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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**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 October 29, 2026, there were 49,126,314 shares of the registrant's common stock outstanding.

Celcuity Inc.
Table of Contents

		Page
PART I. FINANCIAL INFORMATION		
ITEM 1.	Financial Statements (unaudited)	5
	Condensed Balance Sheets	5
	Condensed Statements of Operations	6
	Condensed Statements of Changes in Stockholders' Equity (Deficit)	7
	Condensed Statements of Cash Flows	8
	Notes to Condensed Financial Statements	9
ITEM 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	39
ITEM 4.	Controls and Procedures	39
PART II. OTHER INFORMATION		
ITEM 1.	Legal Proceedings	40
ITEM 1A.	Risk Factors	40
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	44
ITEM 3.	Defaults Upon Senior Securities	44
ITEM 4.	Mine Safety Disclosures	44
ITEM 5.	Other Information	44
ITEM 6.	Exhibits	45
Signatures		46

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 beliefs with respect to the potential rate and degree of market acceptance and clinical utility of REVTORPYK™ (gedatolisib) both in the United States and internationally;
- our plans to develop and commercialize our products, and our expectations about the market opportunity for REVTORPYK in the United States and internationally, and our ability to serve those markets;
- our revenue expectations;
- our expectations with respect to pricing in the United States and internationally, and our ability to obtain reimbursement for REVTORPYK, 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 regarding our ability to maintain U.S. Food and Drug Administration ("FDA") approval of REVTORPYK, obtain approval for supplemental new drug applications ("sNDAs") submitted to the FDA, and obtain regulatory approvals to commercialize REVTORPYK outside the United States;
- our expectations regarding our ability to obtain and maintain intellectual property protection for REVTORPYK, including its current and future formulations, indications and methods of use;
- our beliefs about our ability to capitalize on the exclusive global development and commercialization rights obtained from our license agreement with Pfizer Inc. ("Pfizer") dated April 8, 2021, with respect to gedatolisib (the "License Agreement");
- our expectations regarding the future milestone and royalty payments that may be owed to Pfizer under the License Agreement;
- 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* mutant-type ("MT") cohort of the VIKTORIA-1 Phase 3 clinical trial;
- our clinical trial plans and the estimated timelines and costs for such trials;
- our expectations regarding the timeline of patient enrollment and results from clinical trials for gedatolisib, including our ongoing VIKTORIA-2 Phase 3 and CELC-G-201 Phase 1b/2 clinical trials;
- our expectations with respect to the development, validation, required approvals, costs, and development and regulatory timelines, of investigational uses of gedatolisib;
- our plans with respect to research and development and related expenses for the foreseeable future;
- our expectations regarding business development activities, including collaborations with pharmaceutical companies;

- our plans with respect to potentially raising capital and our expectations as to the use of proceeds from our financing activities;
- our expectations with respect to availability of capital in the future, and our assumption that we will have adequate authorized shares for future equity issuances; and
- 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.

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, the uncertainty regarding market acceptance of REVTORPYK by physicians, patients, third-party payors and others in the medical community, and with the size of market opportunities available to us in the United States and internationally; obtaining, and maintaining continuity of, clinical and commercial supply of REVTORPYK and/or gedatolisib; challenges we may face in developing and maintaining relationships with pharmaceutical company partners, including our current and any future suppliers supporting REVTORPYK and any future product candidate; our inability to maintain regulatory approval for REVTORPYK; the complexity and difficulty of demonstrating the safety and sufficient magnitude of benefit to obtain regulatory approval of sNDAs for REVTORPYK and/or gedatolisib and other products we may develop; our potential inability to develop, validate, and obtain future regulatory approvals, in the United States and internationally, for additional formulations, indications and methods of use of REVTORPYK and/or gedatolisib; changes in government regulations, including, without limitation, "Most-Favored-Nation" ("MFN") drug pricing in the United States and internationally; obtaining and maintaining intellectual property protection for REVTORPYK and future formulations of gedatolisib, and the 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; the uncertainties and costs associated with clinical studies and with developing and commercializing pharmaceuticals; difficulties we may face in managing growth, such as retaining a qualified sales force and attracting and retaining key personnel; tightening credit markets and limitations on access to capital; and stock market volatility or other factors that may affect our ability to access capital on favorable terms or at all.

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

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

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 178,165	$ 165,703
Investments	464,538	275,794
Inventory	1,476	—
Prepaid clinical trial costs	19,669	18,896
Other current assets	10,108	5,266
Total current assets	673,956	465,659
Property and equipment, net	901	499
Intangible assets, net	50,000	—
Operating lease right-of-use assets	1,061	51
Other non-current assets	951	349
Total assets	$ 726,869	$ 466,558
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 12,407	$ 6,407
Accrued clinical trial costs	11,277	16,826
Other accrued expenses	22,159	20,865
Operating lease liabilities, current	259	54
Total current liabilities	46,102	44,152
Operating lease liabilities, non-current	848	—
Convertible notes	753,958	195,324
Note payable	—	126,527
Total liabilities	800,908	366,003
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 2,500,000 shares authorized as of September 30, 2026, and December 31, 2025; 0 shares issued and outstanding as of September 30, 2026, and December 31, 2025	—	—
Common stock, $0.001 par value; 95,000,000 shares authorized as of September 30, 2026, and December 31, 2025; 49,122,601 and 48,244,960 shares issued and outstanding as of September 30, 2026, and December 31, 2025, respectively	49	48
Additional paid-in capital	579,851	549,404
Accumulated deficit	(653,939)	(448,897)
Total stockholders' equity (deficit)	(74,039)	100,555
Total liabilities and stockholders' equity (deficit)	$ 726,869	$ 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 37,519	$ 30,425	$ 101,659	$ 96,598
Selling, general and administrative	39,800	12,424	92,285	26,393
Total operating expenses	77,319	42,849	193,944	122,991
Loss from operations	(77,319)	(42,849)	(193,944)	(122,991)
Other (expense) income:				
Interest expense	(2,691)	(4,595)	(14,199)	(10,982)
Interest income	6,673	3,640	14,578	7,904
Loss on debt extinguishment	—	—	(11,477)	—
Other (expense) income, net	3,982	(955)	(11,098)	(3,078)
Net loss before income taxes	(73,337)	(43,804)	(205,042)	(126,069)
Income taxes	—	—	—	—
Net loss	$ (73,337)	$ (43,804)	$ (205,042)	$ (126,069)
Net loss per share, basic and diluted	$ (1.33)	$ (0.92)	$ (3.74)	$ (2.81)
Weighted average common shares outstanding, basic and diluted	55,143,356	47,589,731	54,810,032	44,785,236

See accompanying notes to the unaudited condensed financial statements.

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

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
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
Stock-based compensation	—	—	—	—	6,904	—	6,904
Employee stock purchases	60,604	—	—	—	798	—	798
Exercise of common stock options, net of shares withheld for exercise price	170,760	—	—	—	1,488	—	1,488
Conversion of Term A Loan outstanding principal to common stock	343,802	1	—	—	3,367	—	3,368
Net loss	—	—	—	—	—	(78,864)	(78,864)
Balance as of June 30, 2026	48,922,556	49	—	—	567,772	(580,602)	(12,781)
Stock-based compensation	—	—	—	—	10,022	—	10,022
Exercise of common stock options, net of shares withheld for exercise price	200,045	—	—	—	2,057	—	2,057
Net loss	—	—	—	—	—	(73,337)	(73,337)
Balance as of September 30, 2026	49,122,601	$ 49	—	$ —	$ 579,851	$ (653,939)	$ (74,039)

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
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
Stock-based compensation	1,029	—	—	—	2,704	—	2,704
Conversion of preferred stock to common stock	1,044,260	1	(104,426)	—	(1)	—	—
Employee stock purchases	26,966	—	—	—	253	—	253
Exercise of common stock options, net of shares withheld for exercise price	2,561	—	—	—	18	—	18
Net loss	—	—	—	—	—	(45,268)	(45,268)
Balance as of June 30, 2025	38,914,208	39	213,151	—	398,456	(354,120)	44,375
Stock-based compensation	—	—	—	—	6,779	—	6,779
Issuance of common stock upon close of equity offering, net of underwriting discounts and offering costs	2,172,368	2	—	—	91,550	—	91,552
Exercise of common stock options, net of shares withheld for exercise price	290,033	—	—	—	2,405	—	2,405
Exercise of common stock warrants, net of shares withheld for exercise price	1,654,809	2	—	—	12,868	—	12,870
Issuance of common stock warrants in connection with note agreement	—	—	—	—	2,786	—	2,786
Conversion of preferred stock to common stock	243,130	—	(24,313)	—	—	—	—
Net loss	—	—	—	—	—	(43,804)	(43,804)
Balance as of September 30, 2025	43,274,548	$ 43	188,838	$ —	$ 514,844	$ (397,924)	$ 116,963

