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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

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 Number: 001-38207

Celcuity Inc.
(Exact name of registrant as specified in its charter)

Delaware	**82-2863566**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
16305 36th Avenue North, Suite 100 Minneapolis, MN	**55446**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (763) 392-0767

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	CELC	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒ Yes ☐ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on $13.35, the closing price of the shares of common stock on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) as reported by The Nasdaq Capital Market on such date, was approximately $457,485,677.

As of March 17, 2026, there were 48,336,675 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED IN PART BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

2025 Annual Report on Form 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. This Annual Report on Form 10-K (this "Annual 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" and elsewhere in this Annual Report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual 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 Annual 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 Annual 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 Annual Report. Additionally, our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements may include, among other things, statements relating to:

- our clinical trial plans and the estimated timelines and costs for such trials;
- our plans to develop and commercialize our products, and our expectations about the market opportunity for gedatolisib in the U.S. and internationally, and our ability to serve those markets;
- our expectations with respect to our competitive advantages, including the potential efficacy of gedatolisib in various patient types alone or in combination with other treatments, and our interpretation of the data from the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial;
- our expectations regarding the timeline of patient enrollment and results from clinical trials for gedatolisib, including our ongoing Phase 3 VIKTORIA-1 clinical trial, ongoing Phase 3 VIKTORIA-2 clinical trial, and ongoing Phase 1b/2 clinical trial;
- our expectations regarding our ability to obtain U.S. Food and Drug Administration ("FDA") approval, and approvals outside the U.S., to commercialize gedatolisib;
- our expectations regarding governmental laws and regulations affecting our operations, including, without limitation, developments in laws and regulations or their interpretation, including, among others, changes in tax laws and regulations internationally and in the U.S., and laws that affect our operations and our laboratory;
- our expectations with respect to the development, validation, required approvals, costs, and development and regulatory timelines, of gedatolisib, including continuity of commercial supply;
- our beliefs related to the potential benefits resulting from Fast Track designation and Breakthrough Therapy designation as it relates to the development of gedatolisib, and Real-Time Oncology Review ("RTOR") and Priority Review as relates to the submission to the FDA, and FDA review of, our New Drug Application ("NDA") for gedatolisib;
- our plans with respect to research and development and related expenses for the foreseeable future;
- our beliefs about our ability to capitalize on the exclusive global development and commercialization rights obtained from our license agreement with Pfizer Inc. ("Pfizer") with respect to gedatolisib;
- our expectations regarding the future payments that may be owed to Pfizer under our license agreement with them;

- our beliefs with respect to the potential rate and degree of market acceptance and clinical utility of gedatolisib, both in the U.S. and internationally;
- our revenue expectations;
- our expectations regarding business development activities, including collaborations with pharmaceutical companies;
- our plans with respect to pricing in the U.S. and internationally, and our ability to obtain reimbursement for gedatolisib, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement from third-party payors, such as commercial insurance companies and health maintenance organizations, and from government insurance programs, such as Medicare and Medicaid;
- our expectations as to the use of proceeds from our financing activities;
- our expectations with respect to availability of capital, including accessing our current debt facility or any other debt facility or other capital sources in the future, and our assumption that we will have adequate authorized shares for future equity issuances;
- our beliefs regarding the adequacy of our cash on hand to fund our clinical trials, anticipated commercial launch expenses, capital expenditures, working capital, and other general corporate expenses, as well as the costs associated with being a public company;
- our plans with respect to potentially raising capital; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for gedatolisib, including its formulations and methods of use.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Certain risks, uncertainties and other factors include, but are not limited to, our limited operating history; our potential inability to develop, validate, obtain regulatory approval for and commercialize gedatolisib on a timely basis or at all; the uncertainties and costs associated with clinical studies and with developing and commercializing pharmaceuticals; the complexity and difficulty of demonstrating the safety and sufficient magnitude of benefit to support regulatory approval of gedatolisib and other products we may develop; challenges we may face in developing and maintaining relationships with pharmaceutical company partners, including our current and any future suppliers of our product candidate; the uncertainty and costs associated with clinical trials; the uncertainty regarding market acceptance by physicians, patients, third-party payors and others in the medical community, and with the size of market opportunities available to us; difficulties we may face in managing growth, such as hiring and retaining a qualified sales force and attracting and retaining key personnel; changes in government regulations; tightening credit markets and limitations on access to capital; stock market volatility or other factors that may affect our ability to access capital on favorable terms or at all; and obtaining and maintaining intellectual property protection for gedatolisib and time and expense associated with enforcing our intellectual property rights against third parties, and defending third-party claims of intellectual property infringement, investigations or litigation threatened or initiated against us. See "Risk Factors" in Part I, Item 1A of this Annual Report for additional risks, uncertainties and other factors applicable to us.

SUMMARY OF RISK FACTORS

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found in the "Risk Factors" section of Part I, Item 1A of this Annual Report and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC before making investment decisions regarding our common stock.

- We have not yet commercialized a pharmaceutical product, and we may never generate revenue or profit;
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize our drug candidate, gedatolisib;
- Future financing activities could dilute the percentage ownership of our stockholders and could cause our stock price to fall, or could result in operating or other restrictions;
- We are dependent on our ability to attract and retain key personnel;
- Changes to trade policy, including new or increased tariffs and changing import and export regulations, could have a material adverse effect on our business, results of operations and financial condition;
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our debt obligations;
- Our near-term revenue prospects depend on the success of our initial drug product, gedatolisib. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, gedatolisib, or if we experience delays in doing so, including supply chain interruptions, our business will be materially and adversely impacted;
- We were not involved in the early development of gedatolisib, so we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials;
- We have not yet successfully completed any registrational clinical trials, and we may be unable to do so for any drug candidates we may develop;
- The successful development of our products is highly uncertain;
- If we encounter difficulties enrolling patients in any of our clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- We face significant competition from other pharmaceutical companies;
- For a new drug to be approved for marketing, the FDA and other regulatory authorities must determine that the drug is safe and effective. Because all drugs can have adverse effects, the data from our Phase 3 clinical study must demonstrate to the satisfaction of the FDA and other health authorities that the benefits of gedatolisib in combination with fulvestrant and with or without palbociclib, or gedatolisib in combination with fulvestrant plus a CDK4/6 inhibitor, outweigh its risks. Failure to demonstrate sufficient magnitude of benefit, even if the benefit is found to be statistically significant, may not support regulatory approval;
- We must navigate lengthy, uncertain, and expensive regulatory approval processes to be able to market our products in the U.S. and other jurisdictions;

- We depend on intellectual property licensed from Pfizer for our lead product candidate, gedatolisib, and termination of this license could result in the loss of significant rights, which would materially and adversely impact our business;

- If we fail to comply with our obligations under our patent license with Pfizer, we could lose certain license rights that are important to our business;

- If we are unable to obtain and maintain intellectual property protection for our 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 our product candidates may be impaired;

- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials and to formulate, manufacture and distribute our drug product. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates;

- We may encounter difficulties in scaling production of, commercializing, marketing and distributing our products, including in hiring and retaining a qualified sales force.

PART I

ITEM 1. Business

Overview

Unless otherwise provided in this Annual Report, references to the "Company," "we," "us," and "our" and similar references refer to Celcuity Inc., a Delaware corporation. We own various unregistered trademarks and service marks, including our corporate logo. Solely for convenience, the trademarks, trade names and service marks in this Annual Report, including those owned by third parties, may be referred to without the ®, ™ or ℠ symbols, but such references should not be construed as any indicator that the owner of such trademarks, trade names and service marks will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks, trade names and service marks to imply an endorsement or sponsorship of us by any other companies.

We are a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. Our lead therapeutic candidate is gedatolisib, a kinase inhibitor of the phosphatidylinositol 3-kinase ("PI3K"), serine/threonine-protein kinase protein kinase B ("AKT"), mechanistic target of rapamycin ("mTOR") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PI3K/AKT/mTOR ("PAM") pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. Our Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant, with or without palbociclib, in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) ("HR+/HER2-") advanced breast cancer ("ABC") has completed enrollment and reported detailed results for cohort 1, patients with *PIK3CA* wild-type ("WT") tumors, and has completed enrollment of cohort 2, patients with *PIK3CA* mutant-type ("MT") tumors. Our Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib in combination with a cyclin-dependent kinase ("CDK") 4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC is ongoing. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer ("mCRPC"), is ongoing.

In January 2022, gedatolisib was granted Fast Track designation for the treatment of patients with HR+/HER2- ABC after progression on CDK4/6 therapy. Fast Track designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need.

In July 2022, gedatolisib was granted Breakthrough Therapy designation for HR+/HER2- ABC after progression on CDK4/6 therapy. Breakthrough Therapy designation is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for Breakthrough Therapy designation requires preliminary clinical evidence that demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy.

In December 2022, we dosed the first patient in our Phase 3, open-label, randomized, two-part clinical trial, VIKTORIA-1. This trial is evaluating the efficacy and safety of gedatolisib in combination with fulvestrant, with and without palbociclib, in adults with HR+/HER2- ABC who have received prior treatment with a CDK4/6 inhibitor in combination with an aromatase inhibitor. Two studies based on *PIK3CA* mutation status are included in the trial. According to confirmed *PIK3CA* mutation status, patients were manually assigned either to a cohort evaluating patients who have *PIK3CA* WT tumors or to a cohort evaluating patients who have *PIK3CA* MT tumors. The two cohorts were randomized separately. The cohort evaluating *PIK3CA* WT patients reported detailed study results in the third and fourth quarters of 2025. The cohort evaluating patients with *PIK3CA* MT tumors has completed enrollment, and topline data is expected to be available in the second quarter of 2026.

In February 2024, we dosed our first patient in our Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with mCRPC. Initial preliminary data for the Phase 1 portion of the trial were reported in the fourth quarter of 2025.

During the third quarter of 2024, we commenced site selection and activation activities to support a Phase 3, open-label, randomized clinical trial, VIKTORIA-2, designed to evaluate the efficacy and safety of gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- endocrine treatment resistant ABC. The first patient was dosed in July 2025. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. This multi-center, international trial enrolled 35 evaluable subjects in the safety run-in portion of the study to evaluate the safety of gedatolisib

when combined with ribociclib and fulvestrant. The safety run-in was completed in the first quarter of 2026. In the Phase 3 portion of the study, approximately 638 subjects are expected to be randomized and assigned to Cohort 1 (*PIK3CA* WT) or Cohort 2 (*PIK3CA* MT) based on their *PIK3CA* status. Subjects in each cohort are expected to be randomized on a 1:1 basis to either Arm A (gedatolisib with fulvestrant and ribociclib or palbociclib) or Arm B (fulvestrant and ribociclib or palbociclib). We intend to provide an update on our final Phase 3 study design in the second quarter of 2026. It is expected that approximately 200 clinical sites across North America, Europe, and Asia-Pacific will participate, including many sites included in the VIKTORIA-1 clinical trial.

In August 2025, the FDA granted our request to submit our NDA for gedatolisib under the FDA's Real-Time Oncology Review ("RTOR") program based on data from the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial. We made our first NDA pre-submission in September 2025 and completed our submission of the NDA in November 2025. The FDA accepted our NDA on January 16, 2026, designating it for Priority Review, with a target user fee goal date of July 17, 2026, pursuant to the Prescription Drug User Fee Act ("PDUFA") VII.

The PI3K/AKT/mTOR (PAM) Pathway

Dysregulation of the PAM signaling pathway is observed in many types of cancer, including breast and prostate cancer. The important role the PAM pathway plays in cancer has led to significant investment in the development of many different PI3K and mTOR inhibitors for solid tumors.

Activities associated with PI3K involve complex essential cell regulatory mechanisms, including feedforward and feedback signaling loops. Overactivation of the pathway is frequently present in human malignancies and plays a key role in cancer progression. Four catalytic isoforms of class I PI3K preferentially mediate signal transduction and tumor cell survival based on the type of malignancy and the genetic or epigenetic alterations an individual patient harbors. Due to the multiple subcellular locations, activities, and importance of the different PI3K complexes in regulating many types of cancer cell proliferation, control of PI3K activity is an important target in cancer therapy.

mTOR is a critical effector in cell-signaling pathways commonly dysregulated in human cancers. The mTOR signaling pathway integrates both intracellular and extracellular signals and serves as a central regulator of cell metabolism, growth, proliferation, and survival. mTOR is a serine/threonine protein kinase, a downstream effector of PI3K, and regulated by hormones, growth factors, and nutrients, that are contained in two functionally distinct protein assemblies – mTORC1 and mTORC2. In cancer, dysfunctional signaling leads to various constitutive activities of the mTOR complexes, making mTOR a good therapeutic target.

Developing efficacious and well-tolerated therapies that target this pathway has been challenging. This reflects the inherent adaptability and complexity of the PAM pathway, where numerous feedforward and feedback loops, crosstalk with other pathways, and compensatory pathways enable resistance to PAM pathway inhibition. Another major hurdle for the development of PAM pathway inhibitors has been the inability to achieve optimal drug-target blockade in tumors while avoiding undue toxicities in patients.

Gedatolisib

By inhibiting multiple components of the PAM pathway, gedatolisib can overcome adaptive resistance mechanisms that inhibitors of single PI3K/AKT/mTOR components do not address. As a result, we believe gedatolisib offers distinct advantages over currently approved and investigational therapies that target PI3Kα, AKT or mTORC1 alone or together.

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

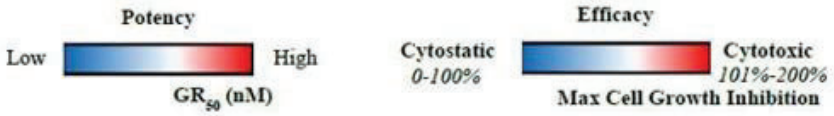
  Gedatolisib is a pan-class I isoform PI3K inhibitor with low nanomolar potency for the p110α, p110β, p110γ, and p110δ isoforms and the mTORC1 and mTORC2 complexes. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. Each PI3K isoform and mTOR complex is known to preferentially affect different signal transduction events that involve tumor cell survival, depending upon the aberrations associated with the linked pathway. When a therapy only inhibits a single class I PI3K isoform (e.g., alpelisib, a PI3Kα inhibitor), AKT (e.g., capivasertib, an AKT inhibitor) or only one mTOR kinase complex (e.g., everolimus, an mTORC1 inhibitor), numerous feedforward and feedback loops between the PI3K isoforms and mTOR complexes cross-activate the uninhibited sub-units. This, in turn, induces compensatory resistance that reduces the efficacy of isoform specific PI3Kα, AKT, or mTORC1 kinase inhibitors. Inhibiting all four PI3K isoforms and both

the mTORC1 and mTORC2 complexes, as getatolisib 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.

To compare the functional effect of inhibiting single versus multiple PAM pathway components, we evaluated gedatolisib, and component-selective inhibitors for PI3Kα (alpelisib), AKT (capivasertib) and mTORC1 (everolimus) in a panel of breast cancer cell lines using a live cell proliferation rate dose response analysis. The results of this analysis are presented in the table below.

Breast Cancer Cell Line Proliferation Rate Dose Response Analysis

Average values for 14 PIK3CA MT and 14 PIK3CA WT breast cancer cell lines



	Geda	Alpe	Evero	Capi	Geda	Alpe	Evero	Capi
All	12	6,308	3,611	8,666	168%	89%	62%	80%
MT	12	2,594	1,867	2,590	174%	116%	68%	99%
WT	12	10,308	5,501	15,209	162%	62%	56%	60%

Note: Growth rate ("GR") was assessed using 28 cell lines by measuring live cells reducing potential with Real Time-Glo MT luciferase assay before and after 72-hour drug treatment. GR50 (concentration required to inhibit growth rate by 50%) is a measure of potency. Max cell growth inhibition (GR at highest drug concentration tested) is a measure of efficacy.

Source: Rossetti S. et.al., npj Breast Cancer, 2024

On average, gedatolisib was at least 300-fold more potent on average than the single component PAM inhibitors analyzed and only gedatolisib induced a significant cytotoxic effect. In addition, gedatolisib's potency and efficacy was comparable in cell lines with and without *PIK3CA* mutations, in contrast to the single component PAM inhibitors.

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

Gedatolisib is administered intravenously ("IV") on a four-week cycle of once a week for three weeks, then one week off, in contrast to the orally administered pan-PI3K or dual PI3K/mTOR inhibitors that are no longer being clinically developed. Oral pan-PI3K or PI3K/mTOR inhibitors have repeatably been found to induce significant side effects that were not well tolerated by patients. This typically leads to a high proportion of patients requiring dose reductions or treatment discontinuation. The challenging toxicity profile of these drug candidates ultimately played a significant role in the decisions to halt their development, despite showing promising efficacy. By contrast, gedatolisib'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 still leads to challenging toxicities. The experience with the FDA approved oral PI3Kα inhibitor, alpelisib, and mTORC1 inhibitor, everolimus, illustrates the challenge. In their Phase 3 pivotal trials, alpelisib and everolimus were found to induce hyperglycemia in 79% and 69% of patients evaluated, respectively. In addition, 26% and 24% of patients discontinued alpelisib and everolimus, respectively, due to treatment related adverse events. By contrast, in the 103-patient dose expansion portion of the Phase 1b clinical trial with gedatolisib, only 7% of patients experienced Grade 3 or 4 hyperglycemia and less than 9% discontinued treatment.

Clinical Development

As of December 31, 2025, 1,127 patients and healthy volunteers have received gedatolisib in 12 completed or ongoing clinical trials. Of these, 123 patients with solid tumors were treated with gedatolisib as a single agent in two clinical trials, 36 healthy volunteers were treated in two clinical trials, and the remaining 968 patients received gedatolisib in combination with other anti-cancer agents in eight clinical trials. Additional patients received gedatolisib in combination with other anti-cancer agents in 10 investigator sponsored clinical trials.

Breast Cancer Program

Breast cancer is the most prevalent cancer in women, accounting for 30% of all female cancers and 7% of cancer-related deaths in the United States. The National Cancer Institute estimated that approximately 316,950 new cases of breast cancer would be diagnosed in the United States in 2025, and approximately 42,170 breast cancer patients would die of the disease.

Four different breast cancer subtypes are currently identified using molecular tests that determine the level of HR and HER2 expression. The most common subtype of ABC is HR+/HER2-. Approximately 70% of all breast cancer tumors express the estrogen receptor ("ER"), which, upon activation, regulates the expression of various genes involved in tumor proliferation. Despite progress in treatment strategies, HR+/HER2- advanced or metastatic breast cancer remains an incurable disease, with a median overall survival (OS) of three years and a five-year survival rate of 34%.

