| Interest expense | (7,005,284) | (3,929,140) | (3,076,144) | 78 |
| Interest income | 8,716,040 | 5,499,555 | 3,216,485 | 58 |
| Other income, net | 1,710,756 | 1,570,415 | 140,341 | 9 |
| **Net loss before income taxes** | **(75,126,064)** | **(44,930,644)** | **(30,195,420)** | **67** |
| Income tax benefits | - | - | - | - |
| **Net loss** | **$ (75,126,064)** | **$ (44,930,644)** | **$ (30,195,420)** | **67%** |

*Research and Development*

Our research and development expenses for the three months ended September 30, 2024 were approximately $27.6 million, representing an increase of approximately $10.1 million, or 58%, compared to the same period in 2023. Of the $10.1 million increase in research and development expense, $6.3 million was primarily related to costs supporting on-going activities for the VIKTORIA-1 and CELC-G-201 trials and the initiation of the VIKTORIA-2 Phase 3 pivotal trial. The remaining $3.8 million was related to increased employee and consulting expenses.

Our research and development expenses for the nine months ended September 30, 2024 were approximately $70.7 million, representing an increase of approximately $28.2 million, or 66%, compared to the same period in 2023. Of the $28.2 million increase in research and development expenses, $20.8 was primarily related to costs supporting on-going activities for the VIKTORIA-1 and CELC-G-201 trials and activities supporting the initiation of the VIKTORIA-2 Phase 3 pivotal trial. The remaining $7.4 million was related to increased employee and consulting expenses.

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 and manage the VIKTORIA-1 Phase 3, the CELC-G-201 Phase 1b/2 and the VIKTORIA-2 Phase 3 pivotal trial.

*General and Administrative*

Our general and administrative expenses for the three months ended September 30, 2024 were approximately $2.5 million, representing an increase of approximately $1.1 million, or 75%, compared to the same period in 2023. Of the $1.1 million increase in general and administrative expense, $0.9 million was related to increased employee and consulting expenses. The remaining $0.2 million of the $1.1 million increase resulted from professional fees and other administrative expenses.

Our general and administrative expenses for the nine months ended September 30, 2024 were approximately $6.1 million, representing an increase of approximately $2.1 million, or 53%, compared to the same period in 2023. Employee related expenses accounted for $1.5 million of the $2.1 million increase. The remaining $0.6 million of the 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, 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 September 30, 2024 was $3.3 million and represents an increase of $2.0 million, or 144%, compared to the same period in 2023. Interest expense is the result of a Loan Agreement that was executed in April 2021, amended in August 2022 and March 2024, and further amended and restated in May 2024. The increase is due primarily to the incremental $61.7 million funding of Term Loan C in May 2024. The $3.3 million of interest expense includes $0.7 million of non-cash interest expense.

Interest expense for the nine months ended September 30, 2024 was $7.0 million and represents an increase of $3.1 million, or 78%, compared to the same period in 2023. The increase is due primarily to the incremental $61.7 million funding of Term Loan C in May 2024. The $7.0 million of interest expense includes $1.9 million of non-cash interest expense.

*Interest Income*

Interest income for the three months ended September 30, 2024 was $3.6 million and represents an increase of $1.7 million compared to the same period in 2023. The increase was primarily from the closing of additional equity and debt financing activities in May 2024, leading to higher cash, cash equivalents and short-term investment balances.

Interest income for the nine months ended September 30, 2024 was $8.7 million and represents an increase of $3.2 million compared to the same period in 2023. The increase was primarily from the closing of additional equity and debt financing activities in May 2024, 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 September 30, 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 September 30, 2024, we raised an aggregate of approximately $368.7 million of net proceeds through sales of our securities, and as of September 30, 2024 had $100.0 million of borrowings under loan agreements, not including payable-in-kind interest. As of September 30, 2024, our cash and cash equivalents and short-term investments were approximately $12.6 million and $251.5 million, respectively, and we had an accumulated deficit of approximately $235.2 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 $50.0 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 October 12, 2022, pursuant to this agreement, the Company sold 500,000 shares of common stock in a single transaction at a price of $10.35 per share generating gross proceeds of $5.2 million ($4.8 million net of commissions and offering expenses) 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 $15.0 million ($14.4 million net of commissions and offering expenses). In April 2024 and May 2024, pursuant to the Open Market Sale Agreement with Jefferies LLC, as agent, the Company sold 285,714 and 149,700 shares of common stock, respectively, 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 $0.3 million. At September 30, 2024, $22.2 million of common stock remains available for sale under the Jefferies agreement.

*Equity Offering*: On May 30, 2024, the Company entered into an underwriting agreement with Leerink Partners LLC, TD Securities (USA) LLC and Stifel, Nicolaus & Company, Incorporated as representatives of the several underwriters relating to the issuance and sale of 3,871,000 shares of common stock, at a price to the public of $15.50, generating gross proceeds of approximately $60.0 million. The offering closed on May 31, 2024 and resulted in net proceeds to the Company of approximately $56.3 million after deducting underwriting discounts and other offering expenses payable by the Company. The Company intends to use the net proceeds from the offering for working capital and general corporate purposes, which may include research and development expenditures, clinical trial expenditures, expansion of business development activities and other general corporate purposes.