See accompanying notes to the unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (205,042)	$ (126,069)
Adjustments to reconcile net loss to net cash and cash equivalents used in operations:		
Depreciation	167	118
Stock-based compensation	22,251	11,927
Amortization of debt issuance costs and discount	3,431	1,866
Payment-in-kind interest	582	773
Non-cash investment income	(4,022)	(840)
Non-cash operating lease expense	65	(5)
Loss on debt extinguishment	11,477	—
Changes in operating assets and liabilities:		
Inventory	(1,476)	—
Prepaid clinical trial costs	(773)	(9,272)
Other current assets	(4,812)	(1,428)
Accounts payable	5,778	1,785
Accrued clinical trial costs	(5,549)	(75)
Other accrued expenses	1,206	4,339
Net cash used in operating activities	(176,717)	(116,881)
Cash flows from investing activities:		
Proceeds from maturities of investments	325,000	229,045
Purchases of investments	(509,722)	(396,342)
Purchase of intangible asset	(50,000)	—
Purchases of property and equipment	(311)	(196)
Purchases of capitalized software	(391)	—
Net cash used in investing activities	(235,424)	(167,493)
Cash flows from financing activities:		
Proceeds from employee stock purchases	798	253
Proceeds from exercise of common stock options	3,992	2,384
Proceeds from exercise of common stock warrants	31	18,470
Proceeds from convertible notes, net of debt issuance costs of $17,998 and $5,774 during the nine months ended September 30, 2026 and 2025, respectively	557,002	195,476
Proceeds from note payable, net of debt issuance costs of $0 and $2,248 during the nine months ended September 30, 2026 and 2025, respectively	—	27,752
Proceeds from equity offering, net of underwriting discounts and offering costs	—	91,823
Repayment of note payable	(137,017)	—
Payments for secondary registration statement costs	(203)	(47)
Net cash provided by financing activities	424,603	336,111
Net change in cash and cash equivalents	12,462	51,737
Cash and cash equivalents:		
Beginning of period	165,703	22,515
End of period	$ 178,165	$ 74,252
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 12,191	$ 7,421
Cash paid for operating leases	$ 140	$ 165
Supplemental disclosures of non-cash investing and financing activities:		
Conversion of Term A Loan to shares of common stock	$ 3,368	$ —
Right-of-use asset obtained in exchange for operating lease liability	$ 1,150	$ —
Debt issuance costs included in other accrued expenses	$ —	$ 273
Exercise of common stock options pending receipt of cash proceeds	$ 8	$ —
Secondary registration statement costs included in accounts payable	$ —	$ 34
Capitalized software included in other accrued expenses	$ 61	$ —
Property and equipment included in accounts payable	$ 340	$ 3
Common stock warrants issued with note payable transaction	$ —	$ 2,786

See accompanying notes to the unaudited condensed financial statements.

1. Organization and Liquidity

Organization

Celcuity Inc., a Delaware corporation (the "Company"), is a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. The Company's first FDA-approved product is REVTORPYK, a potent pan-PI3K and mTORC1/2 inhibitor that comprehensively blocks the phosphatidylinositol 3-kinase ("PI3K"), serine/threonine-protein kinase protein kinase B ("AKT"), and mechanistic target of rapamycin ("mTOR"), or 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. The Company's Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib plus fulvestrant with or without palbociclib in patients with hormone receptor-positive ("HR+"), human epidermal growth factor receptor 2-negative ("HER2-") locally advanced or metastatic breast cancer ("ABC"), supported FDA approval of REVTORPYK for use in adult patients without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting (the "FDA Approval"). Results for the *PIK3CA* MT cohort of the VIKTORIA-1 clinical trial have been released.

The Company's Phase 3 clinical trial, VIKTORIA-2, is an ongoing trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib plus palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. The Company's Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib plus 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 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, supporting the commercialization of REVTORPYK, including 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 September 30, 2026, the Company had an accumulated deficit of $653.9 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 September 30, 2026, the Company had $642.7 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 early commercialization stage including, but not limited to, the uncertain commercial future of REVTORPYK and its adoption by physicians and consumers; its ability to maintain the FDA Approval, obtain approval for sNDAs submitted to the FDA, and obtain regulatory approvals to commercialize REVTORPYK internationally; the clinical success of investigational uses of gedatolisib; the potential need for additional financing to achieve its goals; 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.

Revenue Recognition

In accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods, in an amount that reflects the consideration the Company expects to receive in exchange for the goods provided. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: identify the contracts with a customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when or as the entity satisfies a performance obligation. At contract inception, the Company assesses the goods promised within each contract and determines those that are performance obligations and assesses whether each promised good is distinct. The Company then recognizes revenue as the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. The Company derives revenue through product sales of REVTORPYK.

Product Revenue

The Company recognizes revenue from sales of a single product, REVTORPYK. The Company has contracted with its third-party logistics (“3PL”) service provider to deliver REVTORPYK to healthcare providers and pharmacies in the United States and Puerto Rico. The 3PL provides services to the Company that include storage, distribution, collection, returns, customer support, and financial and system access support. Under this model, healthcare providers and pharmacies place orders with the specialty distributors and specialty pharmacies.

The Company recognizes revenue when control of REVTORPYK transfers to the healthcare providers or pharmacies, which generally occurs upon delivery of REVTORPYK based on contractual shipping terms. Shipments of REVTORPYK commenced on September 30, 2026. Because no product was received by the healthcare providers or pharmacies until after September 30, 2026, the Company did not recognize any product revenue during the three and nine months ended September 30, 2026.

The Company records product revenue net of estimated variable consideration, including chargebacks, government and commercial rebates, specialty distributor fees, product returns, copayment assistance programs, prompt-pay discounts and other customary deductions. Reserves for these amounts are established in the same period that the related product revenue is recognized.

Because REVTORPYK was commercially launched in September 2026, the Company estimates variable consideration using available contractual terms, expected payer mix, anticipated channel inventory levels, historical industry data for comparable oncology products, and third-party market information. Estimates will be reassessed each reporting period and adjusted as additional information becomes available.

Accounting Policy Elections

The Company's product is shipped to its customers by a third-party logistics provider, and control transfers to the customer upon delivery. Shipping and handling activities performed before the customer obtains control are fulfillment activities. The Company has elected to account for any shipping and handling activities performed after the customer obtains control as fulfillment costs rather than as a separate performance obligation. Shipping and handling costs are included in cost of sales.

The Company has also elected to exclude from the transaction price all sales, use and similar taxes assessed by governmental authorities that are imposed on and concurrent with a specific revenue-producing transaction and collected from customers.

The Company does not adjust the transaction price for the effects of a significant financing component, as the period between the transfer of control of the product and customer payment is expected to be one year or less. The Company expenses incremental costs of obtaining a contract as incurred, as the amortization period of the related asset would be one year or less.

Inventory

The Company capitalizes inventory costs once it determines that future commercialization is probable and future economic benefit is expected to be realized; otherwise, such costs are expensed. The Company expensed pre-launch inventory as research and development expense prior to the FDA Approval.

Inventory is measured at the lower of cost or net realizable value, with cost determined using the first-in, first-out (FIFO) method. Inventory costs include raw materials, third-party contract manufacturing organizations ("CMOs") direct conversion costs, and an allocation of internal production overhead. Allocated overhead includes costs associated with commercial manufacturing, quality control and supply-chain activities. Overhead capitalized into inventory is recognized in cost of sales when the related product is sold. Only material costs designated for commercial use are capitalized as inventory. Material costs designated for use in research activities or clinical trials are expensed as research and development when incurred.

The Company periodically reviews the recoverability of inventory to determine any changes to net realizable value arising from excess, slow-moving or obsolete inventory. If net realizable value is lower than cost, the inventory will be written down to net realizable value and an impairment charge will be recognized in cost of sales.

Property and Equipment

As the Company prepared for the commercial launch of REVTORPYK, it reevaluated the estimated useful lives of its property and equipment as follows:

Asset description	Estimated useful life
Lab equipment	5 years
Furniture and fixtures	5 years
Office and computer equipment	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

The change in estimated useful lives did not have a material impact on the Company's depreciation expense.

License Agreement

The License Agreement is being accounted for as an asset acquisition under U.S. GAAP.

The License Agreement requires payments for upfront fees and upon the achievement of certain development and commercial milestones. Upfront fees and developmental milestone payments incurred prior to regulatory approval are expensed as research and development expense, with upfront fees recognized upon receipt of the license and development milestones recognized when achievement of the milestone becomes probable. Payments for development milestones incurred upon or after regulatory approval, for which the related intangible asset has an alternative future use, are capitalized as finite-lived intangible assets. Commercial milestone payments are expensed as cost of sales when the related sales threshold is achieved.

Finite-Lived Intangible Assets

Finite-lived intangible assets consist of milestone payments capitalized under license agreements upon or after regulatory approval and are recorded at cost. These assets are amortized on a straight-line basis over their estimated remaining useful lives. Amortization begins when the intangible asset is available for its intended use, which occurs upon commercial launch of the related product, and is recorded as a component of cost of sales on the condensed statements of operations. The Company evaluates the remaining useful lives of finite-lived intangible assets each reporting period and accounts for any revision to the remaining amortization period prospectively.

Long-Lived Assets

Long-lived assets, such as property and equipment and finite-lived intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values, and third-party independent appraisals, as considered necessary.

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of employee-related costs, including compensation, benefits, recruiting and travel costs for personnel in executive, sales, market access, marketing, commercial operations, 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 to support the commercialization of REVTORPYK, legal services associated with being a public company, director and officer insurance, investor relations, and travel expenses.

In connection with the FDA Approval, 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 and nine months ended September 30, 2025, the Company reclassified $4.5 million and $10.8 million, respectively, from research and development expenses to selling, general and administrative expenses. There were no changes to previously reported total operating expenses or net loss.

The stock-based compensation amounts included in Note 9 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 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 convertible notes, options, 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:

	As of September 30,	
	2026	**2025**
Convertible notes as-if-converted-to-common stock	11,760,359	5,296,053
Options to purchase common stock	5,274,943	5,696,327
Warrants to purchase common stock	225,705	3,206,822
Restricted stock awards and restricted stock units	738,736	1,029
Preferred stock as-if-converted-to-common stock	—	1,888,380
Total	17,999,743	16,088,611

The maximum number of shares of common stock issuable upon conversion of the Company's 2.750% Senior Notes due 2031 (the "2031 Notes") is 5,296,053. As of September 30, 2026, the number of shares issuable would be 3,923,002 if the 2031 Notes were converted in full. The maximum number of shares of common stock issuable upon conversion of the Company's 0.250% Senior Notes due 2032 (the "2032 Notes") is 6,464,306. As of September 30, 2026, the number of shares issuable would be 4,617,361 if the 2032 Notes were converted in full.

As of each of September 30, 2026 and 2025, pre-funded warrant shares of 6,147,787 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 U.S. 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 September 30, 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):

	September 30, 2026			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. treasury securities	$ 464,538	$ —	$ (218)	$ 464,320
Total	$ 464,538	$ —	$ (218)	$ 464,320

	December 31, 2025			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	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. Inventory

Inventory consisted of the following (in thousands):

	As of	
	September 30, 2026	December 31, 2025
Raw materials	$ 18	$ —
Work-in-process	1,071	—
Finished goods	387	—
Total inventory	$ 1,476	$ —

The Company began capitalizing inventory upon the FDA Approval. Manufacturing and inventory-related costs incurred prior to the FDA Approval were expensed as research and development expense in the accompanying condensed statements of operations. As a result, the Company's inventory balances do not reflect the full manufacturing cost of product on hand.