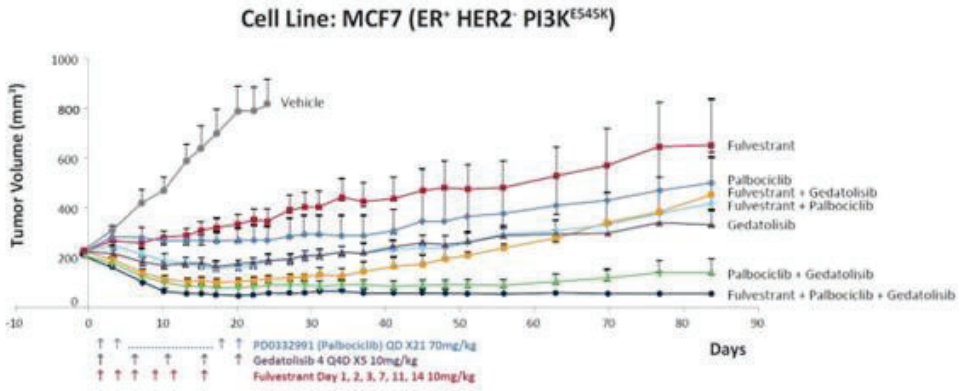
Three different classes of targeted therapies are currently used to treat HR+/HER2- tumors: endocrine-based therapies, CDK4/6 inhibitors, and PAM inhibitors. Each of the CDK4/6 inhibitors and PAM inhibitors are generally used to respond to the related mechanisms of resistance to endocrine therapy, namely, activation of the CDK4/6 and PAM pathways.

Nearly 80% of breast cancers have direct or indirect activation of the PAM pathway. The upregulation of the PAM pathway promotes hormone-dependent and independent ER transcriptional activity, which contributes to endocrine resistance, leading to tumor cell growth, survival, motility, and metabolism. Clinical studies have demonstrated that PAM inhibition can restore sensitivity to endocrine therapy (ET).

Additionally, the PAM pathway, like other mitogenic pathways, can also promote the activities of cyclin D and CDK4/6 to drive proliferative cell cycling. The available evidence indicates that resistance to CDK4/6 inhibition in patients with HR+/HER2- ABC is a transient adaptive mechanism, most likely involving the PAM pathway. This data indicates that CDK4/6 signaling may be restored in CDK4/6 resistant tumors when PAM inhibitors are applied. Thus, continuing CDK4/6 inhibitor treatment in combination with a PAM inhibitor in patients who progressed on their prior CDK4/6 inhibitor, would both blockade the potentially reactivated CDK4/6 pathway and prevent adaptive activation of the PAM pathway. This suggests the limited efficacy induced by current standard-of-care (SOC) therapies in patients who have progressed on a CDK4/6 therapy reflects the mechanistic inadequacy of relying on partial PAM inhibition (e.g., alpelisib or everolimus) and no CDK4/6 inhibition to address this complex disease mechanism.

We believe the complex connection between the PAM and CDK4/6 pathways can potentially enable gedatolisib to adaptively reactivate CDK4/6 signaling that reportedly occurs in CDK4/6 resistant tumors when the PAM pathway is comprehensively inhibited. By re-activating CDK4/6 signaling, we believe gedatolisib can restore the therapeutic effect of CDK4/6 inhibition when it is combined with a CDK4/6 inhibitor. The contributory effect of a CDK4/6 inhibitor when combined with gedatolisib would thus largely reflect the interaction between the two therapies that gedatolisib initiates.

Evidence of gedatolisib's anti-tumor activity in breast cancer cells was provided in a study evaluating the MCF7 xenograft model (ER+/HER2-/PIK3CA mutant), where the combination of gedatolisib with palbociclib and fulvestrant caused 90% tumor regression with no tumor regrowth observed for more than 60 days after the final dose.



Source: Layman SABCS 2021

Clinical Experience with Gedatolisib in Breast Cancer

The favorability of preliminary results from a Phase 1b clinical trial (B2151009, further described below) which evaluated 138 patients with HR+/HER2- ABC led us to focus our initial clinical development program on ABC.

On January 13, 2022, gedatolisib was granted Fast Track designation for the treatment of patients with HR+/HER2- ABC after progression on CDK4/6 therapy. Fast Track designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening diseases or conditions and which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and to ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of an NDA.

On July 18, 2022, gedatolisib was granted Breakthrough Therapy designation for HR+/HER2- ABC after progression on CDK4/6 therapy. Breakthrough Therapy designation is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for Breakthrough Therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapies. The benefits of Breakthrough Therapy designation include more intensive guidance from the FDA on an efficient development program, access to a scientific liaison to help accelerate review time, and potential eligibility for Priority Review if relevant criteria are met. Our breakthrough application was supported by data from a Phase 1b clinical trial that assessed the safety, tolerability and clinical activity of gedatolisib in combination with palbociclib and fulvestrant in patients with HR+/HER2- ABC whose disease progressed during treatment with a CDK4/6 therapy and an aromatase inhibitor.

Phase 3 HR+/HER2- ABC Clinical Trial (VIKTORIA-1)

In 2022, we initiated VIKTORIA-1, a Phase 3, open-label, randomized clinical trial to evaluate the efficacy and safety of gedatolisib in combination with fulvestrant with or without palbociclib in adults with HR+/HER2- ABC whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor. This multi-center, international trial has completed enrollment of 754 subjects at nearly 200 clinical sites across North America, Europe, Latin America, and Asia-Pacific. The first patient was dosed in December 2022.

The clinical trial is separately evaluating subjects according to their *PIK3CA* status.

- Subjects who meet eligibility criteria and do not have confirmed *PIK3CA* mutations (i.e., WT) 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). During the fourth quarter of 2024, we achieved our enrollment goal of 351 subjects who are *PIK3CA* WT. We reported topline data and detailed results for this group in the third and fourth quarters of 2025, as described below.

- Subjects who meet eligibility criteria and have *PIK3CA* mutations (i.e., MT) 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). Enrollment of up to 350 subjects who are PIK3CA MT is ongoing. We expect topline data for this group to be available in the second quarter of 2026.

The clinical trial primary endpoints are progression free survival ("PFS"), per RECIST 1.1 criteria, as assessed by blinded independent central review ("BICR"). Two primary endpoints will be evaluated in subjects who are *PI3KCA* WT, and one primary endpoint will be evaluated in subjects who are *PI3KCA* MT. In subjects who are *PI3KCA* WT, the PFS of gedatolisib in combination with palbociclib and fulvestrant (Arm A) will be compared to fulvestrant monotherapy (Arm C), and the PFS in gedatolisib in combination with fulvestrant (Arm B) will be compared to fulvestrant monotherapy (Arm C). In subjects who are *PI3KCA* MT, the PFS of gedatolisib in combination with palbociclib and fulvestrant (Arm D) will be compared to alpelisib combined with fulvestrant (Arm E).

All subjects will receive treatment according to the assigned study arm until objective progressive disease, unacceptable toxicity, death, or withdrawal of consent, whichever occurs first. Subjects in Arm C will have the option to receive the treatment regimen provided in Arm A or Arm B upon radiographically confirmed disease progression. Subjects will be followed for adverse events, safety laboratory testing, tumor assessment by RECIST v1.1, quality of life, and overall survival.

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

- The gedatolisib triplet (gedatolisib, fulvestrant and palbociclib) demonstrated a statistically significant and clinically meaningful improvement in PFS among patients, reducing the risk of disease progression or death by 76% compared to fulvestrant (based on a hazard ratio [HR] of 0.24, 95% confidence interval [CI] 0.17-0.35; $p<0.0001$). The median PFS, as assessed by 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 of 0.33, 95% CI 0.24-0.48; $p<0.0001$). The median PFS, as assessed by BICR, was 7.4 months with the gedatolisib doublet versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months.
- The objective response rate ("ORR") of the gedatolisib triplet was 31% compared to 1% with fulvestrant and the median duration of response ("DOR") was 17.5 months. The ORR of the gedatolisib doublet was 28.3% and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.
- The gedatolisib triplet and doublet were generally well tolerated in the trial with mostly low-grade treatment-related adverse events ("TRAEs"). The most common Grade 3 TRAEs for the gedatolisib triplet, gedatolisib doublet, and fulvestrant groups included neutropenia (52.3%, 0%, and 0.8% of patients, respectively); stomatitis (19.2%, 12.3%, and 0% of patients, respectively) rash (4.6%, 5.4%, and 0% of patients, respectively); and hyperglycemia (2.3%, 2.3%, and 0% of patients, respectively). The primary Grade 4 TRAEs for the gedatolisib triplet and gedatolisib doublet groups were neutropenia (10.0% and 0.8%, respectively), leukopenia (0.8% in the gedatolisib triplet group) and pneumonitis (0.8% in gedatolisib doublet group). TRAEs led to the discontinuation of study treatment in 2.3% of patients in the gedatolisib triplet group, 3.1% in the gedatolisib doublet group, and 0% in the fulvestrant group.

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

- The hazard ratios for the gedatolisib triplet and doublet are more favorable than have ever been reported by any Phase 3 trial for patients with HR+/HER2- ABC.

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

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

- For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, median PFS was 16.6 months with the gedatolisib triplet and 7.1 months with the gedatolisib doublet versus 1.9 months for fulvestrant (HR=0.14; 95% CI: 0.08-0.28; p<0.0001).

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

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

With these results, the gedatolisib regimens represent a potential new standard of care for patients with HR+/HER2-, *PIK3CA* WT ABC whose disease progressed on or after treatment with a CDK4/6 inhibitor.

Results from cohort 2 of the VIKTORIA-1 Phase 3 clinical trial, the *PIK3CA* MT cohort, are expected to be available in the second quarter of 2026.

B2151009 Phase 1b HR+/HER2- ABC Clinical Trial

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

A total of 138 patients with HR+/HER2- ABC were dosed in the clinical trial. Four patients from this study continue to receive study treatment, as of December 31, 2025, each of whom has received study treatment for more than six years.

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

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

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

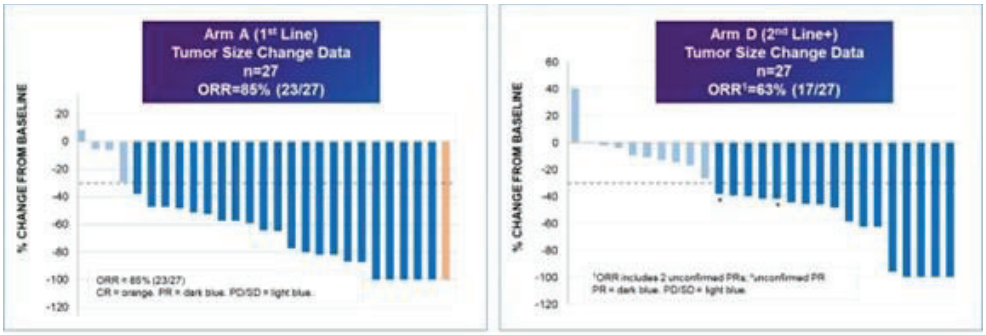
    - **Arm B**: ABC with progression during one or two prior endocrine-based systemic therapies in the advanced setting, with no prior therapy with any CDK inhibitor. Second- or third-line endocrine-based therapy for metastatic disease.

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

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

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

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



Source: Layman SABCS 2021

- Safety analysis:

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

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

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

	Total Expansion Arms (N=103)							
	Arm A		Arm B		Arm C		Arm D	
Prior Therapy	1L CDKi-naive		2L+ CDKi-naive		2L/3L CDKi-pretreated		2L/3L CDKi-pretreated	
n (Full, response evaluable)	31, 27		13,13		32, 28		27, 27	
Study Treatment	P + L + G		P + F + G		P + F + G		P + F + G	
Gedatolisib schedule	weekly		weekly		weekly		3 wks on/1 wk off	
ORR [(1)] (evaluable)	85%		77%		36%		63%	
mPFS [(2)], mos (range)	48.4 (16.9, NR)		12.9 (7.6, 38.3)		5.1 (3.3, 7.5)		12.9 (7.4, 16.7)	
PFS % at 12 mos [(2)]	72.1%		54.5%		23.6%		53.2%	
	WT	**MT**	**WT**	**MT**	**WT**	**MT**	**WT**	**MT**
PIK3CA status	81%	16%	69%	31%	75%	25%	56%	41%
ORR (evaluable)	81%	100%	78%	75%	25%	63%	60%	73%
PFS at 12 months	74%	60%	50%	67%	22%	29%	49%	60%

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

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

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

Additional results from the Phase 1b portion of the clinical trial were presented at the ESMO congress in October 2025. The analyses reported efficacy data from patients who were treated with the same drug regimen being evaluated in the VIKTORIA-1 study, gedatolisib combined with fulvestrant and palbociclib. This included patients from Escalation Arm B and Expansion Arms B, C and D of the Phase 1b study.

As described above, patients in Escalation Arm B and Expansion Arms B and C received a 180 mg dose of gedatolisib once weekly ("weekly dose"). Patients in Expansion Arm D received a 180 mg dose of gedatolisib on days 1, 8, and 15 of a four-week cycle ("intermittent dose"), which is the same dose regimen patients in the VIKTORIA-1 study receive. The proportion of patients who received the intermittent dose of gedatolisib was 37% for those with *PIK3CA* MT tumors and 25% for those with *PIK3CA* WT tumors. The proportion of patients who received prior treatment with a CDK4/6 inhibitor was 73% for those with *PIK3CA* WT tumors, and 71% for those with *PIK3CA* MT tumors.

Median PFS and the ORR were assessed in sub-groups of patients according to their *PIK3CA* status (Table 1). For all analyzed patients with *PIK3CA* MT tumors (n=30), median PFS was 14.6 months and the ORR in response evaluable patients was 48%. Median PFS was 19.7 months and the ORR was 64% in patients with *PIK3CA* MT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study. For patients with *PIK3CA* WT tumors (n=60), median PFS was 9.0 months and the ORR in response evaluable patients was 41%. Median PFS was 9.1 months and the ORR was 53% in patients with *PIK3CA* WT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study.

Table 1: Efficacy Analysis of Phase 1b Patients Treated with Gedatolisib Plus Palbociclib Plus Fulvestrant

	PIK3CA MT		***PIK3CA WT***	
	All	**Intermittent Dose**	**All**	**Intermittent dose**
N	30	11	60	15
Median PFS (months)	14.6	19.7	9.0	9.1
ORR	48%	64%	41%	53%

Phase 3 HR+/HER2- ABC Clinical Trial (VIKTORIA-2)

In July 2025, we dosed the first patient in VIKTORIA-2, a Phase 3, multi-center, open-label, randomized, clinical trial designed to evaluate the efficacy and safety of gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- endocrine treatment resistant ABC. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. This multi-center, international trial enrolled 35 evaluable subjects in the safety run-in portion of the

study to evaluate the safety of gedatolisib when combined with ribociclib and fulvestrant. The safety run-in was completed in the first quarter of 2026. In the Phase 3 portion of the study, approximately 638 subjects are expected to be randomized and assigned to Cohort 1 (*PIK3CA* WT) or Cohort 2 (*PIK3CA* MT) based on their *PIK3CA* status. Subjects in each cohort are expected to be randomized on a 1:1 basis to either Arm A (gedatolisib with fulvestrant and ribociclib or palbociclib) or Arm B (fulvestrant and ribociclib or palbociclib). We intend to provide an update on our final Phase 3 study design in the second quarter of 2026. It is expected that approximately 200 clinical sites across North America, Europe, and Asia-Pacific will participate, including many sites included in the VIKTORIA-1 clinical trial.

Prostate Cancer Program

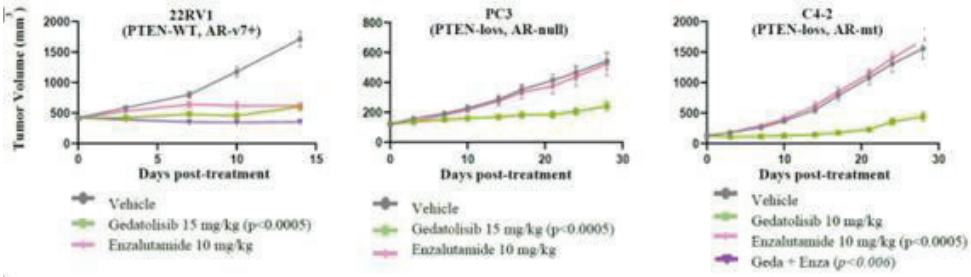
In the United States, prostate cancer is the second leading cause of cancer death in men. Current estimates predict that one in eight men will be diagnosed with prostate cancer in his lifetime. The National Cancer Institute estimated that in 2025 there would be over 313,780 new cases of prostate cancer in the United States and approximately 35,770 deaths from the disease. Although approximately 69% of patients are diagnosed with localized prostate cancer, about 8% of patients present with metastatic disease with a 5-year survival rate of 38%. Androgen deprivation therapy ("ADT") via medical or surgical castration has been the mainstay treatment for metastatic prostate cancer. However, prostate cancer cells develop resistance to ADT and progress to castration resistance, leading to poor prognosis and a median overall survival of about three to five years.

Men with mCRPC have a poor prognosis and a predicted survival rate of fewer than two years from the initial time of progression. Treatment options for prostate cancer depend on many different factors, including the stage of the cancer. Castration-resistant prostate cancer is defined by disease progression despite ADT and is often indicated by rising levels of PSA. Current standard of care for men with castration-resistant prostate cancer provides that patients should initially receive a combination of ADT and either abiraterone, which works by decreasing androgen levels, or enzalutamide, which works by blocking androgen binding to androgen receptors ("AR"). If the disease progresses despite these second-generation hormonal therapies, chemotherapy is considered the next treatment option. Treatment with chemotherapy is generally postponed for as long as possible due to the potential for severe side effects including neuropathies, nausea, diarrhea, decreased mental capacity and increased risk of infections.

Preclinical studies have demonstrated a potential association between the PAM pathway and AR signaling in prostate cancer cells developing resistance to ADT. In these studies, the AR and PAM pathways were shown to cross-regulate each other. This is similar to the relationship demonstrated in breast cancer with the estrogen receptor pathway and the PAM pathway. Additionally, 70% - 100% of mCRPC tumors have PAM related pathway alterations.

