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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2026

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.)**

2800 Campus Drive, Suite 140
Minneapolis, Minnesota 55441

(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: (763) 392-0123

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 ☒

As of May 7, 2026, there were 48,766,288 shares of the registrant's common stock outstanding.

Celcuity Inc.
Table of Contents

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements regarding us, our business prospects and our results of operations that are subject to certain risks and uncertainties that could cause our actual business, prospects and results of operations to differ materially from those that may be anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 26, 2026 (the "2025 10-K"), and Part II, Item 1A, "Risk Factors" of this Quarterly Report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report. We expressly disclaim any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Readers are urged to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the Securities and Exchange Commission (the "SEC") that advise interested parties of the risks and uncertainties that may affect our business.

All statements, other than statements of historical facts, contained in this Quarterly Report, including statements regarding our plans, objectives and expectations for our business, operations and financial performance and condition, are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "ongoing," "plan," "potential," "predict," "should," "target," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our results, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this Quarterly Report. Additionally, our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements may include, among other things, statements relating to:

- our clinical trial plans and the estimated timelines and costs for such trials;
- our plans to develop and commercialize our products, and our expectations about the market opportunity for gedatolisib in the U.S. and internationally, and our ability to serve those markets;
- 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, and our interpretation of the data from the *PIK3CA* wild-type ("WT") and mutant-type ("MT") cohorts of the Phase 3 VIKTORIA-1 clinical trial;
- our expectations regarding the timeline of patient enrollment and results from clinical trials for gedatolisib, including our ongoing Phase 3 VIKTORIA-1 clinical trial, ongoing Phase 3 VIKTORIA-2 clinical trial, and ongoing Phase 1b/2 clinical trial;
- our expectations regarding our ability to obtain U.S. Food and Drug Administration ("FDA") approval of our New Drug Application ("NDA") for gedatolisib, any supplemental NDAs ("sNDAs") we submit to FDA, and approvals outside the U.S., to commercialize gedatolisib;
- our expectations regarding governmental laws and regulations affecting our operations, including, without limitation, developments in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations internationally and in the U.S., and laws that affect our operations and our laboratory;
- our expectations with respect to the development, validation, required approvals, costs, and development and regulatory timelines, of gedatolisib;
- our beliefs related to the potential benefits resulting from Fast Track designation and Breakthrough Therapy designation as it relates to the development of gedatolisib, and Real-Time Oncology Review ("RTOR") and Priority Review as relates to the submission to the FDA, and FDA review of, our NDA and any sNDAs for gedatolisib;

- our plans with respect to research and development and related expenses for the foreseeable future;
- our beliefs about our ability to capitalize on the exclusive global development and commercialization rights obtained from our license agreement with Pfizer Inc. ("Pfizer") with respect to gedatolisib;
- our expectations regarding the future payments that may be owed to Pfizer under our license agreement with them;
- our beliefs with respect to the potential rate and degree of market acceptance and clinical utility of gedatolisib, both in the U.S. and internationally;
- our revenue expectations;
- our expectations regarding business development activities, including collaborations with pharmaceutical companies;
- our plans with respect to pricing in the U.S. and internationally, and our ability to obtain reimbursement for gedatolisib, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement from third-party payors, such as commercial insurance companies and health maintenance organizations, and from government insurance programs, such as Medicare and Medicaid;
- our expectations as to the use of proceeds from our financing activities;
- 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;
- our beliefs regarding the adequacy of our cash on hand to fund our clinical trials, anticipated commercial launch expenses, capital expenditures, working capital, and other general corporate expenses, as well as the costs associated with being a public company;
- our plans with respect to potentially raising capital; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for gedatolisib, including its formulations and methods of use.

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 potential inability to develop, validate, obtain regulatory approval for and commercialize gedatolisib on a timely basis or at all; the uncertainties and costs associated with clinical studies and with developing and commercializing pharmaceuticals; 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, including our current and any future suppliers of our product candidate; maintaining continuity of clinical and commercial supply of gedatolisib; 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; 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 gedatolisib and time and expense associated with enforcing our intellectual property rights against third parties, and defending third-party claims of intellectual property infringement, investigations or litigation threatened or initiated against us.

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Celcuity Inc.
Condensed Balance Sheets
(in thousands, except share and par value amounts)

	March 31, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 145,191	$ 165,703
Investments	241,873	275,794
Prepaid clinical trial costs	15,374	18,896
Other current assets	6,491	5,266
Total current assets	408,929	465,659
Property and equipment, net	619	499
Operating lease right-of-use assets	13	51
Other non-current assets	603	349
Total assets	$ 410,164	$ 466,558
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,454	$ 6,407
Accrued clinical trial costs	8,771	16,826
Other accrued expenses	13,973	20,865
Operating lease liabilities, current	13	54
Total current liabilities	33,211	44,152
Convertible notes	195,566	195,324
Note payable	127,862	126,527
Total liabilities	356,639	366,003
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,500,000 shares authorized as of March 31, 2026, and December 31, 2025; 0 shares issued and outstanding as of March 31, 2026, and December 31, 2025	—	—
Common stock, $0.001 par value; 95,000,000 shares authorized as of March 31, 2026, and December 31, 2025; 48,347,390 and 48,244,960 shares issued and outstanding as of March 31, 2026, and December 31, 2025, respectively	48	48
Additional paid-in capital	555,215	549,404
Accumulated deficit	(501,738)	(448,897)
Total stockholders' equity	53,525	100,555
Total liabilities and stockholders' equity	$ 410,164	$ 466,558

See accompanying notes to the unaudited condensed financial statements.

Celcuity Inc.
Condensed Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 33,063	$ 29,759
Selling, general and administrative	17,444	6,374
Total operating expenses	50,507	36,133
Loss from operations	(50,507)	(36,133)
Other (expense) income:		
Interest expense	(6,085)	(3,183)
Interest income	3,751	2,319
Other (expense) income, net	(2,334)	(864)
Net loss before income taxes	(52,841)	(36,997)
Income taxes	—	—
Net loss	$ (52,841)	$ (36,997)
Net loss per share, basic and diluted	$ (0.97)	$ (0.86)
Weighted average common shares outstanding, basic and diluted	54,462,826	43,052,757

See accompanying notes to the unaudited condensed financial statements.

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2024	37,143,242	$ 37	317,577	$ —	$ 387,437	$ (271,855)	$ 115,619
Stock-based compensation	—	—	—	—	2,444	—	2,444
Exercise of common stock options, net of shares withheld for exercise price	500	—	—	—	2	—	2
Exercise of common stock warrants, net of shares withheld for exercise price	695,650	1	—	—	5,599	—	5,600
Net loss	—	—	—	—	—	(36,997)	(36,997)
Balance as of March 31, 2025	37,839,392	$ 38	317,577	$ —	$ 395,482	$ (308,852)	$ 86,668

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2025	48,244,960	$ 48	—	$ —	$ 549,404	$ (448,897)	$ 100,555
Stock-based compensation	215	—	—	—	5,325	—	5,325
Exercise of common stock options, net of shares withheld for exercise price	56,427	—	—	—	455	—	455
Exercise of common stock warrants, net of shares withheld for exercise price	45,788	—	—	—	31	—	31
Net loss	—	—	—	—	—	(52,841)	(52,841)
Balance as of March 31, 2026	48,347,390	$ 48	—	$ —	$ 555,215	$ (501,738)	$ 53,525

See accompanying notes to the unaudited condensed financial statements.

Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (52,841)	$ (36,997)
Adjustments to reconcile net loss to net cash and cash equivalents used in operations:		
Depreciation	47	37
Stock-based compensation	5,325	2,444
Amortization of debt issuance costs and discount	1,252	551
Payment-in-kind interest	325	249
Non-cash interest income	(883)	(946)
Non-cash operating lease expense	(3)	(1)
Changes in operating assets and liabilities:		
Prepaid clinical trial costs	3,522	(2,118)
Other current assets	(976)	(318)
Accounts payable	4,080	613
Accrued clinical trial costs	(8,055)	1,504
Other accrued expenses	(6,858)	(871)
Net cash used in operating activities	(55,065)	(35,853)
Cash flows from investing activities:		
Proceeds from maturities of investments	50,000	66,808
Purchases of investments	(15,196)	(42,486)
Purchases of property and equipment	(249)	(60)
Purchases of capitalized software	(36)	—
Net cash provided by investing activities	34,519	24,262
Cash flows from financing activities:		
Proceeds from exercise of common stock options	206	—
Proceeds from exercise of common stock warrants	31	5,600
Payments for secondary registration statement costs	(203)	(46)
Net cash provided by financing activities	34	5,554
Net change in cash and cash equivalents	(20,512)	(6,037)
Cash and cash equivalents:		
Beginning of period	165,703	22,515
End of period	$ 145,191	$ 16,478
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,889	$ 2,383
Cash paid for operating leases	$ 56	$ 54
Supplemental disclosures of non-cash investing and financing activities:		
Capitalized software included in accounts payable	$ 85	$ —
Exercise of stock options pending receipt of cash proceeds	$ 249	$ 2

See accompanying notes to the unaudited condensed financial statements.

1. Organization and Liquidity

Organization

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. The Company's lead therapeutic candidate is gedatolisib, a kinase inhibitor of the phosphatidylinositol 3-kinase ("PI3K"), serine/threonine-protein kinase protein kinase B ("AKT"), mechanistic target of rapamycin ("mTOR") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PI3K/AKT/mTOR ("PAM") pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) ("HR+/HER2-") locally advanced or metastatic breast cancer ("ABC"), has reported detailed results for Study 1, which evaluated patients with *PIK3CA* WT tumors, and announced topline results for Study 2, which evaluated patients with *PIK3CA* MT tumors. The Company's Phase 3 clinical trial, VIKTORIA-2, is ongoing and incorporates two independent studies, Study 1 and Study 2, evaluating two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib combined with palbociclib and fulvestrant as first-line treatment for patients with endocrine resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib combined with palbociclib and letrozole as first-line treatment for patients with endocrine sensitive HR+/HER2- ABC. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer ("mCRPC"), is ongoing. The Company was co-founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota.