6. Other Accrued Expenses

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

	As of	
	September 30, 2026	December 31, 2025
Employee compensation and benefits	$ 12,227	$ 8,338
License milestone	—	5,000
Research and development costs	3,426	1,218
Consulting and professional fees	3,443	2,335
Interest	1,374	3,379
Other	1,689	595
Total other accrued expenses	$ 22,159	$ 20,865

7. Commitments

Operating Leases

In November 2025, the Company entered into a lease for clinical laboratory and office space in Minnesota for 19,594 square feet. The lease term commenced in April 2026 and is 62 months with two options to extend the lease term for five years each. The Company also has a one-time option to terminate the lease at the end of the third year, provided certain conditions are met. To exercise this option, the Company must pay a termination fee equal to eight months' rent plus the landlord's unamortized transaction costs, which include abated rent, tenant improvement allowances and broker fees. The initial annual lease payment is $0.3 million and increases by 3.5% on an annual basis, resulting in total undiscounted future minimum lease payments of $1.5 million over the initial 62-month term. The Company classified the lease as an operating lease and recognized an initial right-of-use asset and lease liability of $1.1 million using a discount rate of 8.7%. As the implicit rate is not readily determinable for the lease, the Company uses an estimated incremental borrowing rate to determine the initial present value of lease payments.

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, 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 September 30, 2026, the Company had $2.5 million of non-cancelable purchase commitments with respect to these arrangements, of which $1.2 million is expected to be incurred in the next 12 months, and $1.3 million thereafter.

Manufacturing and Supply Commitments

The Company enters into contracts in the normal course of business with third-party CMOs and suppliers to manufacture drug substance, drug product, and finished goods for research activities, clinical trials and commercial sale. Agreements with certain CMOs and suppliers are non-cancelable or cancelable only upon payment of termination fees. As of September 30, 2026, the Company had $3.0 million of non-cancelable purchase commitments under these arrangements, all of which are expected to be paid within the next 12 months.

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 September 30, 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.

8. Stockholders' Equity (Deficit)

Capital Stock

As of September 30, 2026, the Company's authorized capital stock consisted of 95,000,000 shares of common stock, of which 49,122,601 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 September 30, 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 "2031 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 2031 Underwriters an option to purchase up to an additional 335,526 shares of common stock (the "Option Shares"), less underwriting discounts and commissions. The 2031 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 2031 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 September 30, 2026	6,373,492	$ 0.48

9. Stock-Based Compensation

2026 Stock Incentive Plan

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.

The 2026 Plan provides for the grant of options, RSAs, RSUs, stock appreciation rights and other stock-based awards. The exercise price of each option granted under the 2026 Plan is not less than the fair market value of one share on the grant date. The maximum permitted term of options granted under the 2026 Plan is ten years. The 2026 Plan is generally administered by the compensation committee of the Board, which has the authority to interpret the 2026 Plan, grant awards and make all other determinations necessary for the administration of the 2026 Plan.

The number of shares reserved for issuance under the 2026 Plan will automatically increase on January 1 of each year from 2027 to 2036 by the number of shares equal to 1.0% of the aggregate number of outstanding shares of common stock as of the immediately preceding December 31. However, the Board may reduce the amount of the increase in any particular year.

As of September 30, 2026, the number of shares available for issuance under the 2026 Plan was 2,651,196.

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. During the nine months ended September 30, 2025, the Board and the stockholders approved a 3,000,000 share increase to the number of shares reserved for issuance under the 2017 Plan.

Upon the approval of the 2026 Plan, no further awards may be made under the 2017 Plan. Outstanding awards granted under the 2017 Plan continue to remain subject to the terms and conditions of the 2017 Plan. Any shares subject to awards outstanding under the 2017 Plan that expire, are cancelled, forfeited, or settled in cash will become available for issuance under the 2026 Plan.

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)
Outstanding as of December 31, 2025	5,842,485	$ 19.62	7.9	$ 468,191
Granted	42,150	106.59		
Exercised	(427,232)	9.36		
Forfeited	(182,460)	25.86		
Outstanding as of September 30, 2026	5,274,943	$ 20.93	7.1	$ 311,182
Exercisable as of September 30, 2026	3,344,196	$ 14.44	6.5	$ 217,648

During the nine months ended September 30, 2026 and 2025, the weighted-average grant date fair value of options granted was $78.90 and $21.63 per share, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2026 and 2025, was $37.5 million and $12.1 million, respectively. Upon the exercise of stock options, the Company issues new shares of its common stock. As of September 30, 2026, the unrecognized compensation cost related to outstanding employee and non-employee options was $39.9 million and is expected to be recognized as expense over a weighted-average period of 1.4 years.

During the three and nine months ended September 30, 2025, the market conditions associated with options previously granted to an employee were satisfied following the achievement of the specified stock price threshold. As a result, the options vested and the Company recognized $3.5 million in stock-based compensation expense related to these awards during the three and nine months ended September 30, 2025.

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

	Nine Months Ended September 30,	
	2026	2025
Risk-free interest rate	3.6% − 3.9%	3.6% − 4.7%
Expected volatility	84.5% − 85.5%	74.4% − 78.2%
Expected life (years)	6.1 − 6.3	5.0 − 10.0
Expected dividend yield	0%	0%

During the three months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense for stock options of $4.8 million and $6.5 million, respectively. During the nine months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense for stock options of $13.5 million and $11.1 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	720,116	101.13
Vested	(1,244)	26.86
Forfeited	(7,575)	114.67
Outstanding as of September 30, 2026	738,736	$ 100.60

As of September 30, 2026, the unrecognized compensation cost related to outstanding RSAs and RSUs was $67.6 million and is expected to be recognized over a weighted-average period of 2.2 years.

During the three months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense for RSAs and RSUs of $4.2 million and less than $0.1 million, respectively. During the nine months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense for RSAs and RSUs of $6.4 million and less than $0.1 million, respectively.

In August 2026, the Company issued 140,000 performance-based restricted stock units ("PRSUs") to several of its employees, which are reflected in the above table summarizing RSA and RSU activity. The PRSUs vest upon achievement of four stock price hurdles, with 25% of the shares vesting upon achievement of each hurdle. As of September 30, 2026, no PRSUs had vested or been forfeited, and all four stock hurdles were deemed probable of achievement, resulting in the Company recognizing stock-based compensation expense of $1.0 million during the three and nine months ended September 30, 2026.

The assumptions used in the Monte Carlo simulation model to determine the fair value of the PRSUs were as follows:

	Nine Months Ended September 30, 2026
Risk-free interest rate	4.7%
Expected volatility	77.8%
Expected life (years)	10.0
Expected dividend yield	0%

Amended and Restated 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.

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.

As of September 30, 2026, the number of shares available for issuance under the Restated ESPP was 939,395.

During the three months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense related to the ESPP and Restated ESPP of $1.1 million and $0.3 million, respectively. During the nine months ended September 30, 2026 and 2025, the Company recognized stock-based compensation expense related to the ESPP and Restated ESPP of $2.4 million and $0.8 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 3,038	$ 1,478	$ 7,390	$ 3,904
Selling, general and administrative	6,984	5,301	14,861	8,023
Total stock-based compensation expense	$ 10,022	$ 6,779	$ 22,251	$ 11,927

During each of the three and nine months ended September 30, 2026, the Company capitalized $0.1 million of stock-based compensation expense into inventory. No stock-based compensation expense was capitalized into inventory during the three and nine months ended September 30, 2025.

10. Debt

June 2026 Convertible Notes Offering

On June 3, 2026, the Company entered into an underwriting agreement (the “2032 Note Underwriting Agreement”) with Jefferies, J.P. Morgan Securities LLC, TD Securities (USA) LLC and Guggenheim Securities, LLC (the "2032 Underwriters"), subject to customary conditions, to issue and sell in a public offering $500.0 million aggregate principal amount of the 2032 Notes to the 2032 Underwriters (the “2032 Note Offering”). In addition, pursuant to the 2032 Note Underwriting Agreement, the Company granted the 2032 Underwriters an option to purchase up to an additional $75.0 million aggregate principal amount of the 2032 Notes, solely to cover over-allotments. On June 4, 2026, the 2032 Underwriters exercised such option in full. The issuance of $575.0 million aggregate principal amount of the 2032 Notes was completed on June 8, 2026.

The 2032 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 second supplemental indenture (the “Second Supplemental Indenture,” and the Base Indenture, as supplemented by the Second Supplemental Indenture, the “2032 Indenture”), dated as of June 8, 2026, between the Company and the Trustee. The net proceeds from the 2032 Note Offering, after deducting underwriting discounts and commissions and offering expenses, were $557.0 million, including the proceeds from the 2032 Underwriters’ exercise of their over-allotment option in full.

The 2032 Notes are general, unsecured, senior obligations of the Company. The 2032 Notes accrue interest payable semi-annually in arrears on February 1 and August 1 of each year, beginning on February 1, 2027, at a rate equal to 0.250% per year. In addition, special interest will accrue on the 2032 Notes upon the occurrence of certain events relating to the Company’s failure to file certain reports with the SEC as provided in the 2032 Indenture and as described below. The 2032 Notes also have customary provisions relating to the occurrence of “Events of Default” (as defined in the 2032 Indenture) with certain interest penalty provisions. The 2032 Notes mature on August 1, 2032, unless earlier converted, redeemed or repurchased by the Company.