Several clinical studies have shown promising results by inhibiting the PAM pathway in combination with an AR inhibitor. In separate Phase 2 and Phase 3 trials, the AKT inhibitor, ipatasertib, showed improvement in radiographic PFS ("rPFS") in patients with mCRPC and tumors with phosphatase and tensin homolog ("PTEN") loss when ipatasertib was combined with the AR inhibitor, abiraterone, versus abiraterone alone. In a Phase 2 trial, the pan-PI3K inhibitor, samotolisib, reported median rPFS of 10.2 when combined with enzalutamide versus 5.5 months for enzalutamide alone.

Evidence of gedatolisib's in vivo activity in prostate cancer was provided in a study evaluating the 22RV-1, PC3, and enzalutamide sensitive model ("C4-2") prostate cancer xenograft models. As seen in the figures below, gedatolisib induced greater than 80% tumor growth inhibition, regardless of the xenograft model's sensitivity to the AR inhibitor, enzalutamide and the cell lines' PTEN or AR status. In addition, gedatolisib combined with enzalutamide induced significantly greater tumor growth inhibition than enzalutamide alone in the C4-2.



*S*ource: Sen, ASCO-GU, 2023

Phase 1b/2 mCRPC Clinical Trial (CELC-G-201)

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

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

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

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

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

Updated clinical results from the Phase 1 portion of the clinical trial were presented at the ESMO congress in October 2025. The Phase 1 data set utilized an August 15, 2025 data cut-off. Median duration of follow-up was 9.0 months.

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

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

In the amended Phase 1/1b portion of the clinical trial, up to six patients are planned to be enrolled in each of three arms and treated with different doses. Upon completion of Phase 1, up to an additional 40 patients will be randomly assigned to up to four Phase 1b cohorts to determine the RP2D. Dose levels will be selected based on the results from the Phase 1 clinical trial. In the Phase 2 dose expansion study, which will include subjects from the Phase 1/1b clinical trial, up to 18 additional subjects will be enrolled to achieve a total of approximately 30 subjects treated with the RP2D. All patients will also receive standard doses of darolutamide.

Investigator-Sponsored Trials

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

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

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

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

Pfizer Gedatolisib License Agreement

In April 2021, we entered into a license agreement (the "Gedatolisib License Agreement") with Pfizer pursuant to which we acquired exclusive (including as to Pfizer) worldwide sublicensable rights to research, develop, manufacture, and commercialize gedatolisib for the treatment, diagnosis and prevention of all diseases. Pursuant to the Gedatolisib License Agreement, we are obligated to use commercially reasonable efforts to develop and seek regulatory approval for at least one product in the U.S. and if regulatory approval is obtained, to commercialize such product in the U.S. and at least one international major market.

We paid Pfizer a $5.0 million upfront fee upon execution of the Gedatolisib License Agreement and issued 349,406 shares of our common stock to Pfizer pursuant to an Equity Grant Agreement. We are also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, including a $5.0 million milestone payment we made in January 2026 following FDA acceptance of our NDA submission, up to an aggregate of $335.0 million. We will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid-teens, that may be subject to deductions for expiration of valid claims, amounts due under third-party licenses and generic competition. Unless earlier terminated, the Gedatolisib 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 herein, a Valid Claim of a Licensed Patent Right. Capitalized terms in this paragraph have the meanings set forth in the Gedatolisib License Agreement.

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

Formulation, Manufacturing and Distribution

We rely on third parties to formulate, manufacture and distribute gedatolisib. We have entered into agreements with contract manufacturing organizations ("CMOs") to produce the drug substance gedatolisib and formulate, produce and package finished drug product for clinical use and, if approved, commercial supply. We have entered into agreements with distributors and a third-party logistics provider ("3PL") to distribute finished product for clinical use and, if approved, commercial supply. We require all of our CMOs, distributors, and our 3PL to conduct manufacturing and distribution activities in compliance with applicable laws, including current good manufacturing practice ("cGMP") and current good distribution practice, requirements. We anticipate that these CMOs, distributors, and 3PL will have the capacity to support both clinical- and commercial-scale production and distribution. We may also elect to enter into agreements with other CMOs to formulate and manufacture supplies of drug substance and finished drug product.

Sales and Marketing

If any of our product candidates are approved, we intend to market and commercialize them in the U.S. and select international markets, either alone or in partnership with others. Cancer patients are primarily treated by medical, surgical, or radiation oncologists, and we believe these physicians, and the multi-disciplinary teams surrounding them, including nurses, advanced practitioners, and pharmacists, can be reached with a targeted sales force.

Competition for Gedatolisib

The pharmaceutical industry is characterized by rapid evolution of technologies and intense competition. We face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with approved treatment options, including off-label therapies, and new therapies that may become available in the future. Key considerations that would impact our ability to effectively compete with other therapies include the efficacy, safety, method of administration, cost, level of promotional activity, and intellectual property protection of our products. Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products.

There are several PI3K, AKT, and mTOR inhibitors approved by the FDA, including PIQRAY and AFINITOR from Novartis AG, TRUQAP from AstraZeneca plc, ITOVEBI from F. Hoffmann-La Roche Ltd, COPIKTRA from Verastem, Inc., and ZYDELIG from Gilead Sciences, Inc. We are aware that other companies are, or may be, developing products for this indication, including BridgeBio Pharma Inc., Eli Lilly and Company, Kazia Therapeutics Limited, Relay Therapeutics, Inc., Revolution Medicines Inc., and Takeda Pharmaceutical Company Limited. There may be additional companies with programs suitable for addressing these patient populations that could be competitive with our efforts but that have not yet disclosed specific clinical development plans. Smaller or early-stage companies, including oncology-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, enrolling patients in clinical trials and acquiring technologies complementary to, or necessary for, our programs. The availability of reimbursement from government and private payors will also significantly impact the pricing and competitiveness of our products. Our competitors may obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approvals for our product candidates, which could result in our competitors establishing a strong market position before we are able to commercialize our product candidates.

Market Opportunity

Based on our analysis of published epidemiological data, we estimate that approximately 37,000 patients in the U.S. have HR+/HER2- ABC who have progressed after a CDK4/6 inhibitor. If gedatolisib ultimately receives FDA approval for the treatment of both *PIK3CA* WT and *PIK3CA* MT populations, using internal duration of treatment estimates and pricing assumptions consistent with currently available novel therapeutics for breast cancer, we estimate the total addressable market for gedatolisib in the second-line setting is more than $5.0 billion. Given the significant penetration our research is suggesting we can achieve, we believe it is reasonable to estimate that a second-line indication for gedatolisib could potentially generate peak revenue of up to $2.5 billion annually.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, to operate without infringing the proprietary rights of others, and to prevent others from infringing our proprietary rights. We plan to protect our proprietary positions using a variety of methods, which include obtaining U.S. and foreign patents related to our inventions and improvements, and prosecuting additional U.S. and foreign patents that we determine are important to the development and implementation of our business. For example, we, directly and via our licensors, currently have, or are pursuing, patents covering the composition of matter, formulation, and methods of using our drug product candidates and we plan to pursue additional patent protection as appropriate. We also rely on trade secrets, trademarks, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

Gedatolisib Patents

We entered into the Gedatolisib License Agreement with Pfizer in April 2021, pursuant to which we acquired exclusive worldwide rights under Pfizer patents and know-how to develop, manufacture and commercialize gedatolisib. We have an exclusive license under the Gedatolisib License Agreement to patent rights in the U.S. and numerous foreign jurisdictions relating to gedatolisib, in addition to our own patents. The patent rights we own or which we have in-licensed under the Gedatolisib License Agreement include 13 granted patents in the U.S. and more than 297 patents granted in numerous foreign jurisdictions. A U.S. patent covering gedatolisib as a composition of matter has a statutory expiration date in December 2029 (including 209 days of Patent Term Adjustment), a U.S. patent that covers the cyclodextrin formulation of gedatolisib that is currently used in our clinical trials expires in January 2041 (including 578 days of Patent Term Adjustment), and a U.S. patent that covers the method of using gedatolisib in breast cancer expires in August 2042 (including 37 days of Patent Term Adjustment), not including any Patent Term Extension that may be awarded by the U.S. Patent and Trademark Office ("USPTO"), and relevant foreign counterparts. Issued patents will, as appropriate, be listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

Product Trademark

We have applied for trademark protection for our preferred commercial product tradename, and the USPTO has allowed the tradename for registration. The FDA has conditionally approved the use of this tradename subject to the FDA's approval of our NDA.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Government Regulation

Approval of Gedatolisib and Other Drug Products

Government authorities in the U.S. at the federal, state and local level and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products, such as gedatolisib and other drugs that may be used in combination with, or compete with, gedatolisib. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority and submitted for review and approved by the regulatory authority. The regulatory approval process is time-consuming and requires significant capital expenditures.

U.S. Approval Process

Overview of FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies according to good laboratory practices ("GLPs"), or other applicable regulations;
- submission to the FDA of an application for an investigational new drug application ("IND"), which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as current good clinical practices ("cGCPs"), to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA pre-approval inspection ("PAI") of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- FDA Bioresearch Monitoring ("BIMO") inspections of the nonclinical and clinical trial sites that generated the data in support of the NDA; and
- FDA acceptance, review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Preclinical and Clinical Stages

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of an IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

The clinical stage of development involves the administration of the investigational product to healthy volunteers or disease-affected patients under the supervision of qualified investigators, generally physicians not employed by, or under control of, the trial sponsor, in accordance with cGCPs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of an IND. Furthermore, each clinical trial must be reviewed and approved by an Institutional Review Board ("IRB"), for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also monitors the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a larger number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

A registrational trial is a clinical trial that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, registrational trials are Phase 3 trials but may be Phase 2 trials if the trial design provides a reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time, or the FDA may impose other sanctions on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the requirements of the IRB or if the drug has been associated with unexpected serious harm to patients.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

FDA Review and Approval Process

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. Prior to granting approval of the NDA, which is required before marketing of the product may begin in the U.S., the FDA must determine whether to accept the submission and, thereafter, conduct an in-depth review. This process may take a year or more. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of an NDA to the FDA, absent an applicable application user fee waiver, is subject to a substantial application user fee, currently $4,682,003 for Fiscal Year 2026, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program fees for eligible products, which are currently $442,213 for Fiscal Year 2026. As a company with fewer than 500 employees submitting its first NDA, we have qualified for the application fee waiver.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically conduct a BIMO inspection, including inspecting one or more clinical sites to assure compliance with cGCPs. Additionally, the FDA will conduct a PAI of the facility or the facilities at which the finished drug is manufactured to assure compliance with cGMP. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter ("CRL"). A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

U.S. Marketing Exclusivity

Upon NDA approval of a new chemical entity ("NCE"), which is a drug (i.e., gedatolisib) that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot accept any Abbreviated New Drug Application ("ANDA"), seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change. An ANDA may be

submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed with the ANDA. If there is no listed patent in the Orange Book, no ANDA may be filed before the expiration of the exclusivity period. If approved, we expect to receive five-year NCE exclusivity for gedatolisib.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply to the USPTO for up to a five-year patent term extension ("PTE") for one patent. The allowable PTE is calculated as half of the drug's testing phase—the time between IND and NDA submission—and all of the review phase—the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the USPTO, in coordination with the FDA, determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from NDA approval. We intend to seek five-year PTE should the FDA approve our NDA for gedatolisib.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Fast Track Designation

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Gedatolisib has received Fast Track designation from the FDA.

Under the Fast Track program and the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees if not waived. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

Breakthrough Therapy designation by the FDA provides more extensive development consultation opportunities with FDA senior staff, allows for the rolling review of the drug's application for approval and indicates that the product could be eligible for Priority Review if supported by clinical data at the time of application submission for drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific

indication as a Breakthrough Therapy concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request. Gedatolisib received Breakthrough Therapy designation.

Real-Time Oncology Review ("RTOR")

RTOR is an FDA review program within the Oncology Center of Excellence that allows sponsors to submit key sections of an oncology NDA on a rolling basis. The intent of RTOR is to start FDA review earlier, improve efficiency, and potentially shorten overall NDA review times. On August 27, 2025, the FDA granted our request to submit our NDA on a rolling basis via the RTOR program.

Priority Review

FDA Priority Review is a designation by the FDA that shortens the review timeline for certain marketing applications, including NDAs. Priority Review reduces the FDA's PDUFA goal review time from the standard 10 months to six months. The FDA grants Priority Review if the NDA is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over available therapies. On January 16, 2026, the FDA accepted our NDA and awarded Priority Review, with a PDUFA goal date of July 17, 2026.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration at www.clinicaltrials.gov. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

European Union Approval Process

Overview

In the EU, our product candidates may also be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

The Clinical Trials Regulation (EU) No 536/2014 came into effect in 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, and repealed the Clinical Trials Directive 2001/20/EC. The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the Clinical Trial Information System; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain a marketing authorization of a drug in the EU, we may submit Marketing Authorisation Applications ("MAA"), either under the so-called centralized or national authorization procedures.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency (the "EMA"), that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS,

cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (the "CHMP"). Accelerated assessment might be granted by the CHMP in exceptional cases when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Under the above-described procedures, before granting an MAA, the EMA or the competent authorities of the Member States of the European Economic Area (the "EEA"), assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

EU Regulatory Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Drug Approval-Related Regulations – Rest of the World

For other countries outside of the EU and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pricing and Reimbursement of our Product Candidates

Significant uncertainty exists as to the coverage and reimbursement status of any products we sell or may sell. Sales of our drug products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as VA, Tricare, Medicare and Medicaid, commercial health insurers, and other managed care organizations.

In order to obtain coverage and reimbursement for our drug product, we will conduct extensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product. Whether or not we conduct such studies, our products may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products, examining the medical necessity and reviewing the cost-effectiveness of drug products and questioning product safety and efficacy. If these third-party payors do not consider our product to be cost-effective compared to other available products, they may not cover our product or, if they do, the level of reimbursement may not be sufficient to allow us to realize a profit on the use of our product. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our product and could adversely affect our net revenue and results.

In August 2022, the Inflation Reduction Act (the "IRA") was signed into law, which, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), 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. Gedatolisib, if approved, will be subject to these provisions of the IRA, and we have taken these provisions into account when developing our business strategy, operations, and our projected financial condition and results. In addition, changes to the Medicaid program or the federal 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities, could have a material impact on our business following commercialization. We expect to see continued focus by Congress and the Trump Administration on regulating drug pricing, which could result in legislative and regulatory changes designed to control costs.

Pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug product to currently available drugs. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new drug products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for our product.

Coverage policies, third-party reimbursement rates and pricing regulation may change at any time.

Other Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, including CMS, the HHS Office of Inspector General and HHS Office for Civil Rights, other divisions of the HHS, the Department of Justice, and state regulatory bodies including Boards of Pharmacy and Price Transparency Boards.

Healthcare systems, physicians, pharmacists, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare systems, physicians and pharmacists may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our drug product. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician payment transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

The U.S. federal Anti-Kickback Statute (the "AKS") prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to

arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. A person does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation of the AKS.

Moreover, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This could apply even if we are not submitting claims directly to payors as would be the case with sales of drug products.

In addition, under a federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare and Medicaid programs by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and there may be significant penalties for violations. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

These regulations present compliance and litigation risks for our business and others in our industry. We incur compliance-related expenses and expect to incur additional expenses if and when our products are commercialized. We may be subject to penalties or limitations on government program participation if we are found to have violated these regulations.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers, and their ownership and investment interests. The Affordable Care Act, imposed, among other things, annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and "transfers of value" to these providers. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Although we are not a "covered entity" and we would not be considered a "business associate" in the normal course of our business and therefore not regulated by HIPAA, our business frequently interacts with covered entities and business associates who are subject to HIPAA. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. See "International Data Collection" below for a discussion of data privacy and security enactments of the EU.

At the state level, the California Consumer Privacy Act, as amended and expanded by the California Privacy Rights Act (collectively, the "CCPA"), imposes data protection obligations on certain businesses. Although we are not currently regulated by any comprehensive state privacy law, we expect we will be regulated by such laws in the future as our business develops. While there are certain limited exceptions under the CCPA for clinical trial data and other health data that would apply to us, these regulations exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information, which causes us to incur compliance costs. Privacy legislation similar to the CCPA has been adopted in many other U.S. states, and regulation of the collection, use, and disclosure of personal information remains a common focus of state legislation.

States and foreign jurisdictions also have fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services. Some state laws also require pharmaceutical companies to comply with the brand pharmaceutical industry's voluntary compliance guidelines (i.e., the PhRMA Code) and the relevant federal government compliance guidances, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing.

In order to sell products, we will need to comply with state laws, including those that require the registration of manufacturers and wholesale distributors of drug and biological products. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. If and when we commercialize our products, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment, especially in light of the lack of applicable precedent and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our business strategy operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource consuming and can divert a company's attention from the business.

International Data Collection

Our contract research organizations ("CROs") and clinical investigators involved in our clinical trials may collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, "process") personal data as defined in data protection laws, from individuals residing outside the U.S. Accordingly, we are subject to numerous foreign privacy and security laws regulating the collection, use, safeguarding, transfer and other processing of personal data.

Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, in the EU/EEA, we are subject to the EU General Data Protection Regulation (the "EU GDPR"), and associated Data Protection Legislation, which govern the collection and use of personal data as it pertains to individuals residing in the EU/EEA. This legislation imposes several requirements, including, but not limited to: providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, processing personal data only under one of the six lawful bases for processing, managing contractual relationships with vendors and other third parties, and notifying the appointment of a data protection officer to the relevant EU/EEA competent national data protection authorities. The EU GDPR also imposes strict rules on the transfer of personal data outside of the EU/EEA. Personal data transferred to a jurisdiction outside the EU/EEA that does not provide adequate protection for personal data (an "adequate jurisdiction") must be protected by standard contractual clauses (a standard form of contract approved by the European Commission). Currently, the U.S. is only an adequate jurisdiction for companies

that certify to the EU-U.S. Data Privacy Framework. As we are not certified to the EU-U.S. Data Privacy Framework, we must rely on standard contractual clauses and other Article 45 protections when transferring personal data from the EU/EEA to the U.S. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. The EU GDPR also confers a private right of action in some circumstances on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU GDPR. We have incurred, and expect to continue to incur, compliance expenses in connection with the EU GDPR. If we are found to be in violation of the EU GDPR, our product development timeline may be affected, which would potentially affect our ability to generate revenue and might impact our competitive position.

Further, following the withdrawal of the United Kingdom from the EU, we have to comply with the GDPR as implemented in the United Kingdom (the "UK GDPR"). The UK GDPR penalty structure mirrors the EU GDPR and has the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from European Union member states to the United Kingdom without additional safeguards. However, the framework for transfer of personal data from the UK to jurisdictions outside the UK, EU, or EEA is different from the EU GDPR. The UK has implemented its own standard contractual clauses to protect UK personal data transferred to countries that are not adequate jurisdictions.