Liquidity

Since inception, the Company has not generated any revenue from product sales or other sources and has incurred operating losses and negative cash flows from operations. The Company's primary uses of cash, cash equivalents, and investments to date have been funding clinical trials and research and development activities, the scaling of commercial launch-related activities such as marketing, supply chain, distribution, market access and other commercial operations, business planning, establishing and maintaining the Company's intellectual property portfolio, hiring personnel, leasing premises and associated capital expenditures, raising capital, and providing general and administrative support for these operations. As of March 31, 2026, the Company had an accumulated deficit of $501.7 million. To date, the Company has funded operations primarily through private placements, registered offerings of its equity securities, convertible notes, and borrowings under loan agreements.

As of March 31, 2026, the Company had $387.1 million in cash, cash equivalents and short-term investments. The Company believes its existing cash, cash equivalents and short-term investments will be sufficient to fund planned operations for at least one year from the issuance of these unaudited condensed financial statements.

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.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and pursuant to the rules and regulations of the SEC.

The accompanying unaudited condensed financial statements include the accounts of the Company and have been prepared in accordance with Article 8 of Regulation S-X promulgated by the SEC. Accordingly, as permitted by Article 8, the unaudited condensed financial statements do not include all of the information required by U.S. GAAP. The balance sheet as of December 31, 2025, was derived from the audited financial statements as of 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 unaudited condensed 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, 2025, and the related footnotes thereto included in the 2025 10-K. Operating results for any interim period are not necessarily indicative of 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 revenue 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 the determination of prepaid or accrued clinical trial costs.

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of salaries and employee-related costs, including stock-based compensation, for personnel in executive, commercial, market access, marketing, legal, finance and support functions. Non-employee-related expenses consist primarily of professional and consulting fees, software costs, the acquisition of data and other launch-related activities incurred in anticipation of the commercialization of gedatolisib, legal services associated with being a public company, director and officer insurance, investor relations, and travel expenses.

In connection with the FDA's acceptance for filing of the Company's NDA for gedatolisib in HR+/HER2- *PIK3CA* WT ABC and the Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026, certain prior period amounts have been reclassified from research and development expenses to selling, general and administrative expenses to conform to the current period presentation. During the three months ended March 31, 2025, the Company reclassified $2.5 million from selling, general and administrative expenses to research and development expenses. There were no changes to previously reported total operating expenses or net loss.

The stock-based compensation amounts included in Note 8 reflect the impact of these prior period reclassifications.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which enhances the annual income tax disclosures for the effective tax rate reconciliation, income taxes paid, and continuing operations. ASU 2023-09 also eliminates certain disclosure requirements related to unrecognized tax benefits. ASU 2023-09 is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-09 on January 1, 2025, on a retrospective basis.

In July 2025, the FASB issued ASU 2025-05, *Measurement of Credit Losses for Accounts Receivable and Contract Assets* ("ASU 2025-05"), which provides certain entities with an additional practical expedient for estimating expected credit losses on current accounts receivable and current contract assets arising from revenue transactions under Accounting Standards Codification ("ASC") 606. ASU 2025-05 is effective for annual and interim periods beginning after December 15, 2025. The Company adopted ASU 2025-05 on January 1, 2026, and the adoption did not have a material impact on its unaudited condensed financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03*, Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires public entities to provide disaggregated disclosure of income statement expense. In January 2025, the FASB issued ASU 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*, to clarify the effective date of ASU 2024-03. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of ASU 2024-03 on its unaudited condensed financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"), which modernizes the accounting for internal-use software. ASU 2025-06 removes all references to software development stages and requires capitalization of software costs when management has committed to the software project, and it is probable the software will be completed and perform to its intended use. In evaluating whether it is probable the project will be completed, management is required to consider whether there is significant uncertainty associated with the development activities of the software. ASU 2025-06 is effective for annual and interim periods beginning after December 15, 2027, with early adoption permitted. ASU 2025-06 may be applied on a prospective basis, a modified basis for in-process projects, or a retrospective basis. The Company is currently evaluating the method of adoption and the impact of ASU 2025-06 on its unaudited condensed financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow Scope Improvements* ("ASU 2025-11"), which provides clarity on the required interim disclosures under Topic 270 by providing a comprehensive list of required interim disclosures, and clarifies the applicability of Topic 270. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. ASU 2025-11 may be applied on a prospective or retrospective basis. The Company is currently evaluating the method of adoption and the impact of ASU 2025-11 on its unaudited condensed financial statements and related disclosures.

3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the options, convertible notes, warrants, restricted stock awards ("RSAs"), restricted stock units ("RSUs") and preferred 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 that have been excluded from the calculation of diluted weighted-average shares outstanding because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2026	**2025**
Options to purchase common stock	5,820,708	4,847,454
Convertible notes as-if-converted-to-common stock	5,296,053	—
Warrants to purchase common stock	225,705	4,825,502
Restricted stock awards and restricted stock units	107,064	1,079
Preferred stock as-if-converted-to-common stock	—	3,175,770
Total	11,449,530	12,849,805

The maximum number of shares of common stock issuable upon conversion of the Company's 2.750% Senior Notes due 2031 (the "Notes") is 5,296,053. As of March 31, 2026, the number of shares issuable would be 3,923,002 if the Notes were converted in full.

During the three months ended March 31, 2026 and 2025, pre-funded warrant shares of 6,147,787 and 5,747,787, respectively, were included in the computation of basic and diluted net loss per share, as the pre-funded warrants are exercisable for nominal consideration.

4. Investments

Debt investments 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 investments are U.S. treasury 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 investments and has no allowance for credit losses recorded for these investments. As of March 31, 2026, all of the Company's held-to-maturity investments had maturities of one year or less.

The following tables summarize the Company's held-to-maturity investments (in thousands):

	As of March 31, 2026			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
U.S. treasury securities	$ 241,873	$ 6	$ (35)	$ 241,844
Total	$ 241,873	$ 6	$ (35)	$ 241,844

	As of December 31, 2025			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
U.S. treasury securities	$ 275,794	$ 225	$ —	$ 276,019
Total	$ 275,794	$ 225	$ —	$ 276,019

The fair value of the Company's U.S. treasury securities is determined using quoted prices in active markets for similar assets or other inputs that are observable or can be corroborated by observable market data, which are considered Level 2 inputs.

There were no changes in valuation techniques or transfers between levels within the fair value hierarchy during the periods presented.

5. Other Accrued Expenses

Other accrued expenses consisted of the following (in thousands):

	As of	
	March 31, 2026	December 31, 2025
Employee compensation and benefits	$ 5,441	$ 8,338
License milestone	—	5,000
Research and development costs	3,011	1,218
Interest	1,998	3,379
Consulting and professional fees	2,271	2,335
Other	1,252	595
Total	$ 13,973	$ 20,865

6. Commitments

Clinical Research Studies

The Company enters into contracts in the normal course of business to conduct research and development programs internally and through third-party service providers that include, among others, arrangements with vendors, consultants, contract manufacturing organizations, and contract research organizations. Contracts related to the Company's ongoing clinical trials are generally cancelable with advance notice 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 subject to amendments as a result of any change orders executed. As of March 31, 2026, the Company had $2.6 million of non-cancelable purchase commitments with respect to these arrangements.

Registration Rights Agreement

In connection with a securities purchase agreement with certain investors pursuant to which the Company agreed to sell to the investors in a private placement pre-funded warrants to purchase up to 5,747,787 shares of the Company's common stock in October 2023 (the "Securities Purchase Agreement"), the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the investors. Under the Registration Rights Agreement, the Company agreed to file a registration statement and to use commercially reasonable efforts to cause such registration statement to become effective and to keep such registration statement effective until such time as there are no longer registrable securities held by the investors.

If the Company fails to meet the specified filing deadlines, effectiveness deadlines, or maintain the effectiveness of the registration statement, the Company is required to make pro rata payments to each holder as liquidated damages in an amount equal to 1.0% of the aggregate amount paid pursuant to the Securities Purchase Agreement by such investor for each 30-day period or pro rata for any portion thereof during which such event continues, provided that the maximum liquidated damages shall not exceed 6.0% of the aggregate amount invested by each such holder in the registrable securities.

The Company accounts for these arrangements in accordance with ASC 825-20, *Registration Payment Arrangements*. The required registration statement has been timely filed and declared effective by the SEC, and as of March 31, 2026, the Company remains in compliance with the maintenance requirements. Management has determined that it is not probable that the Company will be obligated to pay any liquidated damages; accordingly, no liability has been recorded for these arrangements.

7. Stockholders' Equity

Capital Stock

As of March 31, 2026, the Company's authorized capital stock consisted of 95,000,000 shares of common stock, of which 48,347,390 shares were outstanding, and 2,500,000 shares of preferred stock, including 1,850,000 shares designated as Series A preferred stock, of which none were outstanding. As of March 31, 2026, no dividends have been declared on the Company's capital stock.

July 2025 Equity Offering

On July 30, 2025, the Company entered into an underwriting agreement (the "Equity Underwriting Agreement") with Jefferies LLC ("Jefferies"), TD Securities (USA) LLC, and Leerink Partners LLC as representatives (the "Representatives") of the several underwriters named therein (collectively, the "Underwriters") agreeing, subject to customary conditions, to issue and sell in a public offering (i) 1,836,842 shares (the "Shares") of the Company's common stock, at a price to the public of $38.00 per Share and (ii) in lieu of Shares to certain investors, pre-funded warrants to purchase up to 400,000 shares of common stock (the "Pre-Funded Warrants"), at a price to the public of $37.999 per Pre-Funded Warrant, which represents the per share public offering price for the Shares less the $0.001 per share exercise price for each such Pre-Funded Warrant (the "Equity Offering"). In addition, pursuant to the Equity Underwriting Agreement, the Company granted the Underwriters an option to purchase up to an additional 335,526 shares of common stock (the "Option Shares"), less underwriting discounts and commissions. The Underwriters exercised their option to purchase the Option Shares in full on July 30, 2025. The Equity Offering was completed on July 31, 2025.