Noteholders may convert their 2032 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 8.0302 shares of common stock, per $1,000 principal amount of the 2032 Notes, which is equivalent to an initial conversion price of $124.53 per share of common stock. The conversion rate is subject to customary adjustments upon the occurrence of certain events as described in the 2032 Indenture. In addition, if certain corporate events that constitute a “Make-Whole Fundamental Change” (as defined in the 2032 Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The 2032 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 31st scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the 2032 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 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 2032 Notes unless at least $50.0 million aggregate principal amount of the 2032 Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. In addition, calling any 2032 Note for redemption will constitute a Make-Whole Fundamental Change with respect to that 2032 Note, in which case the conversion rate applicable to the conversion of that 2032 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 2032 Indenture) occurs, then, subject to certain conditions and except as set forth in the 2032 Indenture, noteholders may require the Company to repurchase their 2032 Notes at a cash repurchase price equal to the principal amount of the 2032 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition in the 2032 Indenture of a Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the common stock.

The fair value of the 2032 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 2032 Notes observed in market trading. The market for trading of the 2032 Notes is not considered to be an active market and therefore the fair value is determined using Level 2 inputs. As of September 30, 2026, the carrying value and fair value of the 2032 Notes was $557.9 million and $551.9 million, respectively.

The issuance costs attributed to the 2032 Notes amounted to $18.0 million and were discounted from the 2032 Notes. The issuance costs will be amortized to interest expense over the term of the 2032 Notes based on the effective interest rate method. During each of the three and nine months ended September 30, 2026, the effective interest rate was 0.8%. During the three and nine months ended September 30, 2026, interest expense related to the 2032 Notes was $1.1 million and $1.3 million, respectively, including $0.7 million and $0.9 million, respectively, related to the amortization of issuance costs.

As of September 30, 2026, the Company was in full compliance with all financial covenants under the 2032 Notes.

July 2025 Convertible Notes Offering

On July 30, 2025, the Company entered into an underwriting agreement (the "2031 Note Underwriting Agreement") with the 2031 Underwriters, subject to customary conditions, to issue and sell in a public offering $175.0 million aggregate principal amount of the 2031 Notes to the 2031 Underwriters (the "2031 Note Offering"). In addition, pursuant to the 2031 Note Underwriting Agreement, the Company granted the 2031 Underwriters an option to purchase up to an additional $26.3 million aggregate principal amount of the 2031 Notes, solely to cover over-allotments. On July 30, 2025, the 2031 Underwriters exercised such option in full. The issuance of $201.3 million aggregate principal amount of the 2031 Notes was completed on August 1, 2025.

The 2031 Notes were issued pursuant to, and are governed by the Base Indenture, as supplemented by a first supplemental indenture (the "First Supplemental Indenture," and the Base Indenture, as supplemented by the First Supplemental Indenture, the "2031 Indenture"), dated as of August 1, 2025, between the Company and the Trustee. The net proceeds from the 2031 Note Offering, after deducting underwriting discounts and commissions and offering expenses, were $194.9 million, including the proceeds from the 2031 Underwriters' exercise of their over-allotment option in full.

The 2031 Notes are general, unsecured, senior obligations of the Company. The 2031 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 2031 Notes upon the occurrence of certain events relating to the Company's failure to file certain reports with the SEC as provided in the 2031 Indenture and as described below. The 2031 Notes also have customary provisions relating to the occurrence of "Events of Default" (as defined in the 2031 Indenture) with certain interest penalty provisions. The 2031 Notes mature on August 1, 2031, unless earlier converted, redeemed or repurchased by the Company.

Noteholders may convert their 2031 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 2031 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 2031 Indenture. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the 2031 Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The 2031 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 2031 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 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 2031 Notes unless at least $50.0 million aggregate principal amount of the 2031 Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. In addition, calling any 2031 Note for redemption will constitute a Make-Whole Fundamental Change with respect to that 2031 Note, in which case the conversion rate applicable to the conversion of that 2031 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 2031 Indenture) occurs, then, subject to certain conditions and except as set forth in the 2031 Indenture, noteholders may require the Company to repurchase their 2031 Notes at a cash repurchase price equal to the principal amount of the 2031 Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition in the 2031 Indenture of a Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the common stock.

The 2031 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 2031 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 2031 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 2031 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 2031 Notes observed in market trading. The market for trading of the 2031 Notes is not considered to be an active market and therefore the fair value is determined using Level 2 inputs. As of September 30, 2026, the carrying value and fair value of the 2031 Notes was $196.1 million and $363.5 million, respectively. As of December 31, 2025, the carrying value and fair value of the 2031 Notes was $195.3 million and $436.5 million, respectively.

The issuance costs attributed to the 2031 Notes amounted to $6.4 million and were discounted from the 2031 Notes. The issuance costs will be amortized to interest expense over the term of the 2031 Notes based on the effective interest rate method. During each of the three and nine months ended September 30, 2026 and 2025, the effective interest rate was 3.3%. During the three months ended September 30, 2026 and 2025, interest expense related to the 2031 Notes was $1.6 million and $1.1 million, respectively, including $0.2 million and $0.2 million, respectively, related to the amortization of issuance costs. During the nine months ended September 30, 2026 and 2025, interest expense related to the 2031 Notes was $4.9 million and $1.1 million, respectively, including $0.7 million and $0.2 million, respectively, related to the amortization of issuance costs.

As of September 30, 2026, the Company was in full compliance with all financial covenants under the 2031 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 could only have been drawn upon FDA approval of gedatolisib in second line wild-type 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 could only have been 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 continued 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% 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 were subject to other customary conditions and limits on when the Company could 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 unamortized discount related to the Third Amendment Warrants was recognized within loss on extinguishment of debt in connection with the June 2026 voluntary prepayment.

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, agreed to make certain term loans ("Term Loans") to the Company in the aggregate principal amount of up to $180.0 million. The A&R Loan Agreement was amended to (i) subject to certain terms and conditions, permit the issuance of the 2031 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 2031 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.

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.

Further, in connection with the release of the topline data from the *PIK3CA* wild-type ("WT") cohort of the VIKTORIA-1 Phase 3 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 had subsequently achieved 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 was entitled to make interest-only payments for 36 months, or up to 48 months if certain conditions had been met. The Term Loans bore 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 was 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 was secured by all assets of the Company. Proceeds were used for working capital purposes and to fund the Company's general business requirements, including the VIKTORIA-1 Phase 3 trial, the CELC-G-201 Phase 1b/2 trial, and the VIKTORIA-2 Phase 3 trial. The A&R Loan Agreement contained customary representations and warranties and covenants, subject to customary carve-outs, and included 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 contained a Final Fee, which was equal to 4.5% of the initial funding of the agreement and was 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 was 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 were no longer operative. The Term D Loan became 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 had achieved the Term E Milestone and (i) failed to draw the full amount of the Term E Loan during the Term E Draw Period and (ii) failed to notify collateral agent, at any time before the date that was 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 would have 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 had 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) provided written notice to collateral agent of its election to prepay the Term Loans at least seven business days prior to such prepayment, and (ii) paid 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 were 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.

Voluntary Prepayment

On June 8, 2026, the Company utilized $137.4 million of the net proceeds from the 2032 Notes to complete a voluntary prepayment of all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Amended A&R Loan Agreement (the "Payoff Amount"). Upon receipt by the Lenders of the Payoff Amount on June 8, 2026, all obligations, covenants, debts and liabilities of the Company under the Amended A&R Loan Agreement were satisfied and discharged in full, and the Amended A&R Loan Agreement and all other documents entered into in connection with the Amended A&R Loan Agreement, were terminated. In connection with the termination of the Amended A&R Loan Agreement, the Company wrote off $7.3 million of unamortized discounts and incurred a loss on debt extinguishment of $11.5 million, which was included in other expense in the Company's condensed statements of operations.

Note payable consisted of the following (in thousands):

	As of	
	September 30, 2026	**December 31, 2025**
Principal amount	$ —	$ 130,000
Add: final fee	—	5,850
Add: PIK interest	—	1,697
Less: unamortized debt issuance costs	—	(2,619)
Less: unamortized debt discount	—	(8,401)
Total note payable	$ —	$ 126,527

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

The debt issuance costs and discount were being amortized to interest expense over the term of the Amended A&R Loan Agreement based on the effective interest rate method. During the nine months ended September 30, 2026 and 2025, the effective interest rate was 12.7% and 12.3%, respectively. During the three months ended September 30, 2026 and 2025, interest expense related to the note payable was zero and $3.5 million, respectively, including zero and $0.4 million, respectively, related to debt issuance costs and discount amortization. During the nine months ended September 30, 2026 and 2025, interest expense related to the note payable was $7.9 million and $9.9 million, respectively, including $0.9 million and $1.7 million, respectively, related to debt issuance costs and discount amortization.

As of September 30, 2026, there are no future payments or financial covenants under the Amended A&R Loan Agreement.

11. License Agreement

On April 8, 2021, the Company entered into the 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 required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of $335.0 million, consisting of up to $155.0 million related to development milestones and up to $180.0 million related to commercial milestones, payable within 60 days of the milestone achievement.

The development milestones include payments of (i) $5.0 million following the FDA regulatory filing of an NDA for gedatolisib; (ii) $50.0 million following the FDA regulatory approval of an NDA for gedatolisib; (iii) and seven other development milestones totaling $100.0 million.

The FDA granted the Company's request to submit its NDA via the FDA's Real-Time Oncology Review program, and the Company completed its final NDA submission to the FDA in November 2025. The FDA accepted the Company's NDA submission on January 16, 2026. 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.

On July 14, 2026, the Company received the FDA Approval, which triggered a one-time regulatory milestone payment of $50.0 million to Pfizer. The Company concluded that the FDA Approval provided additional evidence with respect to the contingent contractual obligation that existed as of June 30, 2026, and accordingly accounted for the FDA Approval as a recognized subsequent event. As a result, the Company recognized an accrued license milestone of $50.0 million and a corresponding intangible asset for the licensed rights as of June 30, 2026. The Company paid the $50.0 million regulatory milestone payment to Pfizer in September 2026. The intangible asset is being amortized on a straight-line basis over its estimated useful life, which commenced upon commercial launch on September 30, 2026, and will be evaluated for impairment whenever events or changes in circumstances indicate the carrying amount may not be recoverable.

Additionally, the Company will pay Pfizer tiered royalties on sales of REVTORPYK 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.

12. 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, the Company did not identify any subsequent events or transactions that would have required adjustment or disclosure in the unaudited condensed financial statements.