Current and Future Legislation

In the U.S. and other jurisdictions, continued healthcare reform measures may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive. Individual states in the U.S. have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Regulations may also prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates.

Other Regulatory Requirements

Our operations use small amounts of hazardous materials in research and development and generate regulated medical waste in the normal course of performing our laboratory tests. This subjects us to a variety of federal, state and local environmental and safety laws and regulations. Some of the regulations under the current regulatory structure provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Corporate History

We were organized as a Minnesota limited liability company in 2011 and commenced operations in 2012. On September 15, 2017, we converted from a Minnesota limited liability company into a Delaware corporation and changed our name from Celcuity LLC to Celcuity Inc.

Employees and Labor Relations

As of December 31, 2025, we had 155 full-time employees, most of which were engaged in research and development activities, though hiring employees in preparation for anticipated commercial launch has begun. None of our employees are currently represented by a labor union or covered by a collective bargaining agreement and we believe that our relations with our employees are good. During 2025, our voluntary turnover rate was approximately 4%.

Information About Our Executive Officers

The following table sets forth information concerning our executive officers.

Name	Age	Position
Brian F. Sullivan	64	Chief Executive Officer and Chairman of the Board
Lance G. Laing, Ph.D.	64	Chief Science Officer, Vice President, Secretary and Director
Vicky Hahne	59	Chief Financial Officer

Brian F. Sullivan is our co-founder and has served as Chairman of the Board and Chief Executive Officer since we commenced operations in 2012. Mr. Sullivan has over 30 years of experience founding and building successful, high-growth technology companies. He was Chairman and CEO of SterilMed, a medical device reprocessing company, from 2003, when he led an investment group to acquire a majority interest, until its sale to Ethicon Endo-Surgery Inc., a Johnson & Johnson company, for $330 million in 2011. Previously, he was co-founder and Chief Executive Officer of Recovery Engineering, a filtration company, which he took public and subsequently sold to Procter & Gamble for $265 million in 1999. Mr. Sullivan previously served on the board of directors of two publicly-held companies, Entegris, Inc. and Virtual Radiologic Inc. Mr. Sullivan has received nine U.S. patents and has several patents pending. He graduated *magna cum laude* with distinction from Harvard College with an A.B. in economics.

Lance G. Laing, Ph.D. is our co-Founder and has served as Chief Science Officer, Vice President, Secretary and a director since we commenced operations in 2012. Dr. Laing's career spans more than 20 years in drug discovery research and technology development. He received his doctorate in biophysics and biochemistry from The Johns Hopkins University and completed a National Institutes of Health post-doctoral fellowship at Washington University Medical School in biophysics. He has received 27 U.S. patents and has several U.S. patents pending. His drug discovery research career began at Scriptgen/Anadys Pharmaceuticals (purchased by Novartis), where he worked under Professor Peter Kim. He also was Director of Chemistry and Bioapplications and Director of Detection Product Development for two companies that each developed instruments similar to those used by Celcuity. His work at these two instrument companies gave him unique expertise and experience in developing a variety of patented applications for these instruments. Most recently, he served as an executive director for an international drug discovery and development company.

Vicky Hahne joined as our Chief Financial Officer in July 2017. She has more than 25 years of financial leadership experience, including the most recent 20 years in the healthcare industry. Prior to joining Celcuity, Ms. Hahne served as Controller of Respiratory Technologies Inc., a medical device manufacturer, from 2015 to 2017. While at Respiratory Technologies, she played a key role in the due diligence process to sell the company to Koninklijke Philips. In 2014, she served as Controller for Ability Network Inc., a healthcare information technology company. From 2007 to 2012, Ms. Hahne served as Controller of SterilMed Inc., a medical device reprocessing company, where she was significantly involved in the sale of the company to Johnson & Johnson. Prior to these roles, Ms. Hahne held several senior financial positions at SimonDelivers Inc., including Chief Financial Officer. Ms. Hahne has extensive experience in early stage, high growth companies with responsibilities including financial controls and stewardship, financial analysis, mergers and acquisitions, building infrastructure and systems. She received a B.S. degree in Finance and Accounting from Northern State University and received her CPA certificate in 1990.

ITEM 1A. Risk Factors

Risk factors that could cause actual results to differ from our expectations and that could negatively impact our financial condition and results of operations are discussed below and elsewhere in this Annual Report. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. If any of the risks or uncertainties described below or any additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected.

Risks Relating to Our Business

We have not yet commercialized a pharmaceutical product, and we may never generate revenue or profit.

We are a clinical-stage biotechnology company that commenced activities in January 2012. We have not yet commercialized a pharmaceutical product, and our commercial business plan has not been tested. Since inception, we have had no revenue and have incurred significant operating losses. We have financed our operations primarily through private placements and registered offerings of our equity securities, unsecured convertible notes, and borrowings under loan agreements. To generate revenue and become and remain profitable, we need to successfully complete our existing clinical trials and develop, obtain regulatory approval for, and commercialize gedatolisib pursuant to our license agreement with Pfizer. We must also build operational and financial infrastructure to support commercial operations, train and manage employees, and market and sell our anticipated drug product, if approved.

We may never succeed in any of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and the net losses we incur may fluctuate significantly from quarter to quarter. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain or expand our research and development efforts, expand our business, or continue our operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize our drug candidate, gedatolisib.

We may require additional capital to finance operating expenses and capital expenditures in the future as we prepare to launch, and if we launch, gedatolisib, and expand our infrastructure, commercial operations and research and development activities. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to our company.

Future financing activities could dilute the percentage ownership of our stockholders and could cause our stock price to fall or could result in operating or other restrictions.

We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, it will result in dilution to current stockholders. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our existing securities. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also include restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms.

We are dependent on our ability to attract and retain key personnel.

Our operations are materially dependent upon the services of our officers and key employees, including Brian F. Sullivan, our Chief Executive Officer, and Dr. Lance G. Laing, our Chief Science Officer. Successful implementation of our business plan will also require the services of other consultants and additional personnel. We cannot assure you that we will be able to attract and retain such persons as employees, independent contractors, consultants or otherwise. If we are not able to attract individuals with the skills required for our business, or if we lose the services of either Mr. Sullivan or Dr. Laing, we may be unable to successfully implement our business plan.

Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the pharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and could limit our ability to sell our product. In addition, product liability insurance for the pharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms for any product we bring to market. Further, our product liability insurance coverage may not provide coverage or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We are expanding our development and regulatory capabilities and implementing sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We are experiencing significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, in anticipation of our product candidate potentially receiving marketing approval, sales, marketing and distribution. To manage this growth, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Due to finite financial and human resources, we may not be able to effectively manage the expansion of our operations or recruit and train sufficient numbers of additional qualified personnel. The expansion of our operations is costly and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Changes to trade policy, including new or increased tariffs and changing import and export regulations, could have a material adverse effect on our business, results of operations and financial condition.

Our business, results of operations, and financial condition could be adversely affected by uncertainty and changes in U.S. or international trade policies, including tariffs, quotas, trade agreements, or other trade restrictions imposed by the U.S. or other governments. For example, the U.S. has instituted certain changes, and has proposed additional changes, in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the U.S., and other government regulations affecting trade between the U.S. and other countries. New tariffs and other changes in U.S. trade policy have triggered, and may in the future trigger, retaliatory actions by affected countries, and foreign governments may institute or may consider imposing trade sanctions on U.S. goods. Several recent tariff announcements have been followed by announcements of limited exemptions, revisions, and temporary pauses, resulting in significant uncertainty.

Further increasing uncertainty related to trade policies, on February 20, 2026, the U.S. Supreme Court ruled against the U.S. presidential administration's use of tariffs under the International Emergency Economic Powers Act (the "IEEPA"). However, the decision creates uncertainty related to various aspects of the tariffs previously collected under the IEEPA, and not all tariffs announced throughout 2025 were impacted by this U.S. Supreme Court decision. Additionally, in response to the U.S. Supreme Court ruling, the U.S. presidential administration imposed a new worldwide tariff effective for 150 days from February 24, 2026. The imposition of these new, worldwide tariffs, as well as the potential for further tariff actions by the U.S. presidential administration or others, represents a significant source of uncertainty. The imposition of tariffs and other trade restrictions, as well as the escalation of trade disputes and any downturns in the global economy resulting therefrom, could materially and adversely affect our business, financial condition and results of operations. The extent and duration of the tariffs and other trade restrictions and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, and availability and cost of alternative sources of supply.

Any imposition of, or increase in, tariffs or other restrictions on imports of active pharmaceutical ingredient ("API"), finished drug product or other materials (or the components of these materials) could increase the cost for such API, finished drug product or other materials and also increase the prices for such materials available domestically or locally, if any, which in turn could increase our costs for API and our finished drug product. Such cost increases could materially and adversely affect our results of operations and financial condition. Tariffs or other trade restrictions may lead to continuing uncertainty and volatility in U.S. and global financial and economic conditions and commodity markets, declining consumer confidence, significant inflation, and diminished expectations for the economy. Such conditions could have a material adverse impact on our business, results of operations and financial position.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our debt obligations.

As of December 31, 2025, we had $338.8 million aggregate principal amount of indebtedness for borrowed money, of which $130.0 million was secured indebtedness consisting of the Term Loans (as defined in Note 10 to our financial statements included elsewhere in this Annual Report). Included in the aggregate principal amount is $201.3 million principal amount of additional indebtedness as a result of the offering of the Company's 2.750% Senior Notes due 2031 (the "Notes"). We may incur additional indebtedness to meet future financing needs. For example, we have an additional $220.0 million in incremental Term Loans that can be drawn under the A&R Loan Agreement (as defined in Note 10 to our financial statements included elsewhere in this Annual Report) upon the achievement of certain regulatory milestones and product revenue thresholds. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;

- limiting our ability to obtain additional financing on acceptable terms or at all;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, and our cash needs may increase in the future. In addition, the A&R Loan Agreement contains, and any future indebtedness that we may incur in the future may contain, financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately due and payable in full.

We may be unable to raise the funds necessary to repurchase the Notes for cash following a fundamental change or to pay any cash amounts due upon maturity, and our other indebtedness may limit our ability to repurchase the Notes or to pay any cash amounts due upon their maturity.

Noteholders may, subject to a limited exception, require us to repurchase their Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. Upon maturity of the Notes, we must pay their principal amount and accrued and unpaid interest in cash, unless they have been previously converted, redeemed or repurchased. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes or pay any cash amounts due upon their maturity. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Notes or to pay any cash amounts due upon their maturity. Our failure to repurchase Notes or to pay any cash amounts due upon their maturity when required will constitute a default under the indenture, dated as of August 1, 2025, between the Company and U.S. Bank Trust Company, National Association, as trustee (the "Base Indenture"), as supplemented by the first supplemental indenture (the "Supplemental Indenture," and the Base Indenture, as supplemented by the Supplemental Indenture, the "Indenture"). A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full after any applicable notice or grace periods. We may not have sufficient funds to satisfy all amounts due under our indebtedness.

Provisions in the Indenture could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the Notes and the Indenture could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then, subject to limited exceptions, Noteholders will have the right to require us to repurchase their Notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate of the Notes. In either case, and in other cases, our obligations under the Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

Risks Related to Our Product Strategy

Our near-term revenue prospects depend on the success of our initial drug product, gedatolisib. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, gedatolisib, or if we experience delays in doing so, including supply chain interruptions, our business will be materially and adversely impacted.

Our future success and ability to generate revenue, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize gedatolisib for one or more intended uses. We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, our current or future product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, gedatolisib, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that gedatolisib is safe and effective;

- negative or inconclusive results from our clinical trials or the clinical trials of others for drug products similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials or by individuals using drugs or therapies similar to gedatolisib;
- poor effectiveness of gedatolisib or companion therapeutics during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of drug products or other materials necessary for the conduct of our clinical trials or to support commercialization;
- greater than anticipated clinical trial or manufacturing costs;
- unfavorable FDA or comparable regulatory authority inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular;
- interruptions to our supply of API, finished drug product or other materials; or
- varying interpretations of our clinical data by the FDA and comparable foreign regulatory authorities.

We were not involved in the early development of gedatolisib; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of gedatolisib.

We had no involvement with or control over the initial preclinical and clinical development of gedatolisib. We are dependent on third parties having conducted their research and development in accordance with the applicable protocols and legal, regulatory and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such drug product; and having correctly collected and interpreted the data from these trials.

We have not yet successfully completed any registrational clinical trials, and we may be unable to do so for any drug candidates we may develop.

We will need to successfully achieve primary clinical endpoints in registrational clinical trials, in order to obtain and maintain the approval of the FDA or comparable foreign regulatory authorities to market our drug product. Carrying out clinical trials, including later-stage registrational clinical trials, is a complicated process. As an organization, we have not previously completed any registrational clinical trials. In order to do so, we continue to build and expand our clinical development and regulatory capabilities, and there is risk that we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission, approval, and maintaining approval of our drug product. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approval of any drug products that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our drug products.

The successful development of our products is highly uncertain.

Our business depends on the successful development of our pharmaceutical products, which is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons including, among other things, that clinical trial results may show the product candidates to be less effective than expected or to have unacceptable side effects or toxicities; we may fail to receive the necessary regulatory approvals or there may be a delay in receiving such approvals; or the proprietary rights of others and their competing products and technologies may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one drug product to the next and from one country to the next and may be difficult to predict. We will incur significant research and development expenses before knowing whether our products are commercially viable, and may abandon development of a specific trial, or a product candidate, at any time for a variety of reasons. If we expend resources on products that are ultimately not commercially viable, our timing for becoming profitable and our ability to invest in other products in our pipeline would be adversely affected.

In addition, if gedatolisib receives marketing approval for the intended uses that we are pursuing, we will continue to be subject to significant post-approval regulatory obligations. Compliance with these requirements is costly, and any failure to comply or other issues with our drug products post-approval could adversely affect our business, financial condition and results of operations. In addition, there is always the risk that we, a regulatory authority, or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency.

If we encounter difficulties enrolling patients in any of our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience, and the ability of these investigators to identify and enroll suitable patients;
- perception of the safety profile of our drug products;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or interim data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or interim results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary or interim data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and marketing efforts.

Further, others, including healthcare providers or payors, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study is based on what is typically extensive information, you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the preliminary or interim data that we report differ from actual results, or if others, including healthcare providers or payors, disagree with the conclusions reached, our ability to commercialize our product candidate may be harmed, which could harm our business, operating results, prospects or financial condition.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any drug product, we must demonstrate through extensive preclinical studies and clinical trials that such drug product is safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Differences in trial design between early-stage clinical trials and later-stage clinical trials, which involve a greater number of patients and take years to complete, make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, we are conducting and plan to conduct some open-label clinical trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in those trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Where a randomized, placebo-controlled clinical trial is designed to allow enrolled subjects to cross-over to the treatment arm, there may be a risk of inadvertent unblinding of subjects prior to cross-over, which may limit the clinical meaningfulness of those data and may require the conduct of additional clinical trials. As such, the results from an open-label clinical trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Successful completion of clinical trials, or achievement of a predefined primary endpoint, is a prerequisite to submitting an NDA, or NDA supplement, to the FDA, and similar marketing applications to comparable foreign regulatory authorities, for each drug product and, consequently, the ultimate approval and commercial marketing of any drug products. We may experience delays in initiating or completing clinical trials, or achieving event thresholds, including if it takes longer than expected to activate the targeted number of clinical sites, if the enrollment of patients is slower than anticipated or negatively affected by staffing shortages at clinical sites, or by other unanticipated factors, or if the FDA or other regulatory authorities require us to pause one or more of our clinical trials due to unexpected safety issues. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our current product candidates or any future product candidates.

Our costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether our clinical trials will begin or continue as planned, will need to be reassigned or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

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 our lead product candidate, gedatolisib. 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, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces.

Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that gedatolisib is also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

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 our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price, and reimbursement.

Even if we obtain 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 our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could face clinical trial delays; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse consequences.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. We rely on contract research organizations, contract manufacturing organizations, distributors, supply chain resources, and other third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, on-site systems and cloud-based data centers, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of sensitive information, including research and development information, patient data, commercial information, and business and financial information. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place. If we or any of our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. We cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

Cybersecurity threats are becoming increasingly difficult to detect, and come from a variety of sources, including without limitation, nation-state actors and activists that create disruption for geopolitical reasons and in conjunction with military conflicts and defense activities. This risk is heightened as a result of global wars and other major conflicts. In addition, we and the third parties upon which we rely face an evolving cybersecurity threat landscape, which includes social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, attacks enhanced or facilitated by artificial intelligence ("AI"), software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, natural disasters, terrorism, and other similar threats.

The majority of our employees and contractors work remotely. Remote work involves risks to our information technology systems and data, as individuals utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Ransomware attacks also continue to increase in prevalence and severity and can lead to significant interruptions in our operations, ability to provide our services, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

While we take steps designed to identify, prevent, assess and mitigate vulnerabilities in our information systems and to mitigate related third-party risks, there can be no assurance that we will be able to detect and remediate all such vulnerabilities, including on a timely basis. The threats and techniques used to exploit vulnerabilities change frequently and are often sophisticated in nature. Therefore, we (or third parties on whom we rely) may be unable to detect a vulnerability until after a security incident has occurred. Further, we or third parties on which we rely may face downtime as a result of adopting new information technology systems that are designed to enhance compliance or reduce vulnerabilities.

A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. This could disrupt our clinical trials, damage our reputation, and negatively affect our ability to conduct our business in the ordinary course, including our ability to collect, process, and prepare company financial information, provide information and educational materials through our website, and manage the administrative aspects of our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information and to notify relevant stakeholders, including affected individuals, regulatory authorities and our stockholders, of certain security incidents. The disclosure decisions are complex, may take time to determine, and may be subject to change as an investigation progresses. Providing disclosure may be costly, and the failure to comply with such requirements could also lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may face government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims) and mass arbitration; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Accordingly, security incidents and attendant consequences may damage our financial position and negatively impact our ability to grow and operate our business.

Further, if the information technology systems of the third parties upon which we rely become subject to security incidents, we may have insufficient recourse against such third parties, and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. There can be no assurance that limitations of liability in our third-party contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our data privacy and security practices. Additionally, we cannot be sure that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data.

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If any of our vendors experiences an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Public health matters may materially and adversely impact our business, including ongoing clinical trials.