The net proceeds from the Equity Offering, after deducting underwriting discounts and commissions and offering expenses, were $91.6 million, including the proceeds from the Underwriters' exercise of their option in full to purchase the Option Shares. The Company may also receive nominal proceeds, if any, from the exercise of the Pre-Funded Warrants.

Common Stock Warrants

The following table summarizes the activity for all common stock warrants outstanding:

	Common stock warrants	Weighted-average exercise price per share
Outstanding as of December 31, 2025	6,422,560	$ 0.53
Issued	—	—
Exercised	(45,788)	7.60
Surrendered upon cashless exercise	(3,280)	7.56
Expired	—	—
Outstanding as of March 31, 2026	6,373,492	$ 0.48

8. Stock-Based Compensation

2017 Amended and Restated Stock Incentive Plan

The number of shares reserved for issuance under the 2017 Amended and Restated Stock Incentive Plan (the "2017 Plan") was automatically increased by 482,450 and 371,432 shares on January 1, 2026 and 2025, respectively. As of March 31, 2026, the number of shares available for issuance under the 2017 Plan was 2,959,809.

Stock Options

The following table summarizes the activity for all stock options outstanding:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term	Aggregate intrinsic value
			(in years)	(in thousands)
Options outstanding as of December 31, 2025	5,842,485	$ 19.62	7.9	$ 468,191
Granted	42,150	106.59		
Exercised	(56,427)	8.08		
Forfeited	(7,500)	10.64		
Options outstanding as of March 31, 2026	5,820,708	$ 20.37	7.7	$ 545,814
Options exercisable as of March 31, 2026	2,954,055	$ 11.71	6.6	$ 302,579

In January 2025, the Company modified previously granted stock option awards to 44 employees by reducing the exercise price of these options to the Company's closing common stock price on the modification date. During the three months ended March 31, 2026 and 2025, the incremental compensation expense recognized as a result of these modifications was less than $0.1 million and $0.1 million, respectively. The effect of these modifications on stock-based compensation over the remaining service periods will be $0.2 million.

During the three months ended March 31, 2026 and 2025, the weighted-average grant date fair value of options granted was $78.90 and $7.43 per share, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2026 and 2025, was $5.6 million and less than $0.1 million, respectively. Upon the exercise of stock options, the Company will issue new shares of its common stock. As of March 31, 2026, the unrecognized compensation cost related to outstanding employee and non-employee options was $51.4 million and is expected to be recognized as expense over a weighted-average period of 1.6 years.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and non-employee stock options granted, were as follows:

	Three Months Ended March 31,	
	2026	**2025**
Risk-free interest rate	3.6% − 3.9%	4.0% − 4.7%
Expected volatility	84.5% − 85.5%	76.2% – 77.3%
Expected life (years)	6.1 − 6.3	5.0 – 6.4
Expected dividend yield	0%	0%

During the three months ended March 31, 2026 and 2025, the Company recognized stock-based compensation expense for stock options of $4.5 million and $2.3 million, respectively.

Restricted Stock Awards and Restricted Stock Units

The following table summarizes the activity for RSAs and RSUs:

	Shares	**Weighted-average grant date fair value per share**
Outstanding as of December 31, 2025	27,439	$ 87.25
Granted	79,625	108.85
Vested	—	—
Forfeited	—	—
Outstanding as of March 31, 2026	107,064	$ 103.31

As of March 31, 2026, the unrecognized compensation cost related to outstanding RSAs and RSUs was $10.6 million and is expected to be recognized over a weighted-average period of 2.3 years. No RSAs or RSUs vested during the three months ended March 31, 2026.

During the three months ended March 31, 2026 and 2025, the Company recognized stock-based compensation expense for RSAs and RSUs of $0.4 million and less than $0.1 million, respectively.

2017 Employee Stock Purchase Plan

The number of shares reserved for issuance under the 2017 Employee Stock Purchase Plan (the “ESPP”) was automatically increased by 241,225 and 185,716 shares on January 1, 2026 and 2025, respectively. As of March 31, 2026, the number of shares available for issuance under the ESPP was 710,801.

During the three months ended March 31, 2026 and 2025, the Company recognized stock-based compensation expense related to the ESPP of $0.4 million and $0.2 million, respectively.

Stock-based Compensation

The Company recognized the following stock-based compensation expense in its unaudited condensed statements of operations (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 2,112	$ 1,164
Selling, general and administrative	3,213	1,280
Total	$ 5,325	$ 2,444

9. Debt

July 2025 Convertible Notes Offering

On July 30, 2025, the Company entered into an underwriting agreement (the "Note Underwriting Agreement") with the Underwriters, subject to customary conditions, to issue and sell in a public offering $175.0 million aggregate principal amount of the Notes to the Underwriters (the "Note Offering"). In addition, pursuant to the Note Underwriting Agreement, the Company granted the Underwriters an option to purchase up to an additional $26.3 million aggregate principal amount of the Notes solely to cover over-allotments. On July 30, 2025, the Underwriters exercised such option in full. The issuance of $201.3 million aggregate principal amount of the Notes was completed on August 1, 2025.

The Notes were issued pursuant to, and are governed by, an indenture (the "Base Indenture"), dated as of August 1, 2025, between the Company and U.S. Bank Trust Company, National Association, as trustee (the "Trustee"), as supplemented by a first supplemental indenture (the "Supplemental Indenture," and the Base Indenture, as supplemented by the Supplemental Indenture, the "Indenture"), dated as of August 1, 2025, between the Company and the Trustee. The net proceeds from the Note Offering, after deducting underwriting discounts and commissions and offering expenses, were $194.9 million, including the proceeds from the Underwriters' exercise of their over-allotment option in full.

The Notes are general, unsecured, senior obligations of the Company. The Notes accrue interest payable semi-annually in arrears on February 1 and August 1 of each year, beginning on February 1, 2026, at a rate equal to 2.750% per year. In addition, special interest will accrue on the Notes upon the occurrence of certain events relating to the Company's failure to file certain reports with the SEC as provided in the Indenture and as described below. The Notes also have customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture) with certain interest penalty provisions. The Notes mature on August 1, 2031, unless earlier converted, redeemed or repurchased by the Company.

Noteholders may convert their Notes at their option at any time prior to the close of business on the scheduled trading day immediately preceding the maturity date based on an initial conversion rate of 19.4932 shares of common stock, per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of $51.30 per share of common stock. The conversion rate is subject to customary adjustments upon the occurrence of certain events as described in the Indenture. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Notes will be redeemable, in whole or in part (subject to certain limitations described below), at the Company's option at any time, and from time to time, on a redemption date on or after August 6, 2029 and on or before the 51st scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. However, the Company may not redeem less than all of the outstanding Notes unless at least $50.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. In addition, calling any Note for redemption will constitute a Make-Whole Fundamental Change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

If a "Fundamental Change" (as defined in the Indenture) occurs, then, subject to certain conditions and except as set forth in the Indenture, noteholders may require the Company to repurchase their Notes at a cash repurchase price equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition in the Indenture of a Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the common stock.

Lastly, the Notes contain a beneficial ownership limitation, and as a result of such limitation, noteholders do not have the right to convert all or any portion of the Notes held by such noteholder, to the extent that immediately prior to, or immediately after giving effect to such conversion by such noteholder, together with its affiliates and any other persons acting as a group together with such noteholder or any of such noteholder's affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately prior to, and immediately after giving effect to, the conversion of all or any portion of the Notes; provided, that such 4.99% beneficial ownership can be increased or decreased at the discretion of the noteholder; provided further, that such limitation in no event can exceed 19.99%.

The fair value of the Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices for the Notes observed in market trading. The market for trading of the Notes is not considered to be an active market and therefore the fair value is determined using Level 2 inputs. As of March 31, 2026, the carrying value and fair value of the Notes was $195.6 million and $491.5 million, respectively. As of December 31, 2025, the carrying value and fair value of the Notes was $195.3 million and $436.5 million, respectively.

The issuance costs attributed to the Notes amounted to $6.4 million and were discounted from the Notes. The issuance costs will be amortized to interest expense over the term of the Notes based on the effective interest rate method. During the three months ended March 31, 2026, the effective interest rate was 3.3% and the interest expense related to the Notes was $1.6 million, including $0.2 million related to discount amortization.

As of March 31, 2026, the Company was in full compliance with all financial covenants under the Notes.

Amended and Restated Loan and Security Agreement

Third Amendment

On September 9, 2025, the Company entered into the Third Amendment (the "Third Amendment") to the Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement") with Oxford Finance LLC, a Delaware limited liability company ("Oxford"), as collateral agent and a lender, Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), as a lender, and the other lenders party thereto (together with Oxford and Innovatus, the "Lenders"), pursuant to which the A&R Loan Agreement was amended to (i) replace Innovatus with Oxford as collateral agent; (ii) recognize the achievement of the Term D Milestone (as defined in the A&R Loan Agreement, as amended by the Third Amendment (the "Amended A&R Loan Agreement")) and provide for the immediate disbursement of the $30.0 million Term D Loan (as defined in the Amended A&R Loan Agreement); (iii) increase the size of the Term E Loan (as defined in the Amended A&R Loan Agreement) from $50.0 million to up to $100.0 million, which Term E Loan may only be drawn upon FDA approval of gedatolisib in second line WT ABC patients post CDK4/6 inhibitor therapy; (iv) add three new up to $40.0 million Term F Loans (as defined in the Amended A&R Loan Agreement), for a total of $120.0 million, which may only be drawn upon achievement of certain trailing three months' product revenue thresholds; (v) replace the prior $45.0 million Term F Loan (as defined in the A&R Loan Agreement) with a new $150.0 million Term G Loan (as defined in the Amended A&R Loan Agreement), which continues to be available only in the Lenders' sole discretion upon the Company's request; (vi) require an amendment fee payable by the Company to the Lenders in the amount of $0.1 million, which was paid at the closing of the Third Amendment; (vii) make certain revisions to the non-utilization fee for the Term E Loan, and add a new non-utilization fee for the Term F Loans, in each case equal to 3.0% of the applicable unfunded commitment, after taking into consideration any reductions to the applicable term loan commitment that the Company may make by notice to the collateral agent before the date that is eight weeks after the achievement of any applicable milestones; and (viii) extend the maturity date of the term loans to November 1, 2029. The Term E Loan and each Term F Loan also are subject to other customary conditions and limits on when the Company can request funding. With the disbursement of the $30.0 million Term D Loan, the Company received net proceeds of $27.7 million.