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 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

We are a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. Our first FDA-approved product is REVTORPYK, a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blocks 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 plus fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, supported the FDA Approval. Results for the *PIK3CA* MT cohort of the VIKTORIA-1 clinical trial have been released.

Our Phase 3 clinical trial, VIKTORIA-2, is an ongoing trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib plus palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib and letrozole as first-line treatment for patients with endocrine- sensitive HR+/HER2- ABC. Our Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib plus darolutamide in patients with mCRPC, is ongoing.

Gedatolisib

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 other 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 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.

Our Marketed Product: REVTORPYK

On July 14, 2026, the FDA approved our NDA for REVTORPYK in HR+/HER2- ABC, for use in adult patients without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

We subsequently announced that REVTORPYK plus fulvestrant, with or without palbociclib, was recommended by the National Comprehensive Cancer Network® ("NCCN®") as a preferred Category 1 second-line and/or subsequent-line therapy for the treatment of patients with HR+/HER2- advanced breast cancer without a *PIK3CA* mutation following progression on or after treatment with at least one line of endocrine therapy. The NCCN Guidelines® play a pivotal role in decision-making processes for individuals involved in cancer care all over the world, including physicians, nurses, pharmacists, payers, and patients and their families. The guidelines present expert recommendations for cancer screening, diagnosis, and treatment, as well as cancer care options, and are utilized in cancer treatment decision-making to drive positive patient outcomes. NCCN is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Shipments of REVTORPYK commenced on September 30, 2026. We recognize revenue when control of REVTORPYK transfers to the healthcare providers or pharmacies, which generally occurs upon delivery of REVTORPYK based on contractual shipping terms. Because no product was received by the healthcare providers or pharmacies until after September 30, 2026, we did not recognize any product revenue during the three and nine months ended September 30, 2026.

In August 2026, before REVTORPYK became commercially available, we opened an Expanded Access Program ("EAP") to provide gedatolisib to eligible patients through participating physicians. Nearly all patients enrolled in the EAP have now been transitioned to commercial product.

Market Opportunity

Second-Line Setting

The Wholesale Acquisition Cost ("WAC") of REVTORPYK, which has been reported to the drug pricing compendia, is $10,000 per vial, or $30,000 per 28-day cycle of treatment. Based on our analysis of published epidemiological data, we estimate that approximately 37,000 patients in the U.S. are receiving second-line treatment for HR+/HER2- ABC. Based on recently released Phase 3 VICTORIA-1 clinical trial data, we expect the mean duration of treatment for patients receiving the gedatolisib regimen in this setting to be approximately 10 treatment cycles. Assuming net receipt of 80% of our $30,000 WAC per cycle, we estimate the total addressable market for gedatolisib in the second-line setting, including *PIK3CA* WT patients and, if approved by the FDA, *PIK3CA* MT patients, is approximately $9 billion annually.

First-Line Setting

Successful development in the first-line setting would offer the potential to advance the standard of care for approximately 90,000 patients who are diagnosed with late-stage HR+/HER2- ABC in the U.S., irrespective of their endocrine sensitivity or PIK3CA status. We estimate the total addressable market for gedatolisib in the first-line setting, using current WAC and a mean 36-month duration of treatment based on results from the Phase 1b study in this population, to be well over $10 billion annually.

Clinical Development

As of September 30, 2026, at least 1,130 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 971 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.

HR+/HER2- Advanced Breast Cancer

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. As of September 30, 2026, four patients from this study continue to receive study treatment, each of whom has received study treatment for more than seven 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.

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

VIKTORIA-1 Phase 3 Trial (Second-Line Setting)

Our Phase 3 clinical trial, VIKTORIA-1, evaluated gedatolisib plus fulvestrant, with or without palbociclib, for the treatment of patients with HR+/HER2- ABC, and is the basis for the FDA Approval. Over 200 clinical sites in North America, Europe, South America, and Asia-Pacific participated in the study.

The VIKTORIA-1 Phase 3 clinical trial involved two independent studies (Study 1 and Study 2) that enabled separate evaluation of subjects according to their *PIK3CA* status. Subjects who met eligibility criteria and had *PIK3CA* wild-type 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.

We expect to provide further updates to results from both the MT and WT cohorts of the Phase 3 VIKTORIA-1 clinical trial at the San Antonio Breast Cancer Symposium in late 2026.

PIK3CA Wild-Type Cohort

On July 28, 2025, we announced topline data from the WT cohort of the VIKTORIA-1 Phase 3 clinical trial and on October 18, 2025, at the European Society of Medical Oncology ("ESMO") Congress, we presented additional efficacy and safety results from this cohort. 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.

- Analyses of the objective response rate ("ORR") and median duration of response ("DOR") for patients with evaluable disease were updated on October 24, 2026, in a presentation at the ESMO Congress. The ORR (confirmed and unconfirmed) of the gedatolisib triplet was 39% compared to 1% with fulvestrant and the median DOR was 19.2 months. The ORR of the gedatolisib doublet was 34% and the median DOR was 13.8 months. The median DOR was not determinable for fulvestrant because there was only one objective response.
- The mean duration of treatment for patients who received the gedatolisib triplet and the gedatolisib doublet, was 9.0 and 9.7 cycles, respectively, with 12% (16) and 12% (15), respectively, of patients still receiving gedatolisib therapy in each arm.
- The gedatolisib triplet and doublet were generally well tolerated in the trial with mostly low-grade adverse reactions ("ARs"). The most clinically significant Grade 3 ARs for the gedatolisib triplet, gedatolisib doublet, and fulvestrant groups included stomatitis (22%, 12%, and 0% of patients, respectively); rash (6%, 5%, and 0% of patients, respectively); and hyperglycemia (0.9%, 1.8%, and 0% of patients, respectively). Serious ARs for the gedatolisib triplet and gedatolisib doublet groups included pneumonia (3.8% in the triplet and doublet group), thrombosis (3.8% and 2.3%, respectively), stomatitis (1.5% in the triplet group), pleural effusion (1.5% in the doublet group), and pneumonitis (1.5% in the doublet group). ARs led to the discontinuation of study treatment in 12% of patients in the gedatolisib triplet group, 9% in the gedatolisib doublet group, and 0% in the fulvestrant 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.
- At the San Antonio Breast Cancer Symposium in 2025, data was reported that showed 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.
- Overall survival, a key secondary endpoint in VIKTORIA-1, while immature at the time of the analysis, showed promising trends for both the gedatolisib triplet and the gedatolisib doublet.

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.

On October 24, 2026, at the ESMO Congress, we presented a comparative analysis of data for the gedatolisib regimens from the *PIK3CA* WT cohort of VIKTORIA-1 and other regimens evaluated in patients with HR+/HER2- ABC. Eight studies were included in this network meta-analysis comparing PFS outcomes in randomized controlled trials of systemic treatments evaluated among patients with HR+/HER2- ABC with CDK4/6 inhibitor experience and *PIK3CA* WT tumors. This analysis found that the gedatolisib triplet and doublet each demonstrated statistically significant or numerically superior improvement in PFS and in the six-month PFS rate relative to the non-gedatolisib regimens evaluated. The analysis found that patients treated with the gedatolisib triplet and doublet were 2x and 1.5x more likely to survive without disease progression or death, respectively, compared to imlunestrant plus abemaciclib.

PIK3CA Mutant-Type Cohort

On May 1, 2026, we announced positive topline results from Study 2 (the *PIK3CA* MT cohort) of the VIKTORIA-1 Phase 3 trial, and on June 2, 2026, in a late-breaking abstract oral session at the American Society of Clinical Oncology ("ASCO") Annual Meeting, we presented detailed efficacy and safety results from this cohort. Additional efficacy and safety data for this cohort was presented at ESMO Congress on October 24, 2026. 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. Efficacy was consistent across various sub-groups. Both gedatolisib regimens were generally well tolerated, with manageable safety profiles, and presented no new safety signals.

- In the trial, the gedatolisib triplet demonstrated a statistically significant and clinically meaningful improvement in median PFS among patients, increasing the likelihood of survival without disease progression or death by two times compared to alpelisib plus fulvestrant (based on a hazard ratio [HR] of 0.50; 95% CI: 0.37-0.68; p<0.0001). The median PFS, as assessed by blinded independent central review, was nearly two-times longer, 11.1 months versus 5.6 months, compared to alpelisib plus fulvestrant.
- For the gedatolisib doublet, the median PFS was more than two-times longer, 11.3 months versus 5.6 months, compared to alpelisib plus fulvestrant (HR=0.51; 95% CI: 0.33-0.79; descriptive p=0.0013).
- For the gedatolisib triplet, the ORR (confirmed and unconfirmed) was 59% compared to 33% for alpelisib plus fulvestrant, and the median DOR was 19.4 months compared to 7.5 months for alpelisib plus fulvestrant. The ORR of the gedatolisib doublet was 43%, and the median DOR was 27.8 months.
- For patients with no liver metastases, the median PFS was 21.5 months with the gedatolisib triplet versus 9.1 months with alpelisib plus fulvestrant (HR=0.46; 90% CI: 0.30-0.72) and 11.5 months with the gedatolisib doublet versus alpelisib plus fulvestrant (HR=0.71; 90% CI: 0.41-1.25). For patients with liver metastases, the median PFS was 9.1 months with the gedatolisib triplet versus 4.6 months with alpelisib plus fulvestrant (HR=0.47; 90% CI: 0.34-0.65) and 11.1 months with the gedatolisib doublet versus alpelisib plus fulvestrant (HR=0.38; 90% CI: 0.23-0.62).
- The mean duration of treatment for patients who received the gedatolisib triplet and the gedatolisib doublet was 10.0 and 11.3 cycles, respectively, with 22% (34) and 19% (10), respectively, of patients still receiving gedatolisib therapy in each arm.
- The gedatolisib triplet and gedatolisib doublet were generally well tolerated in the trial with mostly low-grade TRAEs. The most common Grade 3+ TRAEs for the gedatolisib triplet, the gedatolisib doublet, and alpelisib plus fulvestrant groups included neutropenia (58.8%, 0%, and 0.7% of patients, respectively); stomatitis (16.3%, 5.8%, and 5.3% of patients, respectively); rash (6.5%, 5.8%, and 15.1% of patients, respectively); and hyperglycemia (2.6%, 0%, and 14.5% of patients, respectively). For patients who received the gedatolisib triplet and gedatolisib doublet, 5.2% and 3.8%, respectively, of patients discontinued gedatolisib due to an AE. For patients who received alpelisib, 19.1% discontinued treatment with alpelisib plus fulvestrant due to an AE. One Grade 5 TRAE in the gedatolisib-triplet group, which was related to palbociclib, was reported; no Grade 5 TRAEs were reported in the gedatolisib-doublet group, and two Grade 5 TRAEs were reported in the alpelisib plus fulvestrant group.
- Grade 3 stomatitis with gedatolisib was transient. By the second cycle of treatment, less than 3% of patients had Grade 3 stomatitis, and all Grade 3 events improved within 1-2 weeks. Discontinuations due to stomatitis for the gedatolisib triplet and gedatolisib doublet were minimal at 1% and 0%, respectively.
- Overall survival, a key secondary endpoint in VIKTORIA-1, while immature at the time of the analysis, showed promising trends for both the gedatolisib triplet and the gedatolisib doublet.