The outbreak of COVID-19 and government measures taken in response demonstrated that public health matters have a significant impact on the global economy, with healthcare systems particularly affected. Future outbreaks or variants of COVID-19, or the emergence of other pandemics or public health disruptions, could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in clinical trials and obtaining the results of completed clinical trials;
- increased rates of patients withdrawing from clinical trials following enrollment as a result of quarantine or public health concerns;
- diversion of healthcare resources away from the conduct of clinical trials;
- delays in prospective clinical trial collaborations with pharmaceutical companies and sponsors;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions; and
- limitations on employee resources that would otherwise be focused on the conduct of clinical trials and research as a result of focus on health matters and loss of productivity from remote work.

Risks Related to Product Development and Product Regulation

If we are unable to obtain approval from the FDA or comparable foreign regulatory authorities to market our products for their intended use, we will not be able to generate revenue. For a new drug to be approved for marketing, the FDA and other regulatory authorities must determine that the drug is safe and effective. Because all drugs can have adverse effects, the data from our Phase 3 clinical study must demonstrate to the satisfaction of the FDA and other health authorities that the benefits of gedatolisib in combination with fulvestrant, and with or without palbociclib, or gedatolisib in combination with fulvestrant plus a CDK4/6 inhibitor, outweigh its risks. Failure to demonstrate sufficient magnitude of benefit, even if the benefit is found to be statistically significant, may not support regulatory approval.

The marketability of our products, particularly gedatolisib, depends on securing approval from the FDA and equivalent foreign regulatory bodies. This requires rigorous pre-clinical and clinical studies, including Phase 3 clinical trials for each intended use, that the benefits of the therapy outweigh its risks. Failure to demonstrate sufficient magnitude of benefit, even if the benefit is found to be statistically significant, may not support regulatory approval. Satisfaction of the FDA's regulatory requirements typically takes many years and requires substantial resources for research, development and testing.

If a drug meets its primary efficacy endpoint objective in a Phase 3 clinical trial, and the drug sponsor has additional nonclinical and clinical data required by the FDA or other regulatory authorities, the drug sponsor may submit an NDA seeking marketing approval. Upon submission of an NDA, these health authorities perform a benefit-risk assessment that considers the strength and quality of evidence available and takes remaining uncertainties into account. These considerations include an assessment of the strengths and limitations of clinical trials, including design, and potential implications for assessing drug efficacy, the magnitude of benefit and interpretation of clinical importance, the benefit attributed to the drug when studied in combination with other therapies, and the clinical relevance of the study endpoints. We are currently conducting a Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib, in patients with HR+/HER2- ABC after progression on CDK4/6 therapy, conducting a Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib in combination with a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC, and conducting a Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer. In November 2025, we completed our NDA submission to the FDA for gedatolisib in HR+/HER2- ABC based on clinical data from the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 clinical trial. On January 16, 2026, the FDA accepted our NDA, designated it for Priority Review, and identified July 17, 2026 as our PDUFA target goal date.

We have sought feedback from the FDA and other regulatory authorities on the design of gedatolisib clinical trials, with the goal of addressing these considerations in the clinical trials' design. However, due to the complexity of clinical trials, the uncertainty of outcomes, and the uncertainty of how the FDA and other regulatory authorities may balance benefits and risks in their review of an NDA, it may not be practical or possible to address all benefit-risk assessment considerations in a clinical trial so that sufficient evidence is generated to support a marketing approval, even if the primary endpoint objective is achieved in the Phase 3 stage of the trial. The FDA or other regulatory authorities may require us to redesign or conduct additional unplanned clinical trials before granting any approval and we may not get approval at all. Regulatory approval may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur during our regulatory review. We cannot predict whether our research and clinical approaches will result in a drug that the FDA considers safe for humans and effective for indicated uses.

If regulatory approvals are delayed or not obtained, especially with respect to gedatolisib, it will negatively impact our ability to commercialize our products and generate revenue and may diminish any competitive advantages that we may otherwise enjoy. If we are required to conduct additional clinical trials or other testing of gedatolisib beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of gedatolisib, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval, supplemental marketing approval, or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way our products are administered;

- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of the FDA's REMS program or through modification to an existing REMS;
- be sued; or
- experience damage to our reputation.

Additionally, if the size of the FDA group dedicated to reviewing oncology-related submissions is reduced, further delays of our regulatory submissions may be encountered.

Breakthrough Therapy Designation, Fast Track Designation, NDA submission via RTOR, and being awarded Priority Review from the FDA may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track Designation. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and to ensure collection of appropriate data needed to support drug approval, as well as eligibility for submission of an NDA.

In addition, a drug may receive Breakthrough Therapy Designation if it is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The benefits of Breakthrough Therapy Designation include more intensive guidance from the FDA on an efficient development program, access to a scientific liaison to help accelerate review time, and potential eligibility for Priority Review if relevant criteria are met. This designation can expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.

Fast Track and Breakthrough Therapy Designations, as well as seeking to submit our NDA on a rolling basis pursuant to the FDA's RTOR program, and receiving Priority Review, are within the discretion of the FDA. The FDA has granted both designations to our lead drug candidate, gedatolisib, and has accepted our NDA which was filed via RTOR and designated it for Priority Review. However, such designations and programs may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA review procedures, and none of these designations and awards assures ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the qualification conditions and may rescind such designations or programs, or the FDA may not approve our NDA by the Priority Review PDUFA target goal date of July 17, 2026.

Obtaining and maintaining FDA approval of our product candidates in the U.S. does not mean that we will be successful in obtaining regulatory approval of our 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, while 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, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive initial regulatory approvals, we will be subject to ongoing regulatory 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 our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies 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 regulatory approvals that we receive for our product candidates 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 our product candidates, 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 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.

The FDA strictly regulates 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 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.

Risks Related to Commercializing Our Products

Even if our products achieve requisite approvals, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any product we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, existing drug therapies may be viewed as more reliable or more easily administered than gedatolisib. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternatives;

- the ability to offer our products, if approved, for sale at acceptable prices;
- convenience and ease of administration compared to other treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe or initiate these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage, market access and adequate reimbursement; and
- the prevalence and severity of any side effects.

If our products do not achieve an adequate level of acceptance, we may never generate significant product revenues and we may not become profitable.

If we commercialize any product candidates, we will be 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.

Even if we or our partners are successful in obtaining marketing approval, commercial success of any approved products will also 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 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.

Availability of reimbursement may 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 also could 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 our products once approved, 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.

We may encounter difficulties in scaling production of, commercializing, marketing and distributing our products, including in hiring and retaining a qualified sales force.

In order to commercialize any of our products in the U.S. and other jurisdictions, we must build production, marketing, sales, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services, and we may not be successful in doing so. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks and material costs involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services.

In particular, there is intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Furthermore, there is no guarantee that the market opportunity for gedatolisib will be as significant as we expect or exist at all. If we are unable to successfully commercialize our products in the U.S. or other jurisdictions, or if we are delayed in doing so, including if we are unable to develop our marketing and sales networks or if our sales personnel do not perform as expected, we may never generate any revenue and our business may fail.

Our business, operational and financial goals may not be attainable if the market opportunities for our products are smaller than we expect. Our internal research and third-party estimates may not accurately reflect the market opportunities for gedatolisib today or in the future.

The total market opportunities that we believe exist are based on a variety of assumptions and estimates, including the size of the addressable patient population in applicable jurisdictions, other available drugs in these markets, payor coverage, anticipated reimbursement, and the price we will be able to charge for our products. In addition, we have relied on third-party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of addressable cancer patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the objective response rates of drug therapies, the number of deaths caused by cancer and the expected growth in cancer drug therapy. Our internal research and estimates on market opportunities have been verified by independent sources, but any or all of our assumptions and/or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our products or such patients becoming difficult to identify and access, limited reimbursement for our products, pricing pressure due to availability of alternative drugs or an inability to obtain the necessary regulatory approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we may not attain our business, operational and financial goals.

Risks Related to Intellectual Property

We depend on intellectual property licensed from Pfizer for our lead product candidate, and termination of this license could result in the loss of significant rights, which would materially and adversely impact our business.

We are dependent on patents and know-how, both our own and licensed from Pfizer. Key patents covering gedatolisib and any combination therapies using our product candidates are licensed from Pfizer pursuant to the Gedatolisib License Agreement. Any termination of the product license could result in the loss of significant rights and would cause material adverse harm to our ability to commercialize our product candidates.

Disputes may also arise between us and Pfizer regarding intellectual property subject to the Gedatolisib License Agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our product candidates and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed assets in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer.

If we fail to comply with our obligations under our patent license with Pfizer, we could lose license rights that are important to our business.

We are a party to a license agreement with Pfizer pursuant to which we in-license key patents for gedatolisib. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, Pfizer may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Further, we cannot be certain that the activities conducted by Pfizer, or its predecessors, were performed in compliance with applicable laws and regulations or will result in additional valid and enforceable patents and other intellectual property rights.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Our clinical trials and other programs currently, and may in the future, involve additional product candidates that require the use of, or reliance on, proprietary rights held by third parties. Accordingly, the growth of our business depends in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which could harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

If we are not able to prevent disclosure of our trade secrets and other proprietary information, the value of our products could be significantly diminished.

We rely on trade secret protection to protect our interests in proprietary know-how and in processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. We have a policy of requiring our consultants, advisors and strategic partners to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and restrictive covenant agreements. However, no assurance can be given that we have entered into appropriate agreements with all parties that have had access to our trade secrets, know-how or other proprietary information. There is also no assurance that such agreements will provide meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information. Furthermore, we cannot provide assurance that any of our employees, consultants, contract personnel, or strategic partners, either accidentally or through willful misconduct, will not cause serious damage to our programs and/or our strategy, for example by disclosing important trade secrets, know-how or proprietary information to our competitors. It is also possible that our trade secrets, know-how or other proprietary information could be obtained by third parties as a result of breaches of our physical or electronic security systems. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us. In addition, others may independently discover our trade secrets and proprietary information. Any action to enforce our rights is likely to be time consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are accentuated in foreign countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States. Any unauthorized disclosure of our trade secrets or proprietary information could harm our competitive position.

We may be subject to claims by employees claiming ownership of what we regard as our own intellectual property.

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to obtain and maintain intellectual property protection for our 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 our 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 13 issued patents in the U.S. and more than 297 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 nonclinical 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

The commercial success of our products depends upon our ability to manufacture, market and sell our products without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Additionally, because current and future employees may have been previously employed at universities or other biotechnology, diagnostic technology or pharmaceutical companies, including our competitors or potential competitors and strategic partners, third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, or they may allege that our employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

Patent litigation could result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar product candidates, or limit the duration of the patent protection of our products. If we are found to infringe a third party's intellectual property rights, we could be required to obtain additional licenses from such third party to continue developing and marketing our applicable products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product.

In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Any lawsuits relating to infringement of intellectual property rights necessary to defend ourselves or enforce our rights will be costly and time consuming and could be unsuccessful.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates.

We depend upon third parties to execute certain aspects of our operational plans and to conduct certain aspects of our preclinical studies. Additionally, we depend on third parties, including independent investigators, to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. Our reliance on third parties may affect our development timelines and increase our costs.

We have limited control over third-party clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed or precluded entirely.

Our reliance on third parties to formulate, manufacture and distribute our drug product exposes us to risks that may delay the development, regulatory approval and commercialization of our drug product or result in higher product and operational costs.

We do not directly formulate, manufacture or distribute our drug product candidate and do not intend to establish our own formulation, manufacturing or distribution facilities. We have contracted with third-party contract manufacturers to formulate, manufacture and supply our drug product, and we use other third parties to package, store and distribute drug product for our clinical trials. If our drug product receives FDA approval, we will rely on one or more third-party contract manufacturers to manufacture and package our commercial drug product, and we will use a 3PL to distribute our commercial drug product.

Our reliance on a limited number of third-party manufacturers, including one primary manufacturer of the active ingredient gedatolisib, exposes us to risks that, among other things, we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement or additional manufacturer; our third-party manufacturers might be unable to manufacture our drugs in the volume and of the quality required to meet our clinical and/or commercial needs, if any; our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials, or to successfully produce, store and distribute our products commercially; and our contract manufacturers may fail to comply with good manufacturing practice and other government regulations and corresponding foreign standards. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

Performance issues or price increases by our shipping carriers could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide our products on a timely basis.

Expedited, reliable shipping is essential to our operations. Should our shipping carriers encounter delivery performance issues such as loss, damage or destruction of our API or product, such occurrences may damage our reputation and adversely affect our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process product orders on a timely basis. There are only a few providers of overnight nationwide transport services, and there can be no assurance that we will be able to maintain arrangements with providers on acceptable terms, if at all.

Other Risks Related to Government Regulation for Our Business

Failure to comply with applicable U.S. data security and privacy regulations may increase our operational costs.

Generally, we are not a covered entity under HIPAA, and our clinical operations are exempt from most state and federal data protection regulations. The personal data of clinical trial subjects collected by our CROs' U.S. clinical sites is considered protected health information, or PHI, subject to the U.S. sites' compliance with HIPAA. We will incur significant costs to establish and maintain data privacy safeguards and, if we are required to comply with HIPAA or U.S. state regulations in the future, our costs could increase further, which would negatively affect our operating results. Furthermore, we cannot guarantee that such safeguards have been and will continue to be adequate under applicable laws.

If we receive FDA approval and launch gedatolisib in the U.S., we expect to be subject to comprehensive state privacy laws. For example, the CCPA applies to personal information of consumers, business representatives, and employees, and requires covered businesses to provide specific disclosures related to a business's processing of personal data, new operational practices, and requirements to respond to certain requests from California residents related to their personal data. New regulations and enforcement actions related to the CCPA and similar state comprehensive privacy laws continue to impact how companies think about and establish compliance mechanisms across the U.S. U.S. privacy compliance is further complicated by inconsistent state laws that require complex operational frameworks for full compliance. Accordingly, the CCPA and other similar state laws may impact our business activities and increase our compliance costs, as well as our legal risks. The regulatory framework for the collection, use, safeguarding, transfer and other processing of information is rapidly evolving and is likely to remain uncertain for the foreseeable future.

Evolving U.S. data privacy regulations may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

Our CROs and clinical investigators involved in our clinical trials may collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, "process") personal data as defined in data protection laws outside the U.S. Accordingly, we are subject to numerous foreign privacy and security laws regulating the collection, use, safeguarding, transfer and other processing of personal data.

Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the UK, the EU, and the EEA, is subject to the UK GDPR and EU GDPR (together, "UK/EU GDPR"), which is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. In addition, the UK/EU GDPR also imposes strict rules on the transfer of personal data

to countries outside the UK/EU/EEA, including the U.S., and, as a result, increases the scrutiny that clinical trial sites located in the UK/EU/EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the U.S. The UK/EU GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the UK/EU GDPR, which can be up to 4% of global revenue or £17 million/€20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associates to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the UK/EU GDPR. In addition, the UK/EU GDPR provides that UK/EU/EEA member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the UK/EU/EEA.

Evolving data privacy regulations may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

We will also need to expend a considerable amount of resources complying with other federal, state and foreign laws and regulations. If we are unable to comply or have not complied with such laws, we could face substantial penalties or other adverse actions.

Our operations are subject, directly or indirectly, to other federal, state and foreign laws and regulations that are complex and their application to our specific products, services and relationships may not be clear and may be applied to our business in ways that we do not anticipate. Compliance with laws and regulations will require us to expend considerable resources implementing internal policies and procedures for compliance and ongoing monitoring and will require significant attention of our management team. This will be challenging as an early-stage company with limited financial resources and human capital. These laws include, for example:

- Title XI of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, which prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in cash or in kind, in return for or to reward the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid;

- The civil False Claims Act, which forbids the knowing submission or "causing the submission" of false or fraudulent information or the failure to disclose information in connection with the submission and payment of claims for reimbursement to Medicare, Medicaid, federal healthcare programs or private health plans;

- The federal Physician Self-referral Law, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies, and similar state equivalents that may apply regardless of payor; and

- The U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and the USA PATRIOT Act, which among other things, prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector.

Many states and foreign governments have adopted similar laws and regulations. Violations of law could subject us to civil or criminal penalties, monetary fines, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations. We could also be required to change or terminate some portions of operations or business or could be disqualified from providing services to healthcare providers doing business with government programs.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, leadership changes, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development programs and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including NDAs, INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the loss of FDA leadership and personnel and new leadership at the U.S. Department of Health & Human Services, the FDA and the Center for Drug Evaluation and Research could lead to disruptions and delays in FDA guidance and review and approval of our product candidate. Further, while the FDA's review of marketing applications and other activities for new drugs is largely funded through the user fee program established under PDUFA, it remains unclear how the administration's recent reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidate in a timely manner.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, the President has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review of our regulatory submissions, including the NDA we submitted in November 2025 that was accepted by the FDA in January 2026, our business would be negatively impacted.

Risks Relating to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any of these provisions of our charter documents or Delaware law could, under certain circumstances, depress the market price of our common stock.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock or could subject us to securities litigation.

Our stock price may be extremely volatile. The stock market in general and the market for smaller medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell our common stock at or above the price they paid for such stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of existing or future clinical trials;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our products or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- operating results that fail to meet expectations of securities analysts that cover our company;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical, biotechnology and medical technology sectors;
- sales of our stock by us, our insiders and our other stockholders;
- general economic and market conditions; and
- the other factors described in this "Risk Factors" section.

Additionally, companies that have experienced volatility in the market price of their stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Future sales of shares of our common stock, including by us and significant stockholders, could negatively affect our stock price.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. Since December 2023, we have issued 6,478,782 shares of common stock pursuant to equity financing arrangements, including pursuant to our Open Market Sale Agreement[SM] with Jefferies LLC ("Jefferies"), as agent, pursuant to which we may currently offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $400.0 million, all of which remains available for sale. In addition, in August 2025, we issued and sold in a public offering $201.3 million aggregate principal amount of Notes, which would result in the issuance of 3,923,002 shares if the Notes were converted in full as of December 31, 2025. We may enter into additional equity or convertible debt financing arrangements in the future. The shares of common stock that we have issued pursuant to equity financings, or may issue in the future pursuant to equity or convertible debt financings, may be resold at any time in the discretion of the investors.