In accordance with the Amended A&R Loan Agreement, a Final Fee of $1.4 million, equal to 4.5% of the $30.0 million Term D Loan, was recognized.

In connection with the Third Amendment, the Company issued warrants with an exercise price of $14.84 per share to purchase an aggregate of 50,537 shares of the Company's common stock to Innovatus, Oxford, and certain of its affiliates (the "Third Amendment Warrants"). The Third Amendment Warrants may be exercised on a cashless basis and are exercisable through the tenth anniversary of the funding date of the Term D Loan. The number of shares of common stock for which each Third Amendment Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Third Amendment Warrant.

A portion of the proceeds from the Term D Loan in the amount of $2.8 million was allocated to the Third Amendment Warrants based on their relative fair value to the underlying Term D Loan. The proceeds allocated to the Third Amendment Warrants were recorded as additional paid in capital in the accompanying condensed balance sheets and were discounted from the Term D Loan. The relative fair value of the Third Amendment Warrants was based on the Black-Scholes model with the following assumptions: risk-free interest rate of 4.1%; expected volatility of 74.4%; expected life of 10.0 years; and expected dividend yield of 0%. The underlying stock price used in the analysis was the traded market price. The discount related to the Third Amendment Warrants is being amortized to interest expense ratably over the term of the Term D Loan.

Second Amendment

On July 28, 2025, the Company entered into the Second Amendment (the "Second Amendment") to the A&R Loan Agreement with Innovatus, as collateral agent, and the Lenders including Innovatus in its capacity as a Lender and 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 was amended to (i) subject to certain terms and conditions, permit the issuance of the Notes discussed above and certain transactions in connection therewith, including the conversion thereof settled solely in common stock (together with cash in lieu of the issuance of any fractional share of common stock), (ii) permit capped call transactions in connection with the pricing of the Notes, (iii) require an amendment fee payable by the Company to Oxford in the amount of less than $0.1 million, which was paid upon execution of the Second Amendment, and (iv) extend to May 9, 2026, the expiration date of Innovatus' right 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.

Further, in connection with the release of the topline data from the WT cohort of the VIKTORIA-1 Phase 3 clinical trial, the Company achieved the Term D Milestone (as defined in the A&R Loan Agreement) and therefore became eligible to draw an additional $30.0 million of indebtedness under the Term D Loan (as defined in the A&R Loan Agreement). As described above, the Term D Loan was disbursed to the Company in connection with the Third Amendment.

First Amendment

On May 13, 2025, the Company entered into the First Amendment (the "First Amendment") to the A&R Loan Agreement, pursuant to which the Company agreed to (i) pay Oxford an amendment fee of less than $0.1 million on the effective date of the First Amendment, (ii) extend to March 9, 2026 the expiration date of Innovatus' right 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, (iii) extend the expiration date of the Term D Draw Period to the earlier of (x) August 31, 2025 and (y) the occurrence of an Event of Default (as defined in the A&R Loan Agreement), (iv) update the liquidity covenant to increase the Minimum Liquidity Percentage (as defined in the First Amendment) to 50% if the Company had failed to achieve the Term D Milestone prior to June 1, 2025, and to decrease the Minimum Liquidity Percentage back to 30% if the Company subsequently achieves the Term D Milestone prior to the end of the Term D Draw Period, and (v) release Innovatus and the Lenders from any and all claims arising out of or related to the A&R Loan Agreement, the First Amendment and related documentation.

Amended and Restated Loan Agreement

On May 30, 2024, the Company entered into the A&R Loan Agreement, which amended and restated, in its entirety, the April 8, 2021 Loan and Security Agreement between the Company and Innovatus, as collateral agent, and the Lenders named therein (the "Prior Loan Agreement").

Pursuant to the A&R Loan Agreement, 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 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 are being used for working capital purposes and to fund the Company's general business requirements, including the ongoing Phase 3 VIKTORIA-1 clinical trial, the Phase 1b/2 CELC-G-201 clinical trial, and 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. Prior to the Second Amendment, Innovatus also had 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 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 the Term E Loans. Following the disbursement of the Term D Loan in connection with the Third Amendment, the non-utilization provisions related to the Term D Loan are no longer operative. 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 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.

The Company evaluated the change of terms under ASC 470-50, *Debt – Modification and Extinguishment*, with respect to the Third Amendment, the Second Amendment, the First Amendment and the A&R Loan Agreement 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.

Note payable consisted of the following (in thousands):

	As of	
	March 31, 2026	**December 31, 2025**
Principal amount	$ 130,000	$ 130,000
Add: Final fee	5,850	5,850
Add: PIK interest (added to principal)	2,022	1,697
Less: unamortized debt issuance costs	(2,094)	(2,619)
Less: unamortized debt discount	(7,916)	(8,401)
Total note payable	$ 127,862	$ 126,527

The fair value of the note payable, which differs from its carrying value, is determined using the Company's estimated discount rate, volatility and risk-free rate, which are considered Level 3 inputs. As of March 31, 2026, and December 31, 2025, the fair value of the note payable was $167.8 million and $160.2 million, respectively.

The debt issuance costs will be amortized to interest expense over the term of the Amended A&R Loan Agreement based on the effective interest rate method. During the three months ended March 31, 2026 and 2025, the effective interest rate was 12.7% and 12.3%, respectively. During the three months ended March 31, 2026, interest expense related to the note payable was $4.5 million, including $1.0 million related to discount amortization. During the three months ended March 31, 2025, interest expense related to the note payable was $3.2 million, including $0.3 million related to discount amortization.

As of March 31, 2026, future principal payments, including the incurred PIK interest and Final Fee, are as follows (in thousands):

Year Ending December 31,		
2028	$	44,008
2029		93,864
Total	$	137,872

As of March 31, 2026, the Company was in full compliance with all financial covenants under the Amended A&R Loan Agreement.

10. License Agreement

On April 8, 2021, the Company entered into a license agreement with Pfizer to research, develop, manufacture and commercialize gedatolisib. During 2021, the Company paid $5.0 million in upfront fees and issued 349,406 shares of the Company's common stock to Pfizer pursuant to an Equity Grant Agreement.

The Company is also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of $335.0 million. One of these milestone events requires a $5.0 million payment within 60 days following the FDA regulatory filing of an NDA for gedatolisib. The FDA granted the Company's request to submit its NDA via the FDA's RTOR program, and the Company completed its final NDA submission to the FDA in November 2025. The Company recorded the $5.0 million NDA filing milestone as research and development expense in June 2025 and paid this amount in January 2026. Additionally, the Company will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid-teens, which may be subject to deductions for expiration of valid patent claims, amounts due under third-party licenses and generic competition. Unless earlier terminated, the license agreement will expire upon the expiration of all royalty obligations. The royalty period will expire on a country-by-country basis upon the later of (a) 12 years following the date of first commercial sale of such product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such product, or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the license agreement, a valid claim of a licensed patent right.

The Company has the right to terminate the license agreement for convenience upon 90 days' prior written notice. Pfizer may not terminate the agreement for convenience. Either the Company or Pfizer may terminate the license agreement if the other party is in material breach and such breach is not cured within the specified cure period. In addition, either the Company or Pfizer may terminate the license agreement in the event of specified insolvency events involving the other party.

11. Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date through the date that the unaudited condensed financial statements were issued. Based upon this review, other than as described below, the Company did not identify any subsequent events or transactions that would have required adjustment or disclosure in the unaudited condensed financial statements.

On April 1, 2026, the board of directors (the "Board") approved the Company's 2026 Stock Incentive Plan ("the 2026 Plan"). The 2026 Plan became effective on May 14, 2026, the date it was approved by the Company's stockholders. As of May 14, 2026, there were 3,000,000 shares available for issuance under the 2026 Plan and no new awards will be made under the 2017 Plan.

On April 1, 2026, the Board approved and adopted the Amended and Restated 2017 Employee Stock Purchase Plan (the "Restated ESPP"). The Restated ESPP became effective on May 14, 2026, upon approval by the Company's stockholders. The Restated ESPP increased the number of shares of common stock available for issuance under the ESPP by 289,199 shares and extended the expiration date of the ESPP for an additional ten-year period.

On May 1, 2026, Innovatus converted $3,438,029 of the outstanding principal of the Term A Loan into 343,802 shares of the Company's common stock.

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 in conjunction with our unaudited condensed financial statements and the related notes included elsewhere in 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 Part I, Item 1A of the 2025 10-K, 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 the treatment of multiple solid tumor indications. Our lead therapeutic candidate is gedatolisib, a kinase inhibitor of the PI3K/AKT/mTOR ("PAM") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. Our Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, has reported detailed results for Study 1, which evaluated patients with *PIK3CA* WT tumors, and announced topline results for Study 2, which evaluated patients with *PIK3CA* MT tumors. Our Phase 3 clinical trial, VIKTORIA-2, is ongoing and incorporates two independent studies, Study 1 and Study 2, evaluating two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib combined with palbociclib and fulvestrant as first-line treatment for patients with endocrine resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib combined with palbociclib and letrozole as first-line treatment for patients with endocrine sensitive HR+/HER2- ABC. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with mCRPC, is ongoing.