*Loan Agreement.* On May 30, 2024, the Company entered into an Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), as collateral agent, and the Lenders including Innovatus in its capacity as a Lender and Oxford Finance LLC ("Oxford"), pursuant to which Innovatus and Oxford, as Lenders, have agreed to make certain term loans ("Term Loans") to the Company in the aggregate principal amount of up to $180 million. The A&R Loan Agreement amends and restates, in its entirety, that certain Loan and Security Agreement, dated April 8, 2021, as amended, between the Company and Innovatus, as collateral agent, and the Lenders named therein.

Funding of the first $100 million under the A&R Loan Agreement occurred on May 30, 2024, including tranche payments of $16.8 million (the "Term A Loan") and $21.5 million (the "Term B Loan") reflecting repayment of the principal amount of loans under the Prior Loan Agreement plus accrued payment-in-kind interest, in addition to $61.7 million of new borrowings (the "Term C Loan"). The Company will be eligible to draw on a fourth tranche of $30 million (the "Term D Loan") and fifth tranche of $50 million (the "Term E Loan"), in each case upon achievement of certain clinical trial milestones and satisfaction of certain financial covenants determined on a pro forma as-funded basis. The Lenders may, in their sole discretion upon the Company's request, make additional term loans to the Company of $45 million (the "Term F Loan"). Funding of these additional tranches is also subject to other customary conditions and limits on when the Company can request funding for such tranches. Costs associated with the new borrowings was approximately $2.4 million.

The Company is entitled to make interest-only payments for thirty-six months, or up to forty-eight months if certain conditions are met. The Term Loans will mature on May 1, 2029 and will bear interest at a rate equal to the sum of (a) the greater of (i) the Prime Rate (as defined in the A&R Loan Agreement) or (ii) 7.75%, plus (b) 2.85%, provided that 1.0% of such interest will be payable in-kind by adding an amount equal to such 1.0% of the outstanding principal amount to the then outstanding principal balance on a monthly basis through May 31, 2027. The A&R Loan Agreement is secured by all assets of the Company. Proceeds will be used for working capital purposes and to fund the Company's general business requirements, including the Phase 3 VIKTORIA-2 clinical trial. The A&R Loan Agreement contains customary representations and warranties and covenants, subject to customary carve-outs, and includes financial covenants related to liquidity and other financial measures. Innovatus has the right, at its election and until August 9, 2025, to convert up to 20% of the outstanding principal of the Term A Loan into shares of the Company's common stock at a price per share of $10.00 (the "Conversion Right"). Innovatus will continue to have the right to exercise a previously disclosed warrant granted to it under the Prior Loan Agreement to purchase 26,042 shares of common stock at a price per share of $14.40 through April 8, 2031.

The A&R Loan Agreement contains a Final Fee, which is equal to 4.5% of the initial funding of the agreement and is due on the earliest to occur of (a) the Maturity Date, (b) the acceleration of any Term Loan, and (c) the prepayment of the Term Loans. There is also a contingent non-utilization fee for both the Term D and Term E loans. If the Company achieves the Term D Milestone and (i) fails to draw the full amount of the Term D Loan during the Term D Draw Period and (ii) fails to notify Collateral Agent, at any time before the date that is four weeks after the Company's achievement of the Term D Milestone, of the Company's intent not to draw the full amount of the Term D Loan, a non-utilization fee of $900,000, with respect to the Term D Loan shall become due and payable on the earliest of (i) the termination of the Term D Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. If the Company achieves the Term E Milestone and (i) fails to draw the full amount of the Term E Loan during the Term E Draw Period and (ii) fails to notify Collateral Agent, at any time before the date that is four weeks after the Company's achievement of the Term E Milestone, of the Company's intent not to draw the full amount of the Term E Loan, a non-utilization fee of $1,500,000, with respect to the Term E Loan shall become due and payable on the earliest of (i) the termination of the Term E Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. After the 18-month anniversary of the Effective Date, the Company shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under the A&R Loan Agreement, provided the Company (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least seven Business Days prior to such prepayment, and (ii) pays to Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Fee, plus (D) all other outstanding Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. At May 30, 2024, the Company recognized the Final Fee of $4.5 million as additional debt principal and a corresponding debt discount to be amortized over the life of the loan.