The efficacy data for the gedatolisib triplet from the VIKTORIA-1 Phase 3 *PIK3CA* MT cohort established several new milestones in the history of drug development for HR+/HER2- ABC:

- First Phase 3 trial to demonstrate superiority of one PAM inhibitor versus another.
- The median PFS of 11.1 months for the gedatolisib triplet is the highest reported by any Phase 3 trial for patients with HR+/HER2- ABC receiving a regimen including endocrine therapy as second-line treatment.
- The ORR of 59% for the gedatolisib triplet is the highest reported by any Phase 3 clinical trial for a regimen including endocrine therapy in second-line HR+/HER2- ABC.

On August 26, 2026, we submitted the data from Study 2, the MT cohort, of the VIKTORIA-1 Phase 3 clinical trial to the FDA as an sNDA. We intend to submit VIKTORIA-1 Phase 3 clinical trial data to other regulatory authorities outside the U.S. later this year or early next year.

VIKTORIA-2 Phase 3 Trial (First-Line Setting)

VIKTORIA-2 is evaluating the safety and efficacy of patients with endocrine-resistant and endocrine-sensitive HR+/HER2- ABC who are treatment-naïve in the metastatic setting. 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. 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 not included. The control arms for Study 1 and Study 2 will evaluate ribociclib combined with either fulvestrant (Study 1) or letrozole (Study 2).

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 or the first half of 2029. 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 250 clinical sites in North America, Europe, South America 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).

Development of a 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.

Metastatic Castration-Resistant Prostate Cancer

CELC-G-201 Phase 1b/2 Trial

We received approval from the FDA in mid-2023 to proceed with the clinical development of gedatolisib plus Nubeqa® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC. We have since initiated the CELC-G-201 Phase 1b/2 trial, that will enroll up to 210 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 plus 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.

On October 23, 2026, at the ESMO Congress, we presented clinical results for the CELC-G-201 Phase 1b/2 trial based on an August 14, 2026, data cut-off. In the Phase 1b/2 portion of the clinical trial, 45 patients with mCRPC were randomly assigned to receive 600 mg of darolutamide twice daily combined with either 120 mg of gedatolisib in Arm 1, 180 mg of gedatolisib in Arm 2 or 240 mg of gedatolisib in Arm 3. In all arms, gedatolisib was administered intravenously on days 1, 8, and 15 of a 28-day treatment cycle, then two weeks off. Additionally, all patients received prophylactic treatment for stomatitis. Baseline characteristics were generally consistent across dose cohorts; over 50% had bone disease and 33% had phosphatase and tensin homolog (“PTEN”) loss.

Key results reported across all arms included:

- The median rPFS rate was 15.7 months with a six-month rPFS rate of 82.2% in patients with prior abiraterone exposure (22 patients).

- The median rPFS rate was 9.1 months with a six-month rPFS rate of 62.5% in patients with prior enzalutamide exposure (18 patients).
- Decreases in prostate-specific antigen ("PSA") of at least 50% from baseline were observed in 36%, 47%, and 67% of patients at the 120 mg, 180 mg, and 240 mg gedatolisib dose levels, respectively, in patients with prior exposure to either abiraterone or enzalutamide.
- Exploratory analyses of patients according to their PTEN status suggest activity is independent of PTEN status.
- Gedatolisib plus darolutamide demonstrated a manageable safety profile across the evaluated dose levels (120 mg, 180 mg, 240 mg) with one dose limiting toxicity (Grade 3 rash), no Grade 4/5 TRAEs, and no TRAEs leading to treatment discontinuation or death. Grade 3 TRAEs occurred in 20% patients with only rash and pruritus occurring in more than one patient.

A randomized Phase 2 study is expected to evaluate two different groups of patients (Groups 1 and 2) with the objective of determining the recommended Phase 3 dose level. Subjects in Group 1 will be those who received prior abiraterone for either hormone-sensitive or castration-resistant prostate cancer. Subjects in Group 2 will be those who received prior enzalutamide or apalutamide for either hormone-sensitive or castration resistant prostate cancer. We anticipate initiating this study in the first half of 2027 after completion of the Phase 1b part of the study.

Collaborations

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 plus abemaciclib and letrozole in patients with endometrial cancer.

Recent Developments

- On August 26, 2026, we announced the submission of our sNDA to the FDA for REVTORPYK for the treatment of patients with HR+/HER2- ABC with a *PIK3CA* mutation, following progression on or after treatment with at least one line of endocrine therapy. The application to the FDA is supported by positive results from the *PIK3CA* MT cohort of the Phase 3 VIKTORIA-1 clinical trial.
- On September 30, 2026, we announced that REVTORPYK is now commercially available in the United States for eligible patients with HR+/HER2- ABC without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.
- On October 23, 2026, at the ESMO Congress, we presented updated clinical results from the CELC-G-201 Phase 1b/2 study evaluating gedatolisib in patients with mCRPC. See the CELC-G-201 Phase 1b/2 Trial update above.
- On October 24, 2026, at the ESMO Congress, we presented new subgroup analyses from the *PIK3CA* MT cohort of the Phase 3 VIKTORIA-1 clinical trial evaluating gedatolisib in patients with HR+/HER2- ABC. See the *PIK3CA* MT Cohort update above. We also presented a comparative analysis of data for the gedatolisib regimens from the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial and other regimens evaluated in patients with HR+/HER2- ABC. See the *PIK3CA* WT Cohort update above.

Results of Operations

We commenced shipments of REVTORPYK on September 30, 2026. We expect our results of operations to vary from period to period depending on, among other factors, the level and timing of product sales, cost of sales, commercial activities, and expenses related to our ongoing operations. Although we have commenced shipments of REVTORPYK, we are not currently profitable and have incurred losses in each period since our inception in 2012.

During the three months ended September 30, 2026 and 2025, we reported a net loss of $73.3 million and $43.8 million, respectively. During the nine months ended September 30, 2026 and 2025, we reported a net loss of $205.0 million and $126.1 million, respectively. As of September 30, 2026, we had an accumulated deficit of $653.9 million and cash, cash equivalents and short-term investments of $642.7 million.

Components of Operating Results

Research and Development

Since our inception, we have primarily focused our research and development on gedatolisib. Research and development expenses primarily include:

- employee-related expenses related to our research and development activities, including compensation, benefits, recruiting and travel expenses;
- consulting fees paid to third parties;
- clinical trial costs;
- costs related to the production of preclinical, clinical and pre-launch inventory, including fees paid to contract manufacturers, which are recorded as research and development expenses prior to the FDA Approval;
- laboratory supplies; and
- facilities expenses.

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

Selling, general and administrative expenses primarily consist of employee-related costs, including compensation, benefits, recruiting and travel costs for personnel in our executive, sales, market access, marketing, commercial operations, legal, finance and support functions.

Non-employee-related expenses consist primarily of professional and consulting fees, launch-related activities incurred to support the commercialization of REVTORPYK, software costs, legal services associated with being a public company, director and officer insurance, investor relations and travel expenses for our selling, general and administrative personnel.

We anticipate that our selling, general and administrative expenses will continue to increase in future periods, reflecting the continued commercialization of REVTORPYK, investments in our commercial infrastructure, and increased professional fees associated with public company regulatory developments and requirements, and other compliance matters.

Interest Expense

Interest expense to date is primarily related to the Amended A&R Loan Agreement, the 2031 Notes and the 2032 Notes.

Loss on Debt Extinguishment

The loss on debt extinguishments relates to the voluntary prepayment of all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Amended A&R Loan Agreement on June 8, 2026.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

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

	Three Months Ended September 30,		Increase (Decrease)	
	2026	2025	$	Percent Change
Statements of operations data:				
Operating expenses:				
Research and development	$ 37,519	$ 30,425	$ 7,094	23%
Selling, general and administrative	39,800	12,424	27,376	220
Total operating expenses	77,319	42,849	34,470	80
Loss from operations	(77,319)	(42,849)	(34,470)	80
Other (expense) income:				
Interest expense	(2,691)	(4,595)	1,904	(41)
Interest income	6,673	3,640	3,033	83
Other (expense) income, net	3,982	(955)	4,937	(517)
Net loss before income taxes	(73,337)	(43,804)	(29,533)	67
Income taxes	—	—	—	—
Net loss	$ (73,337)	$ (43,804)	$ (29,533)	67%

Research and Development

During the three months ended September 30, 2026, our research and development expenses were $37.5 million, representing an increase of $7.1 million, or 23%, compared to the same period in 2025. The increase was primarily due to a $5.3 million increase in employee-related and consulting expenses, of which $1.5 million related to stock-based compensation, and a $2.1 million increase in manufacturing and other costs. These increases were partially offset by a $0.3 million decrease in clinical trial costs.