In April 2021, we obtained exclusive global development and commercialization rights to gedatolisib under a license agreement with Pfizer. We believe gedatolisib's unique mechanism of action, differentiated chemical structure, favorable pharmacokinetic properties, and intravenous route of administration offer distinct advantages over currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together.

- **Overcomes limitations of therapies that only inhibit a single class I PI3K isoform, AKT, or 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 the mTORC1 and mTORC2 complexes. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. 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 PI3K isoform (e.g., alpelisib, a PI3Kα inhibitor), AKT (e.g., capivasertib, an AKT 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 reduces the efficacy of isoform specific PI3Kα, AKT, or mTORC1 kinase 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, AKT, and mTOR.

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

  Gedatolisib is administered intravenously 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 repeatedly 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's comprehensive inhibition of the PAM pathway at low nanomolar potency, IV route of administration, and pharmacokinetic properties enables it to achieve optimal anti-proliferative effects on tumor cells without inducing the levels of hyperglycemia, rash, and diarrhea typically associated with oral single-component inhibitors of the PAM pathway.

Isoform-specific PI3K or mTORC1 inhibitors administered orally were developed to reduce toxicities in patients. While the range of toxicities associated with single-component PAM inhibitors is narrower than oral pan-PI3K or PI3K/mTOR inhibitors, administering them orally on a continuous basis can still lead 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 March 31, 2026, 1,127 patients and healthy volunteers have received gedatolisib in 12 completed or ongoing clinical trials. Of these, 123 patients with solid tumors were treated with gedatolisib as a single agent in two clinical trials, 36 healthy volunteers were treated in two clinical trials, and the remaining 968 patients received gedatolisib in combination with other anti-cancer agents in eight clinical trials. Additional patients received gedatolisib in combination with other anti-cancer agents in 10 investigator-sponsored clinical trials.

B2151009 Phase 1b Trial

A Phase 1b dose-finding trial with an expansion portion for safety and efficacy evaluated gedatolisib when added to either the standard doses of palbociclib plus letrozole or palbociclib plus fulvestrant in patients with HR+/HER2- ABC. PI3K mutation status was not used as an eligibility criterion. Patient enrollment for the trial is complete.

A total of 138 patients with HR+/HER2- ABC were dosed in the clinical trial. Four patients from this study continue to receive study treatment, as of March 31, 2026, each of whom has received study treatment for more than six years.

- 35 patients were enrolled in two dose escalation arms to evaluate the safety and tolerability and determine the maximum tolerable dose ("MTD") of gedatolisib when used in combination with the standard doses of palbociclib and endocrine therapies. The MTD was determined to be 180 mg administered intravenously once weekly.

- 103 patients were enrolled in one of four expansion arms (A, B, C, D) to determine if the triplet combination of gedatolisib plus palbociclib and letrozole or gedatolisib plus palbociclib and fulvestrant produced a superior objective response (OR), compared to historical control data of the doublet combination (palbociclib plus endocrine therapy). All patients received gedatolisib in combination with standard doses of palbociclib and endocrine therapy (either letrozole or fulvestrant). In Arms A, B, and C, patients received an intravenous dose of 180 mg of gedatolisib once weekly. In Arm D, patients received an intravenous dose of 180 mg of gedatolisib on a four-week cycle of three-weeks-on, one-week-off. Objective response was determined using Response Evaluation Criteria in Solid Tumors v1.0, or RECIST v1.0.

    - **Arm A**: ABC with progression and no prior endocrine-based systemic therapy or a CDK4/6 inhibitor in the metastatic setting. First-line endocrine-based therapy for advanced disease (CDK4/6 treatment naive).

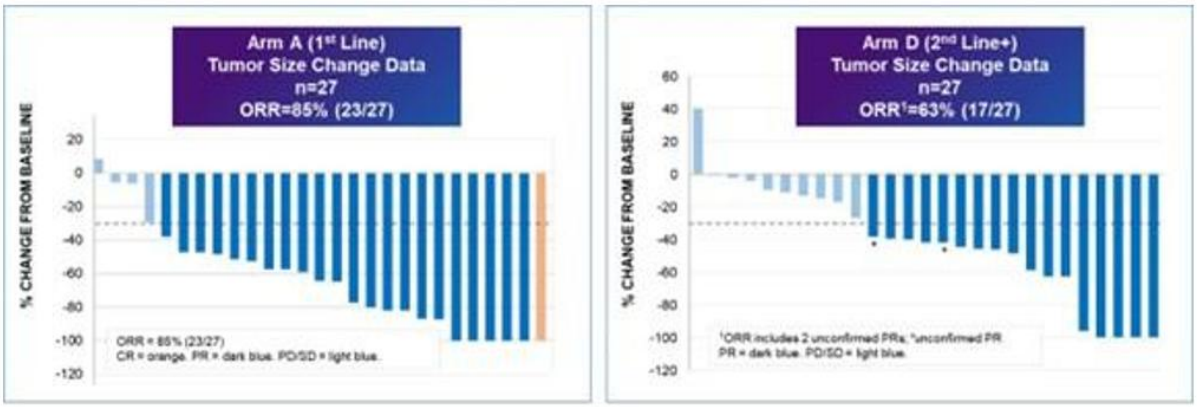
    - **Arm B**: ABC with progression during one or two prior endocrine-based systemic therapies in the advanced setting, with no prior therapy with any CDK inhibitor. Second- or third-line endocrine-based therapy for metastatic disease.

- **Arm C**: ABC with progression during one or two prior endocrine-based systemic therapies in the advanced setting and following prior therapy with a CDK inhibitor. Second- or third-line endocrine-based therapy for advanced disease.

- **Arm D**: ABC with progression during one or two prior endocrine-based systemic therapies in the advanced setting and following prior therapy with a CDK inhibitor. Second- or third-line endocrine-based therapy for advanced disease.

- For the 103 patients enrolled in the expansion portion of the Phase 1b clinical trial, the objective response rate ("ORR") in aggregate among patients with evaluable tumors was 63%.

- Best responses, as measured by RECIST v1.0, are shown in the following chart for Arm A (1st line patients) and Arm D (2nd/3rd line patients who received the VIKTORIA-1 Phase 3 trial dosing regimen). The dotted line represents the cutoff for partial response (PR), defined as a 30% reduction from the baseline tumor assessment.



Source: Layman SABCS 2021

- Safety analysis:

  - For all arms in aggregate, all patients experienced at least one Grade 1 or Grade 2 treatment-emergent adverse event. The Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (63%), stomatitis (27%) and rash (20%). Neutropenia is a known class effect of CDK4/6 inhibitors. Stomatitis was reversible in most patients with a steroidal mouth rinse. All grades of treatment-related adverse events related to hyperglycemia were reported in 22% of patients; Grade 3 or 4 hyperglycemia was reported in 7% of patients. Gedatolisib was discontinued in less than 9% of patients.

  - For the patients in Arm D, who received the Phase 3 dosing schedule, Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (67%), leukopenia (22%), and stomatitis (22%). All grades of treatment-related adverse events related to hyperglycemia were reported in 26% of patients; Grade 3 or 4 hyperglycemia were reported in 7% of patients. Gedatolisib was discontinued in 4% of patients.

- Best overall response data for each arm is presented in the table below:

Total Expansion Arms (N=103)

	Arm A		Arm B		Arm C		Arm D	
Prior Therapy	1L CDKi-naive		2L+ CDKi-naive		2L/3L CDKi-pretreated		2L/3L CDKi-pretreated	
n (Full, response evaluable)	31, 27		13,13		32, 28		27, 27	
Study Treatment	P + L + G		P + F + G		P + F + G		P + F + G	
Gedatolisib schedule	weekly		weekly		weekly		3 wks on/1 wk off	
ORR (1) (evaluable)	85%		77%		36%		63%	
mPFS (2), mos (range)	48.4 (16.9, NR)		12.9 (7.6, 38.3)		5.1 (3.3, 7.5)		12.9 (7.4, 16.7)	
PFS % at 12 mos (2)	72.1%		54.5%		23.6%		53.2%	
	WT	**MT**	**WT**	**MT**	**WT**	**MT**	**WT**	**MT**
PIK3CA status	81%	16%	69%	31%	75%	25%	56%	41%
ORR (evaluable)	81%	100%	78%	75%	25%	63%	60%	73%
PFS at 12 months	74%	60%	50%	67%	22%	29%	49%	60%

(1) ORR represents PR, except in Arm A, which had 1 CR = Complete response. Responses per RECIST 1.1; (2) Includes 2 unconfirmed PR

Abbreviations: 1L = first line; 2L = second line; mos = months; NR = not reached; ORR = objective response rate; PFS = progression free survival

Source: Layman R. et. al, Lancet Oncol., 2024

VIKTORIA-1 Phase 3 Trial

We have completed primary analysis of our Phase 3, open-label, randomized clinical trial, VIKTORIA-1, that is evaluating the efficacy and safety of gedatolisib treatment regimens in adults with HR+/HER2- ABC whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor. Over 200 clinical sites in North America, Europe, Latin America, and Asia-Pacific are participating in the study.

The VIKTORIA-1 Phase 3 clinical trial involves two independent studies (Study 1 and Study 2) that enable separate evaluation of subjects according to their *PIK3CA* status. Subjects who met eligibility criteria and had *PIK3CA* WT tumors (Study 1) were 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). The primary completion date and the database cut-off date for Study 1 was May 30, 2025. Subjects who met eligibility criteria and had *PIK3CA* MT tumors (Study 2) were randomly assigned (3:3:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm D), alpelisib and fulvestrant (Arm E), or gedatolisib and fulvestrant (Arm F). The primary completion date and the database cut-off date for Study 2 was March 9, 2026.