Under our A&R Loan Agreement, as amended by the First Amendment to the A&R Loan Agreement, the Second Amendment to A&R Loan Agreement and the Third Amendment to the A&R Loan Agreement, Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus"), has the right, at its election and until May 9, 2026, 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. In addition, Innovatus continues to have the right to exercise a previously disclosed warrant to purchase 26,042 shares of common stock at an exercise price of $14.40 per share, and Innovatus and Oxford Finance LLC, a Delaware limited liability company, and certain of its affiliates, continue to have the right to exercise previously disclosed warrants to purchase 154,413 shares of common stock at an exercise price of $14.84 per share.

Sales of substantial amounts of shares of our common stock or other securities by these investors or our other stockholders or by us under the Open Market Sale Agreement[SM], or the perception in the market that the holders of a large number of shares of our common stock intend to sell their shares, could reduce the trading price of our common stock, make it more difficult for you to sell your shares at a price that you desire and impair our ability to raise capital through the sale of equity or equity-related securities.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 1C. Cybersecurity

Risk Management & Strategy

Our cybersecurity risk management process is a component of our overall approach to managing material risks that could impact our operations, including cybersecurity threats. In general, we seek to manage material internal and third-party cybersecurity risks through an approach that focuses on: (i) protecting information systems and the information residing therein; (ii) identifying, preventing, and mitigating cybersecurity threats; and (iii) assessing and responding to cybersecurity incidents when they occur. Maintaining, monitoring, and updating our information security program—in an effort to ensure that it remains reasonable and appropriate in light of changes in the security threat landscape, available technology, and applicable legal and contractual requirements—is an ongoing effort.

We have implemented and maintain various processes, procedures, and measures to support our overall risk management strategy and to manage and mitigate the material risks posed by cybersecurity threats to our systems and data. With respect to cybersecurity, these measures include conducting risk assessments of our operations and using a risk register to assess identified risks; developing business continuity, disaster recovery and incident response plans; implementing technical safeguards and tools; conducting ongoing cybersecurity awareness training; and using contractual protections where appropriate. Our incident response plan outlines the procedures for reporting, investigating, and remediating cybersecurity incidents, including a framework to facilitate the escalation to our management team and board of cybersecurity incidents, so that our management team is alerted in a timely manner to material information that would be required to be disclosed or reported.

Our IT department maintains policies and procedures regarding network security, data protection and incident response. Pursuant to those policies, IT engages with the Chief Financial Officer, General Counsel and other experts when assessing cybersecurity threats, incident response, and making disclosure determinations following a data or network breach. The Vice President, IT is accountable at the management level for our overall IT risk management program. Additionally, our Chief Executive Officer and Audit Committee receive regular updates from the Chief Financial Officer, General Counsel and the Vice President, IT about significant threats and incidents involving cybersecurity and data protection, as well as security enhancements made to our IT infrastructure.

We use third-party service providers for a variety of services throughout our business, ranging from infrastructure support and maintenance, cybersecurity incident response, data protection and privacy compliance. In addition, we engage with contract research organizations, contract manufacturing organizations, distributors, and other supply chain resources.

We believe that the use of external service providers improves our operational capabilities, and we have implemented a vendor qualification and management program that applies to our service providers, including those that handle health information, personal information, or other information subject to protection under applicable privacy and data protection regulations. This program is designed to identify, address and seek to mitigate potential cybersecurity and data protection risks that arise from our use of external service providers. While we do not have full visibility into the cybersecurity risk management processes of our vendors, we require new service providers to complete a vendor questionnaire that identifies the vendor's network and user protections, such as the use of multi-factor authentication, and other cybersecurity risk management processes. Vendors that store or access our confidential information are required to certify that their information systems comply with applicable industry guidelines for cybersecurity, backup, and system recovery. We rely on our third-party service providers to provide notification of, and remediate, significant cybersecurity threats and cybersecurity incidents that jeopardize the confidentiality, integrity, or availability of our information.

We periodically evaluate, test, and update our policies, standards, and processes to mitigate cybersecurity threats and manage incidents effectively. These efforts include risk assessments, vulnerability assessments and remediations, phishing tests and employee education, and external scans. Additionally, to enhance our capabilities, we periodically engage third-party service providers, including cybersecurity consultants, to incorporate threat intelligence into our processes.

As of the date of this Form 10-K, we are not aware of any risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents experienced by us or, to our knowledge, by any of our third-party service providers, that have materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition. For further discussion of cybersecurity and data privacy risks that may materially affect the Company and how they may do so, see "Risk Factors—If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could face clinical trial delays; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse consequences," included in Item 1A of this Annual Report on Form 10-K.

Governance

Our Audit Committee oversees Celcuity's management of risks arising from cybersecurity threats. Our CEO delivers periodic briefings to the Board and Audit Committee on material cybersecurity risks that are pertinent to our business operations. Additionally, we have processes to promptly notify the Audit Committee and Board of a significant cybersecurity incident and to inform the Audit Committee and Board of remediation progress, as appropriate.

The Vice President, IT has overall responsibility for our information security program, with support from our management team and specialized partners in cybersecurity incident response and privacy. The process includes managing our incident response strategy. If a cybersecurity incident meets certain criteria, however, our CEO, CFO and General Counsel will become involved with the response strategy, including decisions about public disclosure and reporting. Our Vice President, IT also coordinates with our CEO, CFO and General Counsel to determine strategic cybersecurity priorities and to establish compliance procedures.

We believe our business leaders have the appropriate expertise, background and depth of experience to manage risks arising from cybersecurity threats. Our Vice President, IT has served in various roles in information technology and information security for over three decades, which includes experience in the biotech, pharmaceutical and healthcare industries and experience in cybersecurity risk management and data privacy compliance.

In the ordinary course of our business, we, and the third parties upon which we rely, collect, process, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and store proprietary, confidential, and sensitive information, including health information, personal information, credit card and other financial information, or other sensitive information owned or controlled by ourselves or our customers, payors, and other parties.

ITEM 2. Properties

We currently lease and occupy approximately 16,000 square feet in Minneapolis, Minnesota, which includes our clinical laboratory and offices. On March 13, 2023, we signed the fourth amendment to our lease agreement, which expires April 30, 2026. The lease provides for monthly rent, real estate taxes and operating expenses. We believe that this leased space is adequate to meet current requirements.

On November 5, 2025, we signed a lease agreement for new clinical laboratory and office space in Minneapolis, Minnesota for approximately 19,594 square feet. The lease term will commence on April 1, 2026. The lease provides for monthly rent, real estate taxes and operating expenses. The lease term is 62 months with two options to extend the lease term for five years each.

ITEM 3. 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 4. Mine Safety Disclosures

Not applicable.

PART II

ITEM 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Price Information

Our common stock has been listed on The Nasdaq Capital Market under the symbol "CELC" since September 20, 2017.

As of March 17, 2026, there were approximately 101 holders of record of our common stock. The actual number of holders of common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and expansion of our business. We do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

Recent Unregistered Sales of Equity Securities

During the three months ended December 31, 2025, we issued 1,496 shares of common stock upon the exercise of previously issued warrants as follows:

- 1,089 shares were issued to the placement agent from private placements that closed on April 28, 2017 and May 17, 2017 pursuant to the exercise of warrants at an exercise price of $8.42 per share, resulting in cash proceeds of less than $0.1 million; and

- 407 shares were issued to the placement agent from private placements that closed on January 21, 2016 and May 2, 2016 pursuant to the exercise of warrants at an exercise price of $7.56 per share, resulting in cash proceeds of less than $0.1 million.

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

Issuer Purchases of Equity Securities

None.

ITEM 6. Reserved

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together in conjunction with our financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual 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 Item 1A of Part I of this Annual Report.

Overview

Celcuity is a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. The Company's lead therapeutic candidate is gedatolisib, a kinase inhibitor of the phosphatidylinositol 3-kinase ("PI3K"), serine/threonine-protein kinase protein kinase B ("AKT"), mechanistic target of rapamycin ("mTOR") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By

targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PI3K/AKT/mTOR ("PAM") pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. Our Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) ("HR+/HER2-") advanced breast cancer ("ABC") has completed enrollment and reported detailed results for cohort 1, patients with *PIK3CA* wild-type ("WT") tumors, and has completed enrollment of cohort 2, patients with *PIK3CA* mutant-type ("MT") tumors. Our Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib in combination with a cyclin-dependent kinase ("CDK") 4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC is ongoing. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer ("mCRPC"), is ongoing.

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

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

  Gedatolisib is a pan-class I isoform PI3K inhibitor with low nanomolar potency for the p110α, p110β, p110γ, and p110δ isoforms and the mTORC1 and mTORC2 complexes. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. Each PI3K isoform and mTOR complex is known to preferentially affect different signal transduction events that involve tumor cell survival, depending upon the aberrations associated with the linked pathway. When a therapy only inhibits a single class I PI3K isoform (e.g., alpelisib, a PI3Kα inhibitor), AKT (e.g., capivasertib, an AKT inhibitor) or only one mTOR kinase complex (e.g., everolimus, an mTORC1 inhibitor), numerous feedforward and feedback loops between the PI3K isoforms and mTOR complexes cross-activate the uninhibited sub-units. This, in turn, induces compensatory resistance that reduces the efficacy of isoform specific PI3Kα, AKT, or mTORC1 kinase inhibitors. Inhibiting all four PI3K isoforms and both mTOR complexes, as gedatolisib does, thus prevents the confounding effect of isoform interaction that may occur with isoform-specific PI3K inhibitors and the confounding interaction between PI3K isoforms, AKT, and mTOR.

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

  Gedatolisib is administered intravenously on a four-week cycle of three weeks-on, one week-off, in contrast to the orally administered pan-PI3K or dual PI3K/mTOR inhibitors that are no longer being clinically developed. Oral pan-PI3K or PI3K/mTOR inhibitors have repeatably been found to induce significant side effects that were not well tolerated by patients. This typically leads to a high proportion of patients requiring dose reductions or treatment discontinuation. The challenging toxicity profile of these drug candidates ultimately played a significant role in the decisions to halt their development, despite showing promising efficacy. By contrast, gedatolisib's comprehensive inhibition of the PAM pathway at low nanomolar potency, IV route of administration, and pharmacokinetic properties enables it to achieve optimal anti-proliferative effects on tumor cells without inducing the levels of hyperglycemia, rash, and diarrhea typically associated with oral single-component inhibitors of the PAM pathway.

  Isoform-specific PI3K or mTORC1 inhibitors administered orally were developed to reduce toxicities in patients. While the range of toxicities associated with single-component PAM inhibitors is narrower than oral pan-PI3K or PI3K/mTOR inhibitors, administering them orally on a continuous basis can still lead to challenging toxicities. The experience with an FDA-approved oral p110-α specific inhibitor, PIQRAY, illustrates the challenge. In its Phase 3 pivotal trial, PIQRAY was found to induce a Grade 3 or 4 adverse event ("AE") related to hyperglycemia in 39% of patients evaluated. In addition, 26% of patients discontinued alpelisib due to treatment related AEs. By contrast, in the 103-patient dose expansion portion of the Phase 1b clinical trial with gedatolisib, only 7% of patients experienced Grade 3 or 4 hyperglycemia and less than 9% discontinued treatment.

As of December 31, 2025, 1,127 patients and healthy volunteers have received gedatolisib in 12 completed or ongoing clinical trials. Of these, 123 patients with solid tumors were treated with gedatolisib as a single agent in two clinical trials, 36 healthy volunteers were treated in two clinical trials, and the remaining 968 patients received gedatolisib in combination with other anti-cancer agents in eight clinical trials. Additional patients received gedatolisib in combination with other anti-cancer agents in 10 investigator sponsored clinical trials.

B2151009 Phase 1b Trial

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

A total of 138 patients with HR+/HER2- ABC were dosed in the clinical trial. Four patients from this study continue to receive study treatment, as of December 31, 2025, each of whom has received study treatment for more than six years.

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

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

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

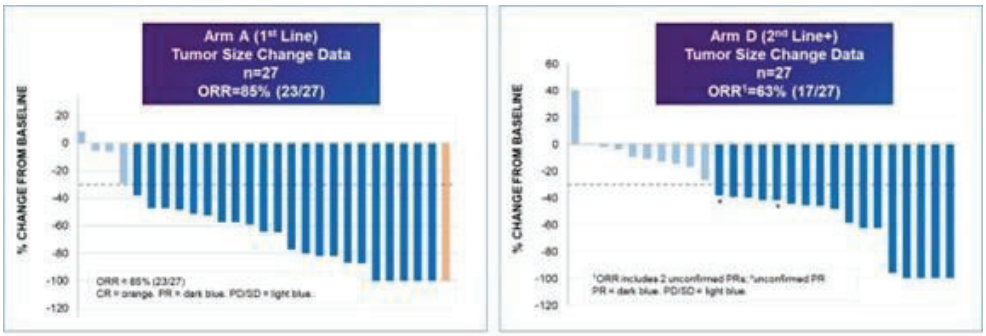
    - **Arm B**: ABC with progression during one or two prior endocrine-based systemic therapies in the advanced setting, with no prior therapy with any CDK inhibitor. Second- or third-line endocrine-based therapy for metastatic disease.

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

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

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

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



Source: Layman SABCS 2021

- Safety analysis:
    - For all arms in aggregate, all patients experienced at least one Grade 1 or Grade 2 treatment-emergent adverse event. The Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (63%), stomatitis (27%) and rash (20%). Neutropenia is a known class effect of CDK4/6 inhibitors. Stomatitis was reversible in most patients with a steroidal mouth rinse. All grades of treatment-related adverse events related to hyperglycemia were reported in 22% of patients; Grade 3 or 4 hyperglycemia was reported in 7% of patients. Gedatolisib was discontinued in less than 9% of patients.
    - For the patients in Arm D, who received the Phase 3 dosing schedule, Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (67%), leukopenia (22%), and stomatitis (22%). All grades of treatment-related adverse events related to hyperglycemia were reported in 26% of patients; Grade 3 or 4 hyperglycemia were reported in 7% of patients. Gedatolisib was discontinued in 4% of patients.

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

Total Expansion Arms (N=103)

	Arm A	Arm B	Arm C	Arm D
Prior Therapy	1L CDKi-naive	2L+ CDKi-naive	2L/3L CDKi-pretreated	2L/3L CDKi-pretreated
n (Full, response evaluable)	31, 27	13,13	32, 28	27, 27
Study Treatment	P + L + G weekly	P + F + G weekly	P + F + G weekly	P + F + G 3 wks on/1 wk off
Gedatolisib schedule				
ORR [1] (evaluable)	85%	77%	36%	63%
mPFS [2], mos (range)	48.4 (16.9, NR)	12.9 (7.6, 38.3)	5.1 (3.3, 7.5)	12.9 (7.4, 16.7)
PFS % at 12 mos [2]	72.1%	54.5%	23.6%	53.2%

	WT	MT	WT	MT	WT	MT	WT	MT
PIK3CA status	81%	16%	69%	31%	75%	25%	56%	41%
ORR (evaluable)	81%	100%	78%	75%	25%	63%	60%	73%
PFS at 12 months	74%	60%	50%	67%	22%	29%	49%	60%

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

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

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

Additional results from the Phase 1b portion of the clinical trial were presented at the ESMO congress in October 2025. The analyses reported efficacy data from patients who were treated with the same drug regimen being evaluated in the VIKTORIA-1 study, gedatolisib combined with fulvestrant and palbociclib. This included patients from Escalation Arm B and Expansion Arms B, C and D of the Phase 1b study.

As described above, patients in Escalation Arm B and Expansion Arms B and C received a 180 mg dose of gedatolisib once weekly ("weekly dose"). Patients in Expansion Arm D received a 180 mg dose of gedatolisib on days 1, 8, and 15 of a four-week cycle ("intermittent dose"), which is the same dose regimen patients in the VIKTORIA-1 study receive. The proportion of patients who received the intermittent dose of gedatolisib was 37% for those with *PIK3CA* MT tumors and 25% for those with *PIK3CA* WT tumors. The proportion of patients who received prior treatment with a CDK4/6 inhibitor was 73% for those with *PIK3CA* WT tumors, and 71% for those with *PIK3CA* MT tumors.

Median PFS and the ORR were assessed in sub-groups of patients according to their *PIK3CA* status (Table 1). For all analyzed patients with *PIK3CA* MT tumors (n=30), median PFS was 14.6 months and the ORR in response evaluable patients was 48%. Median PFS was 19.7 months and the ORR was 64% in patients with *PIK3CA* MT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study. For patients with *PIK3CA* WT tumors (n=60), median PFS was 9.0 months and the ORR in response evaluable patients was 41%. Median PFS was 9.1 months and the ORR was 53% in patients with *PIK3CA* WT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study.

Table 1: Efficacy Analysis of Phase 1b Patients Treated with Gedatolisib Plus Palbociclib Plus Fulvestrant

	PIK3CA MT		***PIK3CA WT***	
	All	**Intermittent Dose**	**All**	**Intermittent dose**
N	30	11	60	15
Median PFS (months)	14.6	19.7	9.0	9.1
ORR	48%	64%	41%	53%

VIKTORIA-1 Phase 3 Trial

We have completed enrollment of our Phase 3, open-label, randomized clinical trial, VIKTORIA-1, to evaluate the efficacy and safety of gedatolisib treatment regimens in adults with HR+/HER2- ABC whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor. Over 200 clinical sites in North America, Europe, Latin America, and Asia-Pacific are participating in the study. The first patient was dosed in this trial in December 2022.

The VIKTORA-1 Phase 3 clinical trial involves two study cohorts that enable separate evaluation of subjects according to their *PIK3CA* status. Subjects who met eligibility criteria and had *PIK3CA* WT tumors (cohort 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). During the fourth quarter of 2024, we achieved our enrollment goal of 351 subjects for the *PIK3CA* WT cohort. The primary completion date for this cohort was achieved in May 2025 and the database cut-off date for this cohort was May 30, 2025. Subjects who met eligibility criteria and had *PIK3CA* MT tumors (cohort 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). Enrollment of approximately 350 subjects who have *PIK3CA* MT tumors is complete. We expect topline data for cohort 2 to be available in the second quarter of 2026.