Selling, General and Administrative

During the three months ended September 30, 2026, our selling, general and administrative expenses were $39.8 million, representing an increase of $27.4 million, or 220%, compared to the same period in 2025. The increase was primarily due to a $14.4 million increase in employee-related expenses, of which $1.7 million related to stock-based compensation. The increase in employee-related expenses was primarily driven by the hiring of additional personnel to support the commercialization of REVTORPYK. The remaining $13.0 million increase was primarily due to an $11.1 million increase in costs to support the commercialization of REVTORPYK, including consulting expenses and expanding infrastructure costs, and a $1.9 million increase in other administrative expenses.

In the aggregate, $25.3 million of the $27.4 million of selling, general and administrative increase related to commercial headcount additions and other activities to support the commercialization of REVTORPYK.

Interest Expense

During the three months ended September 30, 2026, our interest expense was $2.7 million, and represents a decrease of $1.9 million, or 41%, compared to the same period in 2025. Interest expense during the three months ended September 30, 2026, was attributable to the 2031 Notes and the 2032 Notes. Interest expense during the three months ended September 30, 2025, was attributable to the 2031 Notes and the Amended A&R Loan Agreement. The decrease was primarily due to the payoff of the Amended A&R Loan Agreement in June 2026, partially offset by the issuance of $201.3 million aggregate principal amount of the 2031 Notes in August 2025, the issuance of $575.0 million aggregate principal amount of the 2032 Notes in June 2026, and the $30.0 million distribution of the Term D Loan in September 2025. The $2.7 million of interest expense includes $1.0 million of amortization of debt issuance costs.

Interest Income

During the three months ended September 30, 2026, our interest income was $6.7 million, and represents an increase of $3.0 million, or 83%, compared to the same period in 2025. The increase was primarily the result of a higher invested cash balance and higher market interest rates.

Comparison of the Nine Months Ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,		Increase (Decrease)	
	2026	**2025**	**$**	**Percent Change**
Statements of operations data:				
Operating expenses:				
Research and development	$ 101,659	$ 96,598	$ 5,061	5%
Selling, general and administrative	92,285	26,393	65,892	250
Total operating expenses	193,944	122,991	70,953	58
Loss from operations	(193,944)	(122,991)	(70,953)	58
Other (expense) income:				
Interest expense	(14,199)	(10,982)	(3,217)	29
Interest income	14,578	7,904	6,674	84
Loss on debt extinguishment	(11,477)	—	(11,477)	NM
Other expense, net	(11,098)	(3,078)	(8,020)	261
Net loss before income taxes	(205,042)	(126,069)	(78,973)	63
Income taxes	—	—	—	—
Net loss	$ (205,042)	$ (126,069)	$ (78,973)	63%

NM indicates that the percentage change is not meaningful.

Research and Development

During the nine months ended September 30, 2026, our research and development expenses were $101.7 million, representing an increase of $5.1 million, or 5%, compared to the same period in 2025. The increase was primarily due to a $12.1 million increase in employee-related and consulting expenses, of which $3.4 million related to stock-based compensation, and a $10.4 million increase in manufacturing and other costs. These increases were partially offset by a $12.4 million decrease in clinical trial costs, which was primarily driven by decreased costs for the VIKTORIA-1 Phase 3 clinical trial, and a $5.0 million decrease in license milestone costs.

Selling, General and Administrative

During the nine months ended September 30, 2026, our selling, general and administrative expenses were $92.3 million, representing an increase of $65.9 million, or 250%, compared to the same period in 2025. The increase was primarily due to a $34.8 million increase in employee-related expenses, of which $6.9 million related to stock-based compensation. The increase in employee-related expenses was primarily driven by the hiring of additional personnel to support the commercialization of REVTORPYK. The remaining $31.1 million increase was primarily due to a $26.1 million increase in costs to support the commercialization of REVTORPYK, including consulting expenses and expanding infrastructure costs, and a $5.0 million increase in other administrative expenses.

In the aggregate, $57.0 million of the $65.9 million of selling, general and administrative increase related to commercial headcount additions and other activities to support the commercialization of REVTORPYK.

Interest Expense

During the nine months ended September 30, 2026, our interest expense was $14.2 million, and represents an increase of $3.2 million, or 29%, compared to the same period in 2025. Interest expense during the nine months ended September 30, 2026, was attributable to the 2031 Notes, the 2032 Notes and the Amended A&R Loan Agreement. Interest expense during the nine months ended September 30, 2025, was attributable to the 2031 Notes and the Amended A&R Loan Agreement. The increase was primarily due to the issuance of $201.3 million aggregate principal amount of the 2031 Notes in July 2025, the issuance of $575.0 million aggregate principal amount of the 2032 Notes in June 2026, and the $30.0 million distribution of the Term D Loan in September 2025. The increase was partially offset by the payoff of the Amended A&R Loan Agreement in June 2026. The $14.2 million of interest expense includes $4.0 million of amortization of debt issuance costs and discount and payment of in-kind interest.

Interest Income

During the nine months ended September 30, 2026, our interest income was $14.6 million, and represents an increase of $6.7 million, or 84%, compared to the same period in 2025. The increase was primarily the result of a higher invested cash balance and higher market interest rates.

Loss on Debt Extinguishment

During the nine months ended September 30, 2026, we recognized an $11.5 million non-cash loss on debt extinguishment related to the voluntary prepayment of all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Amended A&R Loan Agreement.

Liquidity and Capital Resources

Liquidity

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through September 30, 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 September 30, 2026, we raised aggregate net proceeds of $475.1 million through sales of our securities and $751.9 million through the issuance of our convertible notes. Additionally, prior to its payoff, we raised aggregate net proceeds of $120.8 million through borrowings under the Amended A&R Loan Agreement. As of September 30, 2026, we had an accumulated deficit of $653.9 million and our cash, cash equivalents and short-term investments were $642.7 million.

Capital Resources

To help meet our liquidity requirements, we have entered into various equity and financing arrangements. As of September 30, 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 nine months ended September 30, 2026 and 2025, we did not sell any shares pursuant to the Open Market Sale Agreement.
- In May 2024, we entered into the A&R Loan Agreement, which amended and restated, in its entirety, the Prior Loan Agreement. In May 2025, we entered into the First Amendment to the A&R Loan Agreement; in July 2025, we entered into the Second Amendment to the A&R Loan Agreement; and in September 2025, we entered into the Third Amendment to the A&R 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.

  In June 2026, we completed a voluntary prepayment of all outstanding principal, accrued and unpaid interest, fees, costs and expenses under the Amended A&R Loan Agreement, resulting in a payment of $137.4 million (see Note 10. Debt).
- 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 2031 Underwriters, resulting in net proceeds of $91.6 million (see Note 8. Stockholders' Equity (Deficit)).

- In August 2025, we issued $201.3 million aggregate principal amount of convertible notes, resulting in net proceeds of $194.9 million (see Note 10. Debt).
- In June 2026, we issued $575.0 million aggregate principal amount of convertible notes, resulting in net proceeds of $557.0 million (see Note 10. Debt).
- During the nine months ended September 30, 2026 and 2025, investors exercised 45,788 and 2,294,867 warrants, net of shares withheld for exercise price, respectively, which generated less than $0.1 million and $18.5 million in cash, respectively (see Note 8. Stockholders' Equity (Deficit)). During the three months ended September 30, 2025, investors exercised 1,654,809 warrants, net of shares withheld for exercise price, which generated $12.9 million in cash. There were no warrant exercises during the three months ended September 30, 2026.

Liquidity and capital resource requirements

We expect that our research and development and selling, general and administrative expenses will increase as we ramp up the commercialization of REVTORPYK, 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 expect to use cash on hand, together with the funds received under the debt and equity financings described above, and cash generated from commercial sales of REVTORPYK, 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, will provide sufficient cash to finance our operations through 2029.

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 expect. In addition, we may seek to raise additional capital to finance capital expenditures and operating expenses over the next several years as we ramp up the commercialization of REVTORPYK, expand our infrastructure, commercial operations and research and development activities, pursue other business 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):

	Nine Months Ended September 30,	
	2026	**2025**
Net cash and cash equivalents provided by (used in):		
Operating activities	$ (176,717)	$ (116,881)
Investing activities	(235,424)	(167,493)
Financing activities	424,603	336,111
Net change in cash and cash equivalents	$ 12,462	$ 51,737

Operating Activities

Net cash used in operating activities was $176.7 million during the nine months ended September 30, 2026, and consisted primarily of a net loss of $205.0 million and a net change of $5.7 million in our operating assets and liabilities, partially offset by non-cash expenses of $34.0 million. The $5.7 million net change in our operating assets and liabilities was primarily due to a $5.6 million increase in prepaid expenses and other current assets and a $1.5 million increase in inventory, partially offset by a $1.4 million increase in accounts payable and accrued expenses. The $34.0 million of non-cash expenses consisted of $22.3 million of stock-based compensation expense, $11.5 million loss on debt extinguishment and $0.2 million of depreciation expense.

Net cash used in operating activities was $116.9 million during the nine months ended September 30, 2025, and consisted primarily of a net loss of $126.1 million and a net change of $4.6 million in our operating assets and liabilities, partially offset by non-cash expenses of $13.8 million. The $13.8 million of non-cash expenses consisted of $11.9 million of stock-based compensation expense and $1.9 million of net non-cash interest expense. The $4.6 million net change in our operating assets and liabilities was primarily due to a $10.7 million increase in prepaid expenses and other current assets, partially offset by a $6.1 million increase in accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities was $235.4 million during the nine months ended September 30, 2026, and consisted of $184.7 million of net purchases of short-term investments in U.S. treasury securities, $50.0 million in purchases of intangible assets and $0.7 million in purchases of property and equipment and capitalized software.

Net cash used in investing activities was $167.5 million during the nine months ended September 30, 2025, and consisted of $167.3 million of net purchases of short-term investments in U.S. treasury securities and $0.2 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $424.6 million during the nine months ended September 30, 2026, and consisted of $557.0 million of net proceeds from the 2032 Notes, $4.8 million of proceeds from the exercise of employee stock options and employee stock purchases, partially offset by $137.0 million of payments for the extinguishment of the Amended A&R Loan Agreement and $0.2 million of payments for secondary registration statement costs.