On July 28, 2025, we announced topline data from the *PIK3CA* WT cohort of the VIKTORIA-1 clinical trial and on October 18, 2025, at the ESMO congress, additional efficacy and safety results from this cohort were presented. The key efficacy and safety data from the *PIK3CA* WT cohort showed:

- The “gedatolisib triplet” (gedatolisib, fulvestrant and palbociclib) demonstrated a statistically significant and clinically meaningful improvement in PFS among patients, reducing the risk of disease progression or death by 76% compared to fulvestrant (based on a hazard ratio [HR] of 0.24, 95% confidence interval [CI] 0.17-0.35; p<0.0001). The median PFS, as assessed by blinded independent central review (“BICR”), was 9.3 months with the gedatolisib triplet versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months.
- The “gedatolisib doublet” (gedatolisib and fulvestrant) also demonstrated a statistically significant and clinically meaningful improvement in PFS among patients, reducing the risk of disease progression or death by 67% compared to fulvestrant (HR = 0.33, 95% CI 0.24-0.48; p<0.0001). The median PFS, as assessed by BICR, was 7.4 months with the gedatolisib doublet versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months.

- The ORR of the gedatolisib triplet was 31% compared to 1% with fulvestrant and the median duration of response ("DOR") was 17.5 months. The ORR of the gedatolisib doublet was 28.3% and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.
- The gedatolisib triplet and doublet were generally well tolerated in the trial with mostly low-grade treatment-related adverse events ("TRAEs"). The most common Grade 3 TRAEs for the gedatolisib triplet, gedatolisib doublet, and fulvestrant groups included neutropenia (52.3%, 0%, and 0.8% of patients, respectively); stomatitis (19.2%, 12.3%, and 0% of patients, respectively) rash (4.6%, 5.4%, and 0% of patients, respectively); and hyperglycemia (2.3%, 2.3%, and 0% of patients, respectively). The primary Grade 4 TRAEs for the gedatolisib triplet and gedatolisib doublet groups were neutropenia (10.0% and 0.8%, respectively), leukopenia (0.8% in the gedatolisib triplet group) and pneumonitis (0.8% in gedatolisib doublet group). TRAEs led to the discontinuation of study treatment in 2.3% of patients in the gedatolisib triplet group, 3.1% in the gedatolisib doublet group, and 0% in the fulvestrant group.

The detailed results from cohort 1, *PIK3CA* WT cohort, established several new milestones in the history of drug development for HR+/HER2- ABC:

- The hazard ratios for the gedatolisib triplet and doublet are more favorable than have ever been reported by any Phase 3 trial for patients with HR+/HER2- ABC.
- The 7.3- and 5.4-months incremental improvements in median PFS for the gedatolisib triplet and gedatolisib doublet over fulvestrant, respectively, are higher than have ever been reported by any Phase 3 trial for patients with HR+/HER2- ABC receiving at least their second line of therapy.
- Gedatolisib is the first inhibitor targeting the PAM pathway to demonstrate positive Phase 3 results in patients with HR+/HER2- *PIK3CA* WT ABC whose disease progressed on or after treatment with a CDK4/6 inhibitor.
- The median DOR and incremental ORR improvement relative to control for the gedatolisib triplet and doublet are the highest reported for an endocrine therapy-based regimen in 2L HR+/HER2- ABC.

The median PFS benefit of the gedatolisib triplet and doublet compared to fulvestrant was consistent across subgroups with the gedatolisib triplet showing higher clinical benefit in nearly all subgroups compared to the gedatolisib doublet, particularly for patients who were pre/perimenopausal, endocrine therapy resistant, or had visceral metastases. For patients enrolled in the United States and Canada, median PFS was 19.3 months (HR=0.13; 90% CI: 0.07-0.29) for the gedatolisib triplet and 14.9 months (HR=0.35; 90% CI: 0.17-0.76) for the gedatolisib doublet.

In December 2025, updated efficacy and safety results from the Phase 3 VIKTORIA-1 *PIK3CA* WT cohort were presented at the 2025 San Antonio Breast Cancer Symposium including patient sub-group analyses, safety analyses and patient reported outcomes for well-being measures.

- For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, median PFS was 16.6 months with the gedatolisib triplet and 7.1 months with the gedatolisib doublet versus 1.9 months for fulvestrant (HR=0.14; 95% CI: 0.08-0.28; $p<0.0001$).
- Both gedatolisib regimens delayed time to definitive deterioration versus fulvestrant according to patient reported outcomes for well-being measures that included mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (the EQ-5D-5L score). The median time to definitive deterioration was 23.7 months (HR=0.39; 95% CI: 0.25-0.67; $p = 0.0003$) for patients treated with the gedatolisib triplet and not reached for the gedatolisib doublet (HR=0.37; 95% CI: 0.24-0.66; $p = 0.0003$) versus 4.0 months for fulvestrant. Additionally, for the first eight cycles of treatment, the patients' assessment of their well-being remained stable relative to their assessment prior to starting treatment with gedatolisib.

With these results, the gedatolisib regimens represent a new potential standard of care for patients with HR+/HER2- *PIK3CA* WT ABC whose disease progressed on or after treatment with a CDK4/6 inhibitor. In January 2026, the FDA accepted for filing our NDA for gedatolisib in HR+/HER2- *PIK3CA* WT ABC. The FDA granted Priority Review and assigned a PDUFA goal date of July 17, 2026.

In March 2026, efficacy and safety results from Study 1 (*PIK3CA* WT cohort) of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib were published in the Journal of Clinical Oncology.

On May 1, 2026, we announced positive topline results from Study 2 (*PIK3CA* MT cohort) of the VIKTORIA-1 Phase 3 clinical trial evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- *PIK3CA* MT ABC, following progression on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor. Detailed results will be presented in a late-breaking abstract ("LBA") oral session on June 2, 2026, at the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, Illinois.

The primary efficacy analysis of the gedatolisib triplet demonstrated a statistically significant and clinically meaningful improvement in PFS compared to alpelisib, a PI3Kα inhibitor, and fulvestrant. The secondary endpoint comparing the gedatolisib doublet versus alpelisib plus fulvestrant, which was not part of the primary efficacy analysis in the hierarchical order, also demonstrated a statistically significant and clinically meaningful improvement in PFS compared to alpelisib and fulvestrant. Both gedatolisib regimens were generally well tolerated, with manageable safety profiles, and no new safety signals.

We intend to submit these data to the FDA as an sNDA and to submit VIKTORIA-1 data to other regulatory authorities outside the U.S. following the sNDA submission.

VIKTORIA-2 Phase 3 Trial

In July 2025, we dosed the first patient in VIKTORIA-2, a Phase 3, multi-center, open-label, randomized, clinical trial designed to evaluate the efficacy and safety of gedatolisib combined with a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- endocrine-resistant ABC. Preceding commencement of the Phase 3 portion of the trial, a safety run-in study to evaluate the safety of gedatolisib combined with ribociclib and fulvestrant was initiated and completed in the first quarter of 2026. Based on the results of this safety run-in study, we have elected to remove ribociclib as a treatment partner with gedatolisib in the study treatment arm of the trial. Additionally, in light of the clinically meaningful improvement in PFS for patients treated with gedatolisib combined with palbociclib and fulvestrant compared to those treated with fulvestrant in the *PIK3CA* WT cohort of the VIKTORIA-1 study, we proposed to amend several important elements of the study design and clinical trial protocol for the VIKTORIA-2 study.

In February 2026, we conducted a Type B meeting with the FDA in order to obtain the FDA's feedback on our proposed study design changes. From this meeting, we gained general alignment with the FDA on our planned amendments to the VIKTORIA-2 study design and protocol. First, VIKTORIA-2 will now evaluate the safety and efficacy of patients with endocrine sensitive HR+/HER2- ABC, in addition to those with endocrine-resistant disease. Patients will be assigned manually according to their endocrine sensitivity status to either Study 1 (endocrine-resistant) or Study 2 (endocrine-sensitive) and subsequently be randomized to a treatment arm. Each study will have independent statistical analysis plans that will include separate primary endpoints. Second, the primary efficacy analyses for both Study 1 and Study 2 of VIKTORIA-2 will evaluate the entire intent-to-treat population enrolled in their respective study (combined WT and MT); primary endpoints for patient cohorts based on their *PIK3CA* status (e.g., WT or MT) are no longer included. And third, the control arms for Study 1 and Study 2 will evaluate ribociclib combined with either fulvestrant (Study 1) or letrozole (Study 2); palbociclib will no longer be included as an option in the control arms.

Study 1 is expected to enroll approximately 440 patients with treatment-naïve endocrine-resistant ABC whose cancer progressed while receiving or within 12 months of completing adjuvant endocrine therapy. The trial will evaluate the efficacy and safety of gedatolisib combined with palbociclib and fulvestrant (Arm A) compared to ribociclib combined with fulvestrant (Arm B). We expect topline data for this group to be available by the end of 2028. Study 2 is expected to enroll approximately 740 subjects with treatment-naïve endocrine-sensitive ABC whose cancer relapsed or progressed 12 months or more after completion of adjuvant endocrine therapy, or those with de novo metastatic disease without prior endocrine therapy exposure. The trial will evaluate the efficacy and safety of gedatolisib combined with palbociclib and letrozole (Arm C) compared to ribociclib combined with letrozole (Arm D). We expect topline data for this group to be available in 2030.

Subjects in each study will be randomized 1:1 to either investigational treatment (Arm A, Study 1; Arm C, Study 2) or standard-of-care control (Arm B, Study 1; Arm D, Study 2). Approximately 200 clinical sites in North America, Europe, and Asia-Pacific will participate in the study, including many sites included in the VIKTORIA-1 clinical trial.