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

- The gedatolisib triplet (gedatolisib, fulvestrant and palbociclib) demonstrated a statistically significant and clinically meaningful improvement in PFS among patients, reducing the risk of disease progression or death by 76% compared to fulvestrant (based on a hazard ratio [HR] of 0.24, 95% confidence interval [CI] 0.17-0.35; $p<0.0001$). The median PFS, as assessed by blinded independent central review ("BICR"), was 9.3 months with the gedatolisib triplet versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months.
- The gedatolisib doublet (gedatolisib and fulvestrant) also demonstrated a statistically significant and clinically meaningful improvement in PFS among patients, reducing the risk of disease progression or death by 67% compared to fulvestrant (HR of 0.33, 95% CI 0.24-0.48; $p<0.0001$). The median PFS, as assessed by BICR, was 7.4 months with the gedatolisib doublet versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months.
- The ORR of the gedatolisib triplet was 31% compared to 1% with fulvestrant and the median DOR was 17.5 months. The ORR of the gedatolisib doublet was 28.3% and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.
- The gedatolisib triplet and doublet were generally well tolerated in the trial with mostly low-grade TRAEs. The most common Grade 3 TRAEs for the gedatolisib triplet, gedatolisib doublet, and fulvestrant groups included neutropenia (52.3%, 0%, and 0.8% of patients, respectively); stomatitis (19.2%, 12.3%, and 0% of patients, respectively) rash (4.6%, 5.4%, and 0% of patients, respectively); and hyperglycemia (2.3%, 2.3%, and 0% of patients, respectively). The primary Grade 4 TRAEs for the gedatolisib triplet and gedatolisib doublet groups were neutropenia (10.0% and 0.8%, respectively), leukopenia (0.8% in the gedatolisib triplet group) and pneumonitis (0.8% in gedatolisib doublet group). TRAEs led to the discontinuation of study treatment in 2.3% of patients in the gedatolisib triplet group, 3.1% in the gedatolisib doublet group, and 0% in the fulvestrant group.

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

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

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

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

- For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, median PFS was 16.6 months with the gedatolisib triplet and 7.1 months with the gedatolisib doublet versus 1.9 months for fulvestrant (HR=0.14; 95% CI: 0.08-0.28; p<0.0001).

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

With these results, the gedatolisib regimens represent a new potential standard of care for patients with HR+/HER2-, *PIK3CA* WT ABC whose disease progressed on or after treatment with a CDK4/6 inhibitor.

Results from cohort 2 of the VIKTORIA-1 Phase 3 clinical trial, the *PIK3CA* MT cohort, are expected to be available in the second quarter of 2026.

VIKTORIA-2 Phase 3 Trial

In July 2025, we dosed the first patient in VIKTORIA-2, a Phase 3, multi-center, open-label, randomized, clinical trial designed to evaluate the efficacy and safety of gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- endocrine treatment resistant ABC. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. This multi-center, international trial enrolled 35 evaluable subjects in the safety run-in portion of the study to evaluate the safety of gedatolisib when combined with ribociclib and fulvestrant. The safety run-in was completed in the first quarter of 2026. In the Phase 3 portion of the study, approximately 638 subjects are expected to be randomized and assigned to Cohort 1 (*PIK3CA* WT) or Cohort 2 (*PIK3CA* MT) based on their *PIK3CA* status. Subjects in each cohort are expected to be randomized on a 1:1 basis to either Arm A (gedatolisib with fulvestrant and ribociclib or palbociclib) or Arm B (fulvestrant and ribociclib or palbociclib). We intend to provide an update on our final Phase 3 study design in the second quarter of 2026. It is expected that approximately 200 clinical sites across North America, Europe, and Asia-Pacific will participate, including many sites included in the VIKTORIA-1 clinical trial.

CELC-G-201 Phase 1b/2 Trial

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

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

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

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

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

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

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

In the amended Phase 1/1b portion of the clinical trial, up to six patients are planned to be enrolled in each of three arms and treated with different doses. Upon completion of Phase 1, up to an additional 40 patients will be randomly assigned to up to four Phase 1b cohorts to determine the RP2D. Dose levels will be selected based on the results from the Phase 1 clinical trial. In the Phase 2 dose expansion study, which will include subjects from the Phase 1/1b clinical trial, up to 18 additional subjects will be enrolled to achieve a total of approximately 30 subjects treated with the RP2D. All patients will also receive standard doses of darolutamide.

Investigator-Sponsored Trials

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

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

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

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

Recent Developments

- In January 2026, the FDA accepted for filing our NDA for gedatolisib in HR+/HER2- PIK3CA WT ABC. The FDA granted Priority Review and assigned a PDUFA goal date of July 17, 2026.

- In March 2026, efficacy and safety results from the PIK3CA WT cohort of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib were published in the Journal of Clinical Oncology. The cohort consisted of patients with HR+/HER2-/PIK3CA WT ABC whose disease progressed while on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor.

Results of Operations

We have not generated any revenue from product sales or other sources to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2012. For the years ended December 31, 2025 and 2024, we reported a net loss of $177.0 million and $111.8 million, respectively. As of December 31, 2025, we had an accumulated deficit of $448.9 million. As of December 31, 2025, we had $441.5 million in cash, cash equivalents and short-term investments.

Components of Operating Results

Revenue

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

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

Research and Development

Since our inception, we have primarily focused on research and development of gedatolisib, a PI3K/mTOR targeted therapy. Research and development expenses primarily include:

- employee-related expenses related to our research and development activities, including salaries, benefits, recruiting, travel and stock-based compensation expenses;
- laboratory supplies;
- consulting fees paid to third parties;
- clinical trial costs;
- validation costs for gedatolisib; and
- facilities expenses.

General and Administrative

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation related to our executive, finance and support functions. Other general and administrative expenses include professional fees for auditing, tax, and legal services associated with being a public company, director and officer insurance, software costs, investor relations and travel expenses for our general and administrative personnel.

Sales and Marketing

Expenses and costs related to marketing, supply chain, distribution, market access and other commercial operations related activities are being incurred in anticipation of the commercialization of gedatolisib. These expenses consist primarily of employee-related expenses, professional and consulting fees related to these functions and operations, software costs, and the acquisition of data required to support our market analysis for gedatolisib. We expect sales and marketing expenses to increase as we get closer to a potential FDA approval date.

Interest Expense

Interest expense to date is primarily related to the A&R Loan Agreement and the Notes (each as defined below).

Interest Income

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		Increase (Decrease)	
	2025	2024	$	%
Statements of operations data:				
Operating expenses:				
Research and development	$ 144,995	$ 104,203	$ 40,792	39%
General and administrative	27,197	9,064	18,133	200
Total operating expenses	172,192	113,267	58,925	52
Loss from operations	(172,192)	(113,267)	(58,925)	52
Other (expense) income:				
Interest expense	(17,148)	(10,280)	(6,868)	67
Interest income	12,298	11,768	530	5
Other (expense) income, net	(4,850)	1,488	(6,338)	(426)
Net loss before income taxes	(177,042)	(111,779)	(65,263)	58
Income taxes	—	—	—	—
Net loss	$ (177,042)	$ (111,779)	$ (65,263)	58%

Research and Development

During the year ended December 31, 2025, our research and development expenses were $145.0 million, representing an increase of $40.8 million, or 39%, compared to 2024. The increase was primarily due to a $26.7 million increase in employee-related and consulting expenses, of which $13.1 million related to commercial headcount additions and other launch activities. The remaining increase was primarily due to a $6.0 million increase in activities supporting our ongoing clinical trials, a $5.0 million development milestone payment under the license agreement with Pfizer, and a $3.1 million increase in other costs primarily related to commercial launch activities.

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 seek to continue to develop gedatolisib, including conducting the VIKTORIA-1 and VIKTORIA-2 Phase 3 clinical trials, and the CELC-G-201 Phase 1b/2 clinical trial.

General and Administrative

During the year ended December 31, 2025, our general and administrative expenses were $27.2 million, representing an increase of $18.1 million, or 200%, compared to 2024. The increase was primarily due to a $14.9 million increase in employee-related and consulting expenses, of which $10.4 million related to non-cash stock-based compensation. The remaining $3.2 million increase was primarily due to an increase in professional fees, expanding infrastructure costs and other administrative expenses.

We anticipate that our general and administrative expenses will continue to increase in future periods, reflecting both increased costs in connection with the potential future commercialization of gedatolisib, an expanding infrastructure, and increased professional fees associated with public company regulatory developments and requirements, and other compliance matters.

Interest Expense

Interest expense during the year ended December 31, 2025, was $17.1 million and represents an increase of $6.9 million, or 67%, compared to 2024. Interest expense in 2025 is attributable to the Notes and the A&R Loan Agreement, and in 2024 is attributable to the A&R Loan Agreement. The increase is primarily due to the incremental $61.7 million funding of the Term Loan C in May 2024, the issuance of $201.3 million aggregate principal amount of Notes in July 2025 and the $30.0 million distribution of the Term Loan D in September 2025. The $17.1 million of interest expense includes $4.2 million of non-cash interest expense.

Interest Income

Interest income during the year ended December 31, 2025 was $12.3 million and represents an increase of $0.5 million, or 5%, compared to 2024. The increase was primarily the result of a higher invested cash balance, partially offset by lower market interest rates.

Liquidity and Capital Resources

Liquidity

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through December 31, 2025, 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 December 31, 2025, we raised an aggregate of $506.8 million of net proceeds through sales of our securities, $194.9 million of net proceeds through the issuance of the Notes, and $130.0 million of gross proceeds through borrowings under loan agreements, not including payable-in-kind interest. As of December 31, 2025, our cash and cash equivalents and short-term investments were $165.7 million and $275.8 million, respectively, and we had an accumulated deficit of $448.9 million.

Capital Resources

To help meet our liquidity requirements, we have entered into various equity and financing arrangements. As of December 31, 2025, our material cash requirements for the operations of our business consisted primarily of the current and long-term liabilities noted on our balance sheets, as well as other commitments, including the following notable items:

- In July 2025, we issued and sold 2,172,368 Shares and Pre-Funded Warrants to purchase up to 400,000 shares of common stock pursuant to the Equity Underwriting Agreement with the Representatives of the Underwriters, resulting in net proceeds of $91.6 million (see Note 8. Stockholders' Equity).
- In August 2025, we issued $201.3 million aggregate principal amount of convertible notes, resulting in net proceeds of $194.9 million (see Note 10. Debt).
- During 2025 and 2024, investors exercised 5,282,375 and 1,827,357 warrants, net of shares withheld for exercise price, respectively, which generated $42.1 million and $14.7 million in cash, respectively (see Note 8. Stockholders' Equity).

- 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. In May 2024 and April 2024, we sold 149,700 and 285,714 shares of common stock, respectively, at an average selling price of $17.55 per share, generating net proceeds of $7.3 million after deducting commissions and other offering expenses of $0.3 million (see Note 8. Stockholders' Equity and Note 13. Subsequent Events).
- In May 2024, we issued and sold 3,871,000 shares of common stock pursuant to an underwriting agreement with Leerink Partners LLC, TD Securities (USA) LLC and Stifel, Nicolaus & Company, Incorporated, resulting in net proceeds of $56.3 million (see Note 8. Stockholders' Equity).
- In September 2025, we entered into the Third Amendment (the "Third Amendment") to the Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement"); in July 2025, we entered into the Second Amendment to the A&R Loan Agreement; and in May 2025, we entered into the First Amendment to the A&R Loan Agreement. In May 2024, we entered into the A&R Loan Agreement, which amended and restated, in its entirety, the Loan and Security Agreement, dated April 8, 2021, as amended, between us and Innovatus, as collateral agent, and the Lenders named therein (the "Prior Loan Agreement").

  In September 2025, we received funding of the $30.0 million Term D Loan (as defined in the Amended A&R Loan Agreement) upon achievement of the Term D Milestone (as defined in the Amended A&R Loan Agreement), resulting in net proceeds of $27.7 million. In connection with the funding of the Term D Loan, we issued warrants with an exercise price of $14.84 per share to purchase an aggregate of 50,537 shares of our common stock to Innovatus, Oxford, and certain of its affiliates. Subsequent to the Third Amendment, we may draw (i) up to $100.0 million under Term E Loan (as defined in the Amended A&R Loan Agreement) upon FDA approval of gedatolisib in second line wild-type ABC patients post CDK4/6 inhibitor therapy; (ii) up to three $40.0 million Term F Loans (as defined in the Amended A&R Loan Agreement), for a total of $120.0 million, upon achievement of certain trailing three months' product revenue thresholds; and (iii) up to $150.0 million Term G Loan (as defined in the Amended A&R Loan Agreement), which continues to be available only in the Lenders' sole discretion upon our request. The term loans include financial covenants related to liquidity and other financial measures and have a maturity date of November 1, 2029.

  In May 2024, we received funding of the first $100 million under the A&R Loan Agreement, including tranche payments of $16.8 million (the "Term A Loan") and $21.5 million (the "Term B Loan") reflecting repayment of the principal amount of loans under the Prior Loan Agreement plus accrued payment-in-kind interest, in addition to $61.7 million of new borrowings (the "Term C Loan"), resulting in net proceeds of $59.2 million. In connection with the funding of the Term C Loan, we issued warrants with an exercise price of $14.84 per share to purchase an aggregate of 103,876 shares of our common stock to Innovatus and Oxford (see Note 10. Debt).

Liquidity and capital resource requirements

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

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

Our expectations as to how long our current capital resources will be sufficient to fund our operations are based on assumptions that may not be accurate, and we could use our current capital resources sooner than we currently expect. In addition, we may seek to raise additional capital to finance capital expenditures and operating expenses over the next several years as we seek to obtain approval for and launch gedatolisib; expand our infrastructure, commercial operations and research and development activities; and take advantage of financing or other opportunities that we believe to be in the best interests of the Company and our stockholders. Additional capital may be raised through the sale of common or preferred equity or convertible debt securities, entry into debt facilities or other third-party funding arrangements. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common stock. Agreements entered into in connection with such capital raising activities could contain covenants that would restrict our operations or require us to relinquish certain rights. Additional capital may not be available on reasonable terms, or at all.

Cash Flows

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

	Year Ended December 31,	
	2025	**2024**
Net cash and cash equivalents (used in) provided by:		
Operating activities	$ (153,280)	$ (83,467)
Investing activities	(64,084)	(63,069)
Financing activities	360,552	138,388
Net increase (decrease) in cash and cash equivalents	$ 143,188	$ (8,148)

Operating Activities

Net cash used in operating activities was $153.3 million during the year ended December 31, 2025, and consisted of a net loss of $177.0 million and working capital changes of $2.7 million, partially offset by non-cash expenses of $26.4 million. The $2.7 million decrease in working capital consisted of a $15.4 million increase in accrued expenses, partially offset by a $15.1 million increase in prepaid expenses and other current and non-current assets and a $3.0 million decrease in accounts payable. The $26.4 million of non-cash expenses consisted of $21.4 million of stock-based compensation expense, net non-cash interest income and expense of $4.8 million, and depreciation expense of $0.2 million.

Net cash used in operating activities was $83.5 million during the year ended December 31, 2024, and consisted of a net loss of $111.8 million, partially offset by working capital changes of $18.3 million and non-cash expenses of $10.0 million. The $18.3 million increase in working capital consisted of a $13.2 million increase in accrued expenses, a $4.3 million increase in accounts payable, and a $0.8 million decrease in prepaid expenses and other current and non-current assets. The $10.0 million of non-cash expenses consisted of $7.0 million of stock-based compensation expense, net non-cash interest income and expense of $2.9 million, and depreciation expense of $0.1 million.

Investing Activities

Net cash used in investing activities was $64.1 million during the year ended December 31, 2025, and consisted of $63.9 million of net purchases of short-term investments in U.S. treasury securities and $0.2 million in purchases of property and equipment.

Net cash used in investing activities was $63.1 million during the year ended December 31, 2024, and consisted of $62.8 million of net purchases of short-term investments in U.S. treasury securities and $0.3 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $360.6 million during the year ended December 31, 2025, and consisted primarily of net proceeds of $195.0 million from the Note Offering, $91.6 million from the Equity Offering, and $27.7 million from the Term D Loan. In addition, cash provided by financing activities consisted of proceeds of $42.1 million from the exercise of common stock warrants and $4.2 million from the exercise of employee stock options and employee stock purchases.

Net cash provided by financing activities was $138.4 million during the year ended December 31, 2024, and consisted primarily of net proceeds of $59.2 million from the Term C Loan incremental funding, $56.3 million from an equity offering, and $7.3 million from the at-the-market offering. In addition, cash provided by financing activities consisted of proceeds of $14.7 million from the exercise of common stock warrants and $1.1 million from the exercise of employee stock options and employee stock purchases, partially offset by $0.2 million of secondary registration statement costs.

RECENT ACCOUNTING PRONOUNCEMENTS

From time-to-time new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed in Note 2 to our financial statements included elsewhere in this Annual Report, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or Generally Accepted Accounted Principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates.

Our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report. Of our significant accounting policies, we believe that the following reflect the critical accounting estimates used in the preparation of our financial statements:

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis with forfeitures recognized as they occur.

We estimate the fair value of option grants using the Black-Scholes option-pricing model and the fair value of awards with market-based vesting conditions using the Monte Carlo simulation model. Estimating the fair value of equity awards using these valuation models is affected by assumptions regarding a number of variables, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, expected dividends, and the price per share of our common stock on the grant date. Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Clinical Trial Costs

We record prepaid or accrued clinical trial costs conducted by third-party service providers, which includes the conduct of clinical trials. These costs can be a significant component of our research and development expenses. We use progress reports from third-party service providers, including the respective invoicing, to record actual expenses, along with determining changes to prepaid or accrued clinical trial costs. With the ongoing clinical trials, our estimated expenses in future periods and actual services performed may vary from these estimates, and these estimates may become more significant. Changes in these estimates that result in material changes to our prepaid or accrued clinical trial costs could materially affect our results of operations and financial position.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

ITEM 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Celcuity Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Celcuity Inc. (the Company) as of December 31, 2025 and 2024, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

We have served as the Company's auditor since 2017.

Minneapolis, Minnesota
March 26, 2026
PCAOB ID: 542

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 165,703	$ 22,515
Investments	275,794	212,589
Prepaid clinical trial costs	18,896	6,769
Other current assets	5,266	2,698
Total current assets	465,659	244,571
Property and equipment, net	499	336
Operating lease right-of-use assets	51	216
Other non-current assets	349	—
Total assets	$ 466,558	$ 245,123
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,407	$ 9,366
Accrued clinical trial costs	16,826	16,708
Other accrued expenses	20,865	5,477
Operating lease liabilities, current	54	172
Total current liabilities	44,152	31,723
Operating lease liabilities, non-current	—	54
Convertible debt	195,324	—
Note payable, non-current	126,527	97,727
Total liabilities	366,003	129,504
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value: 2,500,000 shares authorized as of December 31, 2025 and 2024; 0 and 317,577 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Common stock, $0.001 par value: 95,000,000 shares authorized as of December 31, 2025 and 2024; 48,244,960 and 37,143,242 shares issued and outstanding as of December 31, 2025 and 2024, respectively	48	37
Additional paid-in capital	549,404	387,437
Accumulated deficit	(448,897)	(271,855)
Total stockholders' equity	100,555	115,619
Total liabilities and stockholders' equity	$ 466,558	$ 245,123

See accompanying notes to the financial statements.