Net cash provided by financing activities was $336.1 million during the nine months ended September 30, 2025, and consisted of net proceeds of $195.5 million from the 2031 Notes, net proceeds of $91.8 million from the Equity Underwriting Agreement and net proceeds of $27.8 million from the Term D Loan. In addition, cash provided by financing activities included $18.5 million from the exercise of common stock warrants and $2.5 million from the exercise of employee stock options and employee stock purchases.

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 nine months ended September 30, 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 September 30, 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 September 30, 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 September 30, 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. Except as set forth below, 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.

Risks Related to Our Product Strategy

We face significant competition, and our operating results will suffer if we fail to compete effectively.

Our industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than REVTORPYK. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources than we do.

REVTORPYK competes with other approved therapies for HR+/HER2- ABC, including other approved inhibitors of PI3K, AKT or mTOR pathways, such as alpelisib, capivasertib and everolimus, as well as other endocrine-based regimens. Competitors may also develop follow-on or next-generation PI3K, AKT or mTOR inhibitors, alternative formulations or combination regimens that do not infringe on our patent rights. In addition, following the expiration of regulatory exclusivity, or upon expiration of or earlier resolution of challenges to our patents, we expect to face competition from generic versions of gedatolisib, which are typically sold at substantially lower prices and preferred by formularies and payors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective, safer, more easily commercialized or less costly than REVTORPYK or any future product candidates, or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. If we are unable to demonstrate to physicians and payors that the differentiating features of REVTORPYK translate into clinical benefit or lower overall cost of care versus our competitors, we may be unable to compete effectively.

Even following regulatory approval of drug products, the availability and price of our competitors' products could limit the demand and the price we are able to charge for REVTORPYK and any future product candidates. We may not be able to implement our business plan if the acceptance of REVTORPYK or any future product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to REVTORPYK or any future product candidates, or if physicians switch to other new drug or biologic products or choose to reserve REVTORPYK or any future product candidates for use in limited circumstances.

Risks Related to Product Development and Product Regulation

REVTORPYK is, and any future approved indications or products will be, subject to ongoing regulatory and legal obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with REVTORPYK or any of our product candidates.

REVTORPYK is, and any additional indications or product candidates that may be approved will be, subject to ongoing regulatory and legal requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping, conduct of post-marketing commitments and requirements, and submission of safety and other post-marketing information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any additional regulatory approvals that we receive for REVTORPYK or any future product may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with REVTORPYK or any of our future approved products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a Risk Evaluation and Mitigation Strategy (REMS) program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

REVTORPYK is currently approved only for adult patients with HR+/HER2- ABC without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. In August 2026, we submitted an sNDA to the FDA seeking approval of REVTORPYK for patients with HR+/HER2- ABC with a *PIK3CA* mutation, based on results from the *PIK3CA* MT cohort of the VIKTORIA-1 Phase 3 clinical trial. The FDA may not approve our sNDA on a timely basis or at all, may approve it for a narrower patient population than we seek or with labeling restrictions, or may require us to provide additional clinical data. Unless and until the sNDA or any future supplemental application is approved, we may not promote REVTORPYK for those uses, which may limit our commercial opportunity. The FDA does not regulate the practice of medicine or behavior of physicians in their choice of treatments. However, the FDA does regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. If we are slow or unable to adapt to changes in existing requirements or adopt new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, our failure to follow FDA, or any applicable foreign regulatory authority, rules and guidelines relating to promotion and advertising may cause the FDA, or such applicable foreign regulatory authority, to suspend or withdraw REVTORPYK or another approved product from the market, require a recall or institute fines or penalties, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. The law or regulatory policies governing pharmaceutical products may also change. New statutory requirements or additional regulations may be enacted that could prevent or delay regulatory approval of our future product candidates. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. or internationally. If we are not able to maintain regulatory compliance, we might not be permitted to market any future approved products and our business could suffer.

Obtaining and maintaining FDA approval of REVTORPYK in the U.S. does not mean that we will be successful in obtaining regulatory approval of REVTORPYK or any future product candidates in other jurisdictions.

Obtaining and maintaining FDA approval of our product candidates in the U.S. does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, and a failure or delay in obtaining FDA approval in the U.S. may have a negative effect on the regulatory approval process in other jurisdictions. For example, even if the FDA grants marketing approval of a product candidate, a comparable foreign regulatory authority must also approve the manufacturing, marketing and promotion of the product candidate in those countries.

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, or fail to obtain acceptable pricing or reimbursement, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We intend to submit VIKTORIA-1 Phase 3 clinical trial data to regulatory authorities outside the U.S. Currently, we supply gedatolisib outside the U.S. only through an international distributor for clinical study. We may implement a named-patient program which would be subject to varying local laws. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, or if we fail to obtain acceptable pricing or reimbursement, our target market will be reduced and our ability to realize the full market potential of REVTORPYK and any future product candidates will be harmed.

Risks Related to Commercializing Our Products

We are subject to U.S. and foreign governmental regulations as well as private payor policies that mandate price controls or limitations on patient access to our products or establish prices paid by government entities or programs for our products. Our business and our future results could be adversely affected by changes in such regulations.

Commercial success of REVTORPYK and any other future approved products will depend in large part on the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors such as the VA, Medicare and Medicaid programs, 340B, and managed care organizations in the U.S. or country specific governmental organizations in foreign countries. Government and private payors routinely seek to manage utilization and control costs, and there is considerable public and government scrutiny of pharmaceutical pricing. Efforts by states and the federal government, and similar government entities outside the U.S., to regulate prices or payment for pharmaceutical products, including proposed actions to facilitate drug importation, limit reimbursement to lower international (i.e., most favored nation) reference prices, require deep discounts, and require manufacturers to report and make public price increases and sometimes provide a written justification for such price increases, could adversely affect our business if and as implemented.

Throughout 2025, the U.S. federal government pursued multiple initiatives aimed at tying U.S. drug prices to those paid in certain other developed countries through an MFN pricing framework. These actions included a 2025 executive order entitled “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” in which Centers for Medicare & Medicaid Services ("CMS") was instructed to create plans to impose MFN pricing on drug manufacturers. Following the executive order, CMS advanced three MFN-based payment models through the Center for Medicare and Medicaid Innovation: the “Global Benchmark for Efficient Drug Pricing”, which would implement a new, mandatory drug rebate program tied to MFN pricing for select drugs in Medicare Part B and is proposed to go into effect on January 1, 2027; “Guarding U.S. Medicare Against Rising Drug Costs”, which would implement a similar mandatory drug rebate program for select drugs in Medicare Part D and is proposed to go into effect on January 1, 2027; and “GENErating cost Reductions for U.S. Medicaid”, launched in January 2026, under which manufacturers who choose to participate in the model would pay MFN-based supplemental rebates under the Medicaid program in exchange for standardized coverage criteria in participating states. These models are likely to face legal and operational challenges, and the implementation of these models remains uncertain. In parallel to these CMS initiatives, several major pharmaceutical manufacturers have entered into voluntary agreements with the U.S. federal government to provide discounted prices aligned to MFN prices on certain of the manufacturers’ drugs to the Medicaid program and direct to patients.

Availability of reimbursement may also be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare, including the Inflation Reduction Act, which requires manufacturers of certain drugs to engage in price negotiations with Medicare, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and replaces the Part D coverage gap discount program with a new discounting program. Some states have implemented, and others are considering implementing, patient access constraints or cost cutting under the Medicaid program, and some are considering measures that would apply to broader segments of their populations that are not Medicaid-eligible. State legislatures also have continued to focus on addressing drug costs, generally by increasing price transparency or limiting drug price increases.

Third-party payors could also require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product and appropriateness for specific patient populations, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide coverage and adequate reimbursement for REVTORPYK and any other future approved products, market acceptance and commercial success would be reduced. Even if coverage is provided, the approved reimbursement amount may not be high enough to support pricing that results in a sufficient return on our research and development investment.

We expect pricing pressures will continue globally. U.S. and foreign governmental regulations that mandate price controls or limitations on patient access to our products or establish prices paid by government entities or programs for our products could impact our business, and our future results could be adversely affected by changes in such regulations or policies.

Risks Related to Intellectual Property

If we are unable to obtain and maintain intellectual property protection for REVTORPYK and any future product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize REVTORPYK or any future product candidates may be impaired.

We have applied for patents that protect our product candidates, and our patent portfolio for our drug candidate, gedatolisib, includes 14 issued patents in the U.S. and more than 300 patents granted in numerous foreign jurisdictions. We cannot ensure that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. We cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. Additionally, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There also may be patent reforms in foreign jurisdictions that could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents in those jurisdictions. It is also possible that we will fail to identify patentable aspects of our discovery and non-clinical development output before it is too late to obtain patent protection.

As a result of these factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Moreover, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

REVTORPYK has been awarded New Chemical Entity (NCE) exclusivity in the United States, and a patent covering REVTORPYK may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984. However, we may not obtain any such extension, or the extension may be shorter than we request. Third parties may submit abbreviated NDAs or 505(b)(2) applications referencing REVTORPYK that contain certifications challenging the validity or enforceability of, or asserting non-infringement of, our listed patents. Any such challenge will require us to engage in costly and time-consuming patent litigation and could result in the earlier introduction of generic competition. In addition, generic entry would substantially reduce our revenue from REVTORPYK.

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

Recent Unregistered Sales of Equity Securities

None.

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

On September 4, 2026, Vicky Hahne, our Chief Financial Officer, adopted a trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 56,500 shares of Celcuity Inc. common stock beginning December 7, 2026 through December 6, 2027.

Except as set forth above, during the three months ended September 30, 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.INS	The following information from the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 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 (Deficit), (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."
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
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: November 5, 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 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 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(s) 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: November 05, 2026

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

Exhibit 31.2

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

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

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

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

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

5. The registrant's other certifying officer(s) 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: November 05, 2026

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

Exhibit 32.1

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

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended September 30, 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; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 05, 2026

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

Exhibit 32.2

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

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended September 30, 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; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 05, 2026

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