The clinical trial primary endpoints for the VIKTORIA-2 clinical trial are PFS, per RECIST 1.1 criteria, as assessed by BICR. The statistical analyses of Study 1 and Study 2 are each independent of the other. For Study 1, the primary objective is to compare the PFS of Arm A (gedatolisib + palbociclib + fulvestrant) to Arm B (ribociclib + fulvestrant). For Study 2, the primary objective is to compare the PFS of Arm C (gedatolisib + palbociclib + letrozole) to Arm D (ribociclib + letrozole).

CELC-G-201 Phase 1b/2 Trial

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 clinical trial, CELC-G-201, that will enroll up to 54 participants with mCRPC who progressed after treatment with an androgen receptor inhibitor. The first patient was dosed in this trial in February 2024.

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 ("RP2D") of gedatolisib. The primary objective of the Phase 2 portion of the trial is to assess the radiographic PFS at six months of patients who received the RP2D.

In the Phase 1b portion of the clinical trial, 38 patients with mCRPC were randomly assigned to receive 600 mg of darolutamide twice daily combined with either 120 mg of gedatolisib in Arm 1 or 180 mg of gedatolisib in Arm 2. In both arms, gedatolisib was administered once weekly for three weeks, then one week off. Additionally, all patients received prophylactic treatment for stomatitis.

On June 30, 2025, we announced preliminary data for the CELC-G-201 Phase 1b trial, utilizing a May 30, 2025, data cut-off. Based on these data, we amended the clinical trial protocol to enable exploration of additional doses in the Phase 1b portion of this clinical trial to determine the RP2D. Once RP2D is determined, an additional 12 participants are planned to be enrolled in the Phase 2 portion of the study at the RP2D level to enable evaluation of 30 participants treated with the RP2D of gedatolisib.

On October 18, 2025, at the ESMO congress, we presented updated clinical results for the CELC-G-201 Phase 1b trial based on an August 15, 2025, data cut-off. Among the 38 patients enrolled, 61% had received one line of prior systemic therapy and 39% had received at least two or more lines of prior therapy. Median duration of follow-up was 9.0 months.

The six-month radiographic progression-free survival ("rPFS") rate and median rPFS for patients from both arms combined was 67% and 9.1 months, respectively. For patients treated with 120 mg of gedatolisib, the six-month rPFS rate was 74% and median rPFS was 9.5 months. For patients treated with 180 mg of gedatolisib, the six-month rPFS rate was 61% and the median rPFS was 7.4 months.

The combination of gedatolisib and darolutamide was generally well tolerated in the trial with mostly low-grade TRAEs. No dose limiting toxicities were observed in either arm. The only Grade 3 TRAEs for patients from both arms combined included rash (5.3%), stomatitis (2.6%), and pruritus (2.6%); no Grade 3 hyperglycemia was reported. Additionally, no Grade 4 or 5 TRAEs were observed, and no patients discontinued study treatment due to a TRAE.

In the amended Phase 1/1b portion of the clinical trial, up to six patients are planned to be enrolled in each of three arms and treated with different doses. Upon completion of Phase 1, up to an additional 24 patients will be randomly assigned to up to two Phase 1b cohorts to determine the RP2D. Dose levels will be selected based on the results from the Phase 1/1b clinical trial. In the Phase 2 dose expansion study, up to 84 additional subjects will be enrolled. All patients will also receive standard doses of darolutamide.

Investigator-Sponsored Trials

In an investigator-sponsored Phase 2 clinical trial, 44 patients with HER2+ *PIK3CA* mutated metastatic breast cancer were treated with gedatolisib plus standard doses of trastuzumab-pkrb. No prophylaxis for stomatitis was administered. The median number of prior anti-HER2 therapies enrolled patients received in the metastatic setting was four or more; 86% of patients had received at least three prior anti-HER2 therapies. The data cut-off was February 10, 2025.

Key efficacy and safety results, as presented at the American Society of Clinical Oncology meeting in June 2025, showed:

- The ORR among all patients enrolled was 43%.
- Median PFS was 6.0 months (95% CI, 5.0-7.7).
- Median overall survival was 24.7 months (95% CI; 17.3-NA).
- No patients discontinued gedatolisib due to a treatment-related AE.
- One (2.3%) patient experienced Grade 3 hyperglycemia.

An investigator sponsored trial has been initiated in collaboration with the Dana-Farber Cancer Institute and Massachusetts General Hospital to evaluate gedatolisib in combination with abemaciclib and letrozole in patients with endometrial cancer.

Recent Developments

- On May 1, 2026, we announced positive topline results from the *PIK3CA* MT cohort of the VIKTORIA-1 Phase 3 clinical trial evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- *PIK3CA* MT ABC, following progression on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor. See VIKTORIA-1 update above.

- On May 14, 2026, we announced the amendment of several important elements of the study design and protocol for the VIKTORIA-2 Phase 3 clinical trial. See VIKTORIA-2 update above.

- On May 14, 2026, we announced that we had submitted our first patent application to the United States Patent and Trademark Office ("USPTO") for a subcutaneous formulation of gedatolisib that would enable a patient to receive gedatolisib as an injection as an alternative to an infusion. Development of the subcutaneous gedatolisib formulation is ongoing with the goal of demonstrating clinical equivalence to the current intravenous formulation of gedatolisib. The subcutaneous formulation is aimed to support potential future indications for gedatolisib regimens that may result in duration of treatment periods greater than several years.

Results of Operations

We have not generated any revenue from product sales or other sources 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. During the three months ended March 31, 2026 and 2025, we reported a net loss of $52.8 million and $37.0 million, respectively. As of March 31, 2026, we had an accumulated deficit of $501.7 million and cash, cash equivalents and short-term investments of $387.1 million.

Components of Operating Results

Revenue

To date, we have not generated any revenue. Upon the execution of the Pfizer license agreement in April 2021, we acquired exclusive world-wide licensing rights to develop and commercialize gedatolisib. In 2022, we initiated VIKTORIA-1, a Phase 3 clinical trial, to support potential regulatory approval to market gedatolisib. Our Phase 3 clinical trial, VIKTORIA-2, and Phase 1b/2 clinical trial, CELC-G-201, are ongoing.

Pursuant to the FDA's RTOR program, in September 2025 we made the first pre-submission of our NDA to the FDA and completed the final NDA submission to the FDA on November 17, 2025. The FDA formally accepted our NDA submission on January 16, 2026, designated it for Priority Review, and assigned a PDUFA target goal date of July 17, 2026. If we obtain FDA approval to market gedatolisib, we expect to generate revenue from sales of the drug commencing in the second half of 2026.

Research and Development

Since our inception, we have primarily focused on research and development of gedatolisib, a PAM inhibitor. 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; and
- facilities expenses.

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of salaries and employee-related costs, including stock-based compensation, for personnel in our executive, commercial, market access, marketing, legal, finance, human resources and support functions.

Non-employee-related selling expenses consist primarily of professional and consulting fees, software costs, the acquisition of data, and other commercial operations related activities incurred in anticipation of the commercialization of gedatolisib. Non-employee-related general and administrative expenses primarily consist of professional fees for auditing, tax, and legal services associated with being a public company, director and officer insurance, software costs, investor relations, and travel expenses for our general and administrative personnel.

We expect selling, general and administrative expenses to increase as we get closer to a potential FDA approval date for gedatolisib.

Interest Expense

Interest expense to date is primarily related to the Amended A&R Loan Agreement and the Notes.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table summarizes our results of operations (in thousands):

	Three Months Ended March 31,		Increase (Decrease)	
	2026	2025	$	%
Statements of operations data:				
Operating expenses:				
Research and development	$ 33,063	$ 29,759	$ 3,304	11%
Selling, general and administrative	17,444	6,374	11,070	174
Total operating expenses	50,507	36,133	14,374	40
Loss from operations	(50,507)	(36,133)	(14,374)	40
Other (expense) income:				
Interest expense	(6,085)	(3,183)	(2,902)	91
Interest income	3,751	2,319	1,432	62
Other (expense) income, net	(2,334)	(864)	(1,470)	170
Net loss before income taxes	(52,841)	(36,997)	(15,844)	43
Income taxes	—	—	—	—
Net loss	$ (52,841)	$ (36,997)	$ (15,844)	43%

Research and Development

During the three months ended March 31, 2026, our research and development expenses were $33.1 million, representing an increase of $3.3 million, or 11%, compared to the same period in 2025. The increase was primarily due to a $3.0 million increase in employee-related and consulting expenses, of which $0.9 million related to stock-based compensation. The remaining increase was primarily due to a $5.4 million increase in manufacturing and other costs, partially offset by a $5.1 million decrease in clinical trial costs, which was primarily driven by decreased costs for the VIKTORIA-1 Phase 3 clinical trial.

Conducting research and development is central to our business model. We plan to continue to increase our research and development expenses for the foreseeable future as we continue to develop gedatolisib, conduct the VIKTORIA-2 Phase 3 and CELC-G-201 Phase 1b/2 clinical trials, continue follow-up activities for the VIKTORIA-1 Phase 3 clinical trial, and conduct other studies and clinical trials.

Selling, General and Administrative

During the three months ended March 31, 2026, our selling, general and administrative expenses were $17.4 million, representing an increase of $11.1 million, or 174%, compared to the same period in 2025. The increase was primarily due to an $8.7 million increase in employee-related and consulting expenses, of which $6.6 million related to commercial headcount additions and other launch-related activities, and a $2.4 million increase primarily due to software costs, professional fees and other costs.

We anticipate that our selling, general and administrative expenses will continue to 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 requirements, and other compliance matters.

Interest Expense

During the three months ended March 31, 2026, our interest expense was $6.1 million, and represents an increase of $2.9 million, or 91%, compared to the same period in 2025. Interest expense during the three months ended March 31, 2026, is attributable to the Notes and the Amended A&R Loan Agreement. Interest expense during the three months ended March 31, 2025, is attributable to the A&R Loan Agreement. The increase was primarily due to the issuance of $201.3 million aggregate principal amount of the Notes in July 2025 and the $30.0 million distribution of the Term Loan D in September 2025. The $6.1 million of interest expense includes $1.6 million of non-cash interest expense.