In connection with the funding of each of the Term C Loan, the Term D Loan, the Term E Loan and the Term F Loan, the Company agreed to issue to Innovatus and Oxford warrants to purchase that number of shares of the Company's common stock equal to 2.5% of the principal amount of the applicable Term Loan divided by the exercise price, which shall, with respect to the Term C Loan, be equal to the lower of (i) the volume weighted average closing price of the Company's common stock for the five-trading day period ending on the last trading day immediately preceding the execution

of the A&R Loan Agreement or (ii) the closing price on the last trading day immediately preceding the execution of the A&R Loan Agreement. Accordingly, on May 30, 2024, the Company issued 103,876 warrants with an exercise price of $14.84 per share. The relative fair value of the warrants was approximately $1.2 million. For the additional Term Loans, the exercise price will be based on the lower of (i) the exercise price for the Warrants issued pursuant to the Term C Loan or (ii) the volume weighted average closing price of the Company's common stock for the five-trading day period ending on the last trading day immediately preceding the applicable Term Loan funding. The Warrants may be exercised on a cashless basis and are exercisable through the tenth anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant.

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 clinical trial, the CELC-G-201 Phase 1b/2 trial and the VIKTORIA-2 Phase 3 pivotal trial, 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. 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 2026.

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 nine months ended September 30:

| | September 30, | |
|---|---|---|
| | **2024** | **2023** |
| Net cash provided by (used in): | | |
| Operating activities | $ (55,696,760) | $ (35,276,332) |
| Investing activities | (100,627,800) | 36,209,923 |
| Financing activities | 138,265,075 | 254,739 |
| Net increase (decrease) in cash and cash equivalents | $ (18,059,485) | $ 1,188,330 |



*Operating Activities*

Net cash used in operating activities was approximately $55.7 million for the nine months ended September 30, 2024 and consisted primarily of a net loss of approximately $75.1 million, partially offset by working capital changes of $13.9 million and non-cash expense items of approximately $5.5 million. Non-cash expense items of approximately $5.5 million primarily consisted of $4.7 million of stock-based compensation expense and net non-cash interest of $0.8 million. The approximately $13.9 million of working capital changes was primarily due to increases in accrued expenses and accounts payable, and a decrease in other current assets.

Net cash used in operating activities was approximately $35.3 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of approximately $44.9 million partially offset by non-cash expense items of approximately $4.8 million and working capital changes of $4.8 million. Non-cash expense items of approximately $4.8 million primarily consisted of $3.7 million of stock-based compensation expense, net non-cash interest of $1.0 million and depreciation expense of $0.1 million. The approximately $4.8 million of working capital changes was primarily due to increases in accounts payable and accrued expenses of $3.0 million and $2.8 million, respectively, offset by an approximately $1.0 million increase in other current assets.

*Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2024 was approximately $100.6 million and consisted primarily of net purchases of short-term investments in government securities (U.S. Treasury Bills and U.S. government securities), partially offset by purchases of property and equipment.

Net cash provided by investing activities for the nine months ended September 30, 2023 was approximately $36.2 million and consisted primarily of net proceeds from maturities of short-term investments in government securities (U.S. Treasury Bills and U.S. government securities) partially offset by minimal purchase of property and equipment.

*Financing Activities*

Net cash provided by financing activities for the nine months ended September 30, 2024 was approximately $138.2 million and primarily consisted of net proceeds of approximately $59.2 million from incremental debt financing, $56.3 million from an equity offering and $7.3 million from an at-the market offering. The remaining $15.4 million consisted of proceeds from the exercise of common stock warrants, the exercise of employee stock options and employee stock purchases.

Net cash provided by financing activities for the nine months ended September 30, 2023 was approximately $0.3 million and primarily consisted of proceeds from the exercise of employee stock options and proceeds from employee stock purchases, partially 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, as well as our planned Phase 3 VIKTORIA-2 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 expectations with respect to availability of capital, including accessing our current debt facility or any other debt facility or other capital sources in the future, and our assumption that we will have adequate authorized shares for future equity issuances; (xiv) 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 (xv) 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; stock market volatility or other factors that may affect our ability to access capital on favorable terms or at all; 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 September 30, 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 September 30, 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

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 September 30, 2024, we issued 65,204 shares of common stock upon the exercise of previously issued warrants as follows:

- 58,282 shares were issued pursuant to the exercise of warrants at an exercise price of $9.50 per share, resulting in cash proceeds of approximately $554,000; and
- 6,922 shares were issued pursuant to the exercise of 17,256 warrants in a cashless exercise whereby 10,334 shares with a value of $15.87 per share were used to settle the exercise price and the remaining 6,922 shares were issued to the warrant holders.

The shares were issued pursuant to an 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 September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) 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 Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on October 9, 2024). |
| 3.2 | Bylaws, (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2017). |
| 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* | The following information from the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 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, (v) the Notes to Condensed Financial Statements and (vi) the information under Part II, Item 5, "Other Information." |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith.
** Furnished herewith.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 14, 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 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: November 14, 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: November 14, 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 September 30, 2024 (the "Report") by Celcuity Inc. ("Registrant"), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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: November 14, 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 September 30, 2024 (the "Report") by Celcuity Inc. ("Registrant"), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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: November 14, 2024

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