Interest Income

During the three months ended March 31, 2026, our interest income was $3.8 million, and represents an increase of $1.4 million, or 62%, compared to the same period in 2025. The increase was primarily the result of a higher invested cash balance, partially offset by lower market interest rates.

Liquidity and Capital Resources

Liquidity

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through March 31, 2026, we have funded our operations primarily through private placements, registered offerings of our equity securities, convertible notes, and borrowings under loan agreements. From inception through March 31, 2026, we raised aggregate net proceeds of $507.3 million through sales of our securities, $194.9 million through the issuance of the Notes, and $120.8 million through borrowings under the Amended A&R Loan Agreement. As of March 31, 2026, we had an accumulated deficit of $501.7 million, our cash and cash equivalents were $145.2 million, and our short-term investments were $241.9 million.

Capital Resources

To help meet our liquidity requirements, we have entered into various equity and financing arrangements. As of March 31, 2026, our material cash requirements for the operations of our business consisted primarily of the current and long-term liabilities noted on our condensed balance sheets, as well as other commitments, including the following notable items:

- In February 2022, we entered into an Open Market Sale Agreement with Jefferies, 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 $50.0 million, which amount was subsequently increased to $400.0 million on January 9, 2026. During the three months ended March 31, 2026 and 2025, we did not sell any shares pursuant to the Open Market Sale Agreement.
- In July 2025, we issued and sold 2,172,368 Shares and Pre-Funded Warrants to purchase up to 400,000 shares of common stock pursuant to the Equity Underwriting Agreement with the Representatives of the Underwriters, resulting in net proceeds of $91.6 million (see Note 7. Stockholders' Equity).
- In August 2025, we issued $201.3 million aggregate principal amount of convertible notes, resulting in net proceeds of $194.9 million (see Note 9. Debt).
- During the three months ended March 31, 2026 and 2025, investors exercised 45,788 and 695,650 warrants, net of shares withheld for exercise price, respectively, which generated less than $0.1 million and $5.6 million in cash, respectively (see Note 7. Stockholders' Equity).
- In September 2025, we entered into the Third Amendment to the A&R Loan Agreement; in July 2025, we entered into the Second Amendment to the A&R Loan Agreement; and in May 2025, we entered into the First Amendment to the A&R Loan Agreement. In May 2024, we entered into the A&R Loan Agreement, which amended and restated, in its entirety, the Prior Loan Agreement.
- In September 2025, we received funding of the $30.0 million Term D Loan (as defined in the Amended A&R Loan Agreement) upon achievement of the Term D Milestone (as defined in the Amended A&R Loan Agreement), resulting in net proceeds of $27.7 million. In connection with the funding of the Term D Loan, we issued warrants with an exercise price of $14.84 per share to purchase an aggregate of 50,537 shares of our common stock to Innovatus, Oxford, and certain of its affiliates. Subsequent to the Third Amendment, we may draw (i) up to $100.0 million under Term E Loan (as defined in the Amended A&R Loan Agreement) upon FDA approval of gedatolisib in second line WT ABC patients post CDK4/6 inhibitor therapy; (ii) up to three $40.0 million Term F Loans (as defined in the Amended A&R Loan Agreement), for a total of $120.0 million, upon achievement of certain trailing three months' product revenue thresholds; and (iii) up to $150.0 million Term G Loan (as defined in the Amended A&R Loan Agreement), which continues to be available only in the Lenders' sole discretion upon our request. The term loans include financial covenants related to liquidity and other financial measures and have a maturity date of November 1, 2029 (see Note 9. Debt).

Liquidity and capital resource requirements

We expect that our research and development and selling, general and administrative expenses will increase as we continue to develop gedatolisib, conduct the VIKTORIA-2 Phase 3 and CELC-G-201 Phase 1b/2 clinical trials, continue follow-up activities for the VIKTORIA-1 Phase 3 clinical trial, conduct other studies and clinical trials, and pursue other business development activities. We also expect sales and marketing expenses to increase as we prepare for and support the planned commercialization of gedatolisib. We expect to use cash on hand, together with the funds received or to be received under the debt and equity financings described above, to fund our research and development expenses, clinical trial costs, sales and marketing expenses, general corporate expenses, capital expenditures and working capital.

Based on our current business plan, we believe that our current cash, cash equivalents and short-term investments, together with available borrowings under the Amended A&R Loan Agreement, will provide sufficient cash to finance our operations through 2027.

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 seek to obtain approval for and launch gedatolisib; expand our infrastructure, commercial operations and research and development activities; and take advantage of financing or other opportunities that we believe to be in the best interests of the Company and our stockholders. Additional capital may be raised through the sale of common or preferred equity or convertible debt securities, entry into debt facilities or other third-party funding arrangements. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common stock. Agreements entered into in connection with such capital raising activities could contain covenants that would restrict our operations or require us to relinquish certain rights. Additional capital may not be available on reasonable terms, or at all.

Cash Flows

The following table summarizes the primary sources and uses of cash and cash equivalents (in thousands):

	Three Months Ended March 31,	
	2026	**2025**
Net cash and cash equivalents (used in) provided by:		
Operating activities	$ (55,065)	$ (35,853)
Investing activities	34,519	24,262
Financing activities	34	5,554
Net increase (decrease) in cash and cash equivalents	$ (20,512)	$ (6,037)

Operating Activities

Net cash used in operating activities was $55.1 million during the three months ended March 31, 2026, and consisted of a net loss of $52.8 million and working capital changes of $8.3 million, partially offset by non-cash expenses of $6.0 million. The $8.3 million decrease in working capital was primarily due to a $14.9 million decrease in accrued clinical trial costs and other accrued expenses, partially offset by a $4.1 million increase in accounts payable and a $2.5 million decrease in prepaid clinical trial costs and other current assets. The $6.0 million of non-cash expenses consisted of $5.3 million of stock-based compensation expense and $0.7 million of net non-cash interest expense.

Net cash used in operating activities was $35.9 million during the three months ended March 31, 2025, and consisted of a net loss of $37.0 million and working capital changes of $1.2 million, partially offset by non-cash expenses of $2.3 million. The $1.2 million decrease in working capital was primarily due to a $2.4 million increase in prepaid clinical trial costs and other current assets, partially offset by a $0.6 million increase in accounts payable and a $0.6 million increase in accrued clinical trial costs and other accrued expenses. The $2.3 million of non-cash expenses consisted of $2.4 million of stock-based compensation expense, partially offset by net non-cash interest income of $0.1 million.

Investing Activities

Net cash provided by investing activities was $34.5 million during the three months ended March 31, 2026, and consisted of $34.8 million of net purchases of short-term investments in U.S. treasury securities, partially offset by $0.3 million in purchases of property and equipment and capitalized software.

Net cash provided by investing activities was $24.3 million during the three months ended March 31, 2025, and consisted of $24.4 million of net purchases of short-term investments in U.S. treasury securities, partially offset by $0.1 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was less than $0.1 million during the three months ended March 31, 2026, and consisted of $0.2 million of proceeds from the exercise of employee stock options, partially offset by $0.2 million of payments for secondary registration statement costs.

Net cash provided by financing activities was $5.6 million during the three months ended March 31, 2025, and consisted of net proceeds of $5.6 million from the exercise of common stock warrants.

Recent Accounting Pronouncements

From time-to-time new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. These pronouncements are more fully described in Note 2 to our unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report. We are currently evaluating the method of adoption and the impact of any recent accounting pronouncements not yet adopted on our unaudited condensed financial statements and related disclosures.

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 unaudited condensed 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 unaudited condensed 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 during the period in which they become known. Actual results may differ materially from these estimates.

Our significant accounting policies are more fully described in the 2025 10-K and in Note 2 to our unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report. There were no changes to our critical accounting estimates, as disclosed in the 2025 10-K, during the three months ended March 31, 2026. Of our significant accounting policies, we believe that the following reflect the critical accounting estimates used in the preparation of our unaudited condensed financial statements:

- Stock-based compensation; and
- Clinical trial costs.

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 management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2026. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2026, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes to our system of internal control over financial reporting during the three months ended March 31, 2026, that have materially affected, or are reasonably likely to materially affect, our system of internal controls 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 "Special Note Regarding Forward-Looking Statements," you should carefully consider the "Risk Factors" discussed in the 2025 10-K, 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. There have been no material changes to the risk factors previously disclosed in the 2025 10-K. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

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

Recent Unregistered Sales of Equity Securities

During the three months ended March 31, 2026, we issued 45,788 shares of common stock upon the exercise of previously issued warrants as follows:

- 43,611 shares were issued to the placement agent from private placements that closed on January 21, 2016, and May 2, 2016, pursuant to the exercise of 46,891 warrants, net of 3,280 warrants surrendered upon cashless exercise, at an exercise price of $7.56 per share, resulting in cash proceeds of less than $0.1 million.
- 2,177 shares were issued to the placement agent from private placements that closed on April 28, 2017, and May 17, 2017, pursuant to the exercise of 2,177 warrants at an exercise price of $8.42 per share, resulting in cash proceeds of less than $0.1 million.

The shares were issued pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

Trading Plans

During the three months ended March 31, 2026, 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 of the Company (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 principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of principal financial officer pursuant to 18 U.S.C. Section 1350, as adopted 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 March 31, 2026, 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 (embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith.
** Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: May 14, 2026

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 OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO 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 unaudited condensed 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 unaudited condensed 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.

Date: May 14, 2026

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO 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 unaudited condensed 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 unaudited condensed 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.

Date: May 14, 2026

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

Exhibit 32.1

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

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 (the "Report"), by Celcuity Inc. (the "Registrant"), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

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

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

Date: May 14, 2026

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

Exhibit 32.2

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

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 (the "Report"), by Celcuity Inc. (the "Registrant"), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

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

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

Date: May 14, 2026

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