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

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 144,995	$ 104,203
General and administrative	27,197	9,064
Total operating expenses	172,192	113,267
Loss from operations	(172,192)	(113,267)
Other (expense) income:		
Interest expense	(17,148)	(10,280)
Interest income	12,298	11,768
Other (expense) income, net	(4,850)	1,488
Net loss before income taxes	(177,042)	(111,779)
Income taxes	—	—
Net loss	$ (177,042)	$ (111,779)
Net loss per share, basic and diluted	$ (3.79)	$ (2.83)
Weighted average common shares outstanding, basic and diluted	46,757,691	39,449,393

See accompanying notes to the financial statements.

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

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2023	25,506,012	$ 26	854,134	$ 1	$ 299,818	$ (160,076)	$ 139,769
Stock-based compensation	1,429	—	—	—	6,988	—	6,988
Conversion of preferred stock to common stock	5,365,570	5	(536,557)	(1)	(4)	—	—
Employee stock purchases	33,215	—	—	—	276	—	276
Exercise of common stock options, net of shares withheld for exercise price	103,245	—	—	—	770	—	770
Exercise of common stock warrants, net of shares withheld for exercise price	1,827,357	2	—	—	14,734	—	14,736
Issuance of common stock in an ATM offering, net of issuance costs	435,414	—	—	—	7,378	—	7,378
Issuance of common stock upon closing of follow-on offering, net of underwriting discounts and offering costs	3,871,000	4	—	—	56,248	—	56,252
Issuance of common stock warrants, note payable	—	—	—	—	1,229	—	1,229
Net loss	—	—	—	—	—	(111,779)	(111,779)
Balance as of December 31, 2024	37,143,242	37	317,577	—	387,437	(271,855)	115,619
Stock-based compensation	1,029	—	—	—	21,383	—	21,383
Conversion of preferred stock to common stock	3,175,770	3	(317,577)	—	(3)	—	—
Employee stock purchases	77,090	—	—	—	711	—	711
Exercise of common stock options, net of shares withheld for exercise price	393,086	—	—	—	3,485	—	3,485
Exercise of common stock warrants, net of shares withheld for exercise price	5,282,375	6	—	—	42,055	—	42,061
Issuance of common stock warrants in connection with note agreement	—	—	—	—	2,786	—	2,786
Issuance of common stock upon closing of equity offering, net of underwriting discounts and offering costs	2,172,368	2	—	—	91,550	—	91,552
Net loss	—	—	—	—	—	(177,042)	(177,042)
Balance as of December 31, 2025	48,244,960	$ 48	—	$ —	$ 549,404	$ (448,897)	$ 100,555

See accompanying notes to the financial statements.

Celcuity Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (177,042)	$ (111,779)
Adjustments to reconcile net loss to net cash and cash equivalents used in operations:		
Depreciation	167	130
Stock-based compensation	21,383	6,988
Amortization of debt issuance costs and discount	3,137	1,331
Payment-in-kind interest	1,104	1,364
Non-cash operating lease expense	(7)	—
Change in accrued interest income	630	150
Changes in operating assets and liabilities:		
Prepaid clinical trial costs	(12,127)	(1,994)
Other current and non-current assets	(2,991)	2,770
Accounts payable	(3,040)	4,316
Accrued clinical trial costs	118	10,244
Other accrued expenses	15,388	3,013
Net cash used in operating activities	(153,280)	(83,467)
Cash flows from investing activities:		
Proceeds from maturities of investments	332,507	642,346
Purchases of investments	(396,342)	(705,165)
Purchases of property and equipment	(249)	(250)
Net cash used in investing activities	(64,084)	(63,069)
Cash flows from financing activities:		
Proceeds from employee stock purchases	711	276
Proceeds from exercise of common stock options	3,485	770
Proceeds from exercise of common stock warrants	42,061	14,736
Proceeds from convertible debt, net of debt issuance costs of $6,246 and $0 during the years ended December 31, 2025 and 2024, respectively	195,004	—
Proceeds from note payable, net of debt issuance costs of $2,255 and $2,438 during the years ended December 31, 2025 and 2024, respectively	27,745	59,226
Proceeds from equity offering, net of underwriting discounts and offering costs	91,592	56,252
Proceeds from an ATM offering, net of issuance costs	—	7,356
Payments for secondary registration statement costs	(46)	(228)
Net cash provided by financing activities	360,552	138,388
Net change in cash and cash equivalents	143,188	(8,148)
Cash and cash equivalents:		
Beginning of period	22,515	30,663
End of period	$ 165,703	$ 22,515
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 10,348	$ 7,586
Cash paid for operating leases	$ 220	$ 325
Supplemental disclosures of non-cash investing and financing activities:		
Common stock warrants issued with the note payable transaction	$ 2,786	$ 1,229
Property and equipment included in accounts payable	$ 82	$ 1
Deferred financing, offering and registration statement costs included in accounts payable	$ —	$ 42

See accompanying notes to the financial statements.

CELCUITY INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization and Liquidity

Organization

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. The Company's lead therapeutic candidate is gedatolisib, a kinase inhibitor of the phosphatidylinositol 3-kinase ("PI3K"), serine/threonine-protein kinase protein kinase B ("AKT"), mechanistic target of rapamycin ("mTOR") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PI3K/AKT/mTOR ("PAM") pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) ("HR+/HER2-") advanced breast cancer ("ABC") has completed enrollment and reported detailed results for cohort 1, patients with *PIK3CA* wild-type ("WT") tumors, and has completed enrollment of cohort 2, patients with *PIK3CA* mutant-type ("MT") tumors. Our Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib in combination with a cyclin-dependent kinase ("CDK") 4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC is ongoing. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is ongoing. The Company was co-founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota. The Company has not generated any revenue to date.

Liquidity

Since inception, the Company has not generated any revenue from product sales or other sources and has incurred operating losses and negative cash flows from operations. The Company's primary uses of cash, cash equivalents, and investments to date have been funding clinical trials and research and development activities, the scaling of commercial launch related activities such as marketing, supply chain, distribution, market access and other commercial operations, business planning, establishing and maintaining the Company's intellectual property portfolio, hiring personnel, leasing premises and associated capital expenditures, raising capital, and providing general and administrative support for these operations. As of December 31, 2025, the Company had an accumulated deficit of $448.9 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 December 31, 2025, the Company had $441.5 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 financial statements.

The Company is subject to risks common to companies in the development stage including, but not limited to, the clinical and commercial success of its initial drug product, gedatolisib, the regulatory approval of gedatolisib, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying 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 Securities and Exchange Commission (the "SEC"). Operating results during the year ended December 31, 2025, are not necessarily indicative of results to be expected for any future year.

Accounting Estimates

Management uses estimates and assumptions in preparing these 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 prepaid or accrued clinical trial costs.

Cash and Cash Equivalents

The Company maintains its accounts at two financial institutions. As of December 31, 2025 and 2024, the Company had $165.7 million and $22.5 million, respectively, in business checking accounts and money market funds that are considered cash equivalents. Cash and cash equivalents are classified as Level 1 assets under the fair value hierarchy.

Investments

The Company maintains its investments in U.S. treasury securities and has classified them as held-to-maturity at the time of purchase. Held-to-maturity purchases are those investments which the Company has the ability and intent to hold until maturity. Held-to-maturity investments are recorded at amortized cost, adjusted for the amortization or accretion of premiums and discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity investment using the straight-line method. The difference between the carrying value, which is based on cost, and the aggregate fair value of the held-to-maturity investments, was immaterial as of December 31, 2025. As of December 31, 2025 and 2024, the Company had $275.8 million and $212.6 million, respectively, of short-term investments.

Fair Value of Financial Instruments

The Company's accounting for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adheres to the Financial Accounting Standards Board ("FASB") fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date.
- Level 2: Other than quoted prices included in Level 1, inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3: Unobservable inputs that are significant to the fair value measurement and supported by little or no market activity.

The level in the fair value hierarchy within which a fair value measurement in its entirety falls, is based on the lowest level input that is significant to the fair value measurement in its entirety.

The carrying values of cash equivalents, accounts payable, accrued expenses and other financial working capital items approximate fair value as of each of December 31, 2025 and 2024, due to the short maturity nature of these items. Refer to Note 10 for disclosures around the Company's 2.750% Senior Notes due 2031 (the "Notes") and note payable.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash, cash equivalents, and investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Allowance for Credit Losses

For investments in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the investment before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the investment's amortized cost basis is written down to fair value through earnings. For investments that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes in interest rates, and any changes to the rating of the security by a rating agency, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the investment. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive loss.

Property and Equipment

Property and equipment are stated at cost. Depreciation is provided over estimated useful lives using the straight-line method. Maintenance and repairs are expensed as incurred; major improvements and betterments are capitalized.

Estimated useful lives of property and equipment are as follows for the major classes of assets:

Asset description	Estimated useful life
Furniture and equipment	4 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances presented in the arrangement, including whether the Company controls the use of identified assets. The Company classifies leases with a term greater than one year as either operating or finance leases at the lease commencement date and records a right-of-use asset and current and non-current lease liabilities, as applicable, on the balance sheets. The Company has elected not to recognize on the balance sheets leases with terms of one year or less, but payments are recognized as expense on a straight-line basis over the lease term.

The Company's leases may include options to extend or terminate the leases. Periods covered by an option to extend the lease are included in the lease term when it is reasonably certain that the Company will exercise that option. Periods covered by an option to terminate the lease are included in the lease term when it is reasonably certain that the Company will not exercise that option. The Company monitors its plans to renew or terminate its material leases each reporting period. If a lease includes provisions for leasehold improvements for which the Company has an obligation to pay, the Company determines if the improvements should be considered lessor or lessee assets. If the improvements are considered lessor assets, the Company records the payments in the calculation of the lease liability and corresponding right-of-use asset.

Lease liabilities and the corresponding right-of-use assets are recorded based on the present value of lease payments over the remaining lease term. The present value of future lease payments is discounted using the interest rate implicit in the lease contracts if that rate is readily determinable; otherwise, the Company utilizes information available at the commencement of the lease to calculate the incremental borrowing rate, which reflects the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment.

Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected to account for the lease and non-lease components together as a single component for all classes of underlying assets.

Capitalized Software Development Costs

The Company capitalizes qualifying costs incurred during the application development stage related to software developed for internal use. Capitalized software development costs are classified as other non-current assets on the balance sheets. As of December 31, 2025 and 2024, the Company had $0.1 million and no capitalized software development costs, respectively.

The Company amortizes the capitalized software development costs on a straight-line basis over the estimated useful life of the software, beginning when the asset is substantially ready for use. The amortization of capitalized software development costs is reflected in general and administrative expenses. The Company did not record any amortization expense during the years ended December 31, 2025 and 2024.

Long-Lived Assets

Long-lived assets, such as property and equipment, 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.

Deferred Transaction Costs

Deferred transaction costs primarily consist of legal fees that are capitalized as incurred and will be offset against the proceeds from future equity financing arrangements. The deferred transaction costs will be reviewed periodically to assess the probability that future securities will be offered. In the event that no future offering will occur, any deferred transaction costs will be expensed. Total costs incurred, but not accounted for as a reduction in equity, were $0.2 million and $0.2 million as of December 31, 2025 and 2024, respectively. Deferred transaction costs are classified as other assets on the balance sheets.

Debt Issuance Costs

The Company recognizes debt issuance costs as deferred costs, which are capitalized and amortized over the term of the related debt using the effective interest method. These costs primarily consist of fees, commissions, and legal and other costs directly attributable to securing debt financing. Debt issuance costs are reported as a direct reduction of the carrying amount of the related debt on the balance sheets. Amortization of these costs is recorded as interest expense in the statements of operations over the life of the debt instrument. In the event of early extinguishment of debt, any related unamortized debt issuance costs are written off and recognized as a component of the gain or loss on extinguishment of debt in the statements of operations.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For all periods presented, there was no difference between net loss and comprehensive loss.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount, the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2025 and 2024.

Stock-Based Compensation

The Company's stock-based compensation consists of stock options, restricted stock awards and restricted stock units issued to certain employees and non-employees of the Company under the 2017 Amended and Restated Stock Incentive Plan, and shares issued under the 2017 Employee Stock Purchase Plan (the "ESPP").

The Company has elected to account for forfeitures as they occur.

Stock Options

The Company recognizes stock-based compensation expense based on the estimated grant date fair value using the Black-Scholes option-pricing model and the expense is recognized on a straight-line basis over the requisite service period. Compensation expense for awards with performance-based conditions is recognized when the achievement of the performance condition is deemed probable.

The Company utilizes the Monte Carlo simulation model for awards with market-based vesting conditions. If the factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

The inputs for the Black-Scholes valuation model and the Monte Carlo simulation model require management's significant assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. The expected volatility is estimated based on historical volatility information of peer companies that are publicly available in combination with the Company's calculated volatility since being publicly traded. The expected term of the award is based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. The risk-free interest rate is based on the rate for U.S. treasury securities at the date of grant with maturity dates approximately equal to the expected term of the award at the grant date. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date.

All assumptions used to calculate the grant date fair value of non-employee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options issued in connection with such agreements would also be cancelled.

Restricted Stock

The Company records compensation expense based on the quoted fair value of the shares on the grant date over the requisite service period.

ESPP

Compensation expense for ESPP rights is recorded in line with each respective offering period.

Research and Development

Research and development costs are expensed as incurred. Research and development costs were $145.0 million and $104.2 million during the years ended December 31, 2025 and 2024, respectively.

Clinical Trial Costs

The Company relies on third-party service providers to conduct certain aspects of clinical studies and to formulate and manufacture its drug product. While there are alternative vendors that can perform these functions, any disruption or delay by the Company's current third-party service providers in carrying out their contractual duties could delay its clinical trials and/or the commercial launch of gedatolisib, if approved by the U.S. Food and Drug Administration ("FDA"). The Company records prepaid or accrued clinical trial costs conducted by third-party service providers, which includes the conduct of clinical trials. These costs can be a significant component of the Company's research and development expenses. The Company uses progress reports from third-party service providers, including the respective invoicing, to record actual expenses, along with determining changes to prepaid or accrued clinical trial costs. With the ongoing clinical trials, the Company's estimated expenses in future periods and actual services performed may vary from these estimates, and these estimates may become more significant. Changes in these estimates that result in material changes to the Company's prepaid or accrued clinical trial costs could materially affect the Company's results of operations and financial position.

Licenses

Upfront payments and other consideration under license agreements are expensed as research and development expense upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

Certain license agreements include milestone payments which are recognized when it becomes probable that the achievement of those milestones will be met. The Company records this expense as research and development expense in its statements of operations.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the statements of operations.

Income Taxes

The Company accounts for income taxes using the asset and liability method, as required by the accounting standard for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, as well as net operating loss and tax credit carryforwards. Deferred taxes are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred taxes of a change in tax rates is recognized in results of operations in the period that includes the enactment date. The effects of any future changes in tax laws or rates have not been considered. The Company regularly reviews deferred tax assets to assess their potential realization and establish a valuation allowance for portions of such assets to reduce the carrying value if the Company does not consider it to be more likely than not that the deferred tax assets will be realized.

The Company recognizes the impact of an uncertain tax position in its financial statements if, in management's judgment, the position is more-likely-than-not sustainable upon audit based on the position's technical merits. This involves the identification of potential uncertain tax positions, the evaluation of applicable tax laws and an assessment of whether a liability for an uncertain tax position is necessary.

Segment Data

The Company has one reportable operating segment, which is the development of targeted therapies for the treatment of multiple solid tumor indications. The Company's chief operating decision makers ("CODMs") are its chief executive officer, chief science officer and chief financial officer, who, together manage the Company's operations as one operating segment for the purpose of evaluating financial performance and allocating resources. The CODMs assess the performance and allocate resources for the reportable segment based on net loss and total assets, which are the same amounts in all material respects as those reported in the statements of operations and balance sheets.

Recently Adopted Accounting Pronouncements

In December 2023, 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.

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 financial statements and related disclosures.

In July 2025, the FASB issued ASU 2025-05, *Measurement of Credit Losses for Accounts Receivable and Contract Assets* ("ASU 2025-05"), which provides certain entities with an additional practical expedient for estimating expected credit losses on current accounts receivable and current contract assets arising from revenue transactions under Accounting Standards Codification ("ASC") 606. ASU 2025-05 is effective for all entities for annual and interim periods in fiscal years beginning after December 15, 2025. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2025-05 on its 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. The guidance may be applied on a prospective basis, a modified basis for in-process projects, or a retrospective basis. The Company is currently evaluating the timing, method of its adoption, and effect of ASU 2025-06 on its financial statements and related disclosures.

3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the options, convertible note, warrants, restricted stock 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:

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	5,842,485	4,306,977
Convertible note as-if-converted-to-common stock	5,296,053	—
Warrants to purchase common stock	274,773	5,521,152
Restricted common stock	27,439	1,079
Preferred stock as-if-converted-to-common stock	—	3,175,770
Total	11,440,750	13,004,978

The maximum number of shares of common stock issuable upon conversion of the Notes is 5,296,053. As of December 31, 2025, the number of shares issuable based on the Company's closing common stock price would be 3,923,002 if the Notes were converted in full.

During the years ended December 31, 2025 and 2024, pre-funded warrant shares of 6,147,787 and 5,747,787, respectively, were included in the computation of basic and diluted net loss per share, as the pre-funded warrants are exercisable for nominal consideration.

4. Investments

Debt investments for which the Company has the positive intent and ability to hold to maturity are classified as held-to-maturity and reported at historical cost adjusted for amortization of premiums and accretion of discounts. Expected credit losses, if any, are recorded through the establishment of an allowance for credit losses. All of the Company's held-to-maturity investments are U.S. treasury securities that are guaranteed or otherwise supported by the United States government and have no history of credit losses. Accordingly, the Company does not expect to incur any credit losses on held-to-maturity investments and has no allowance for credit losses recorded for these investments. As of December 31, 2025, all of the Company's held-to-maturity investments had maturities of one year or less.

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

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

	As of December 31, 2024			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
U.S. treasury securities	$ 212,589	$ 82	$ —	$ 212,671
Total	$ 212,589	$ 82	$ —	$ 212,671

The Company's U.S. treasury securities are classified as Level 2 investments within the fair value hierarchy. These assets have been valued based on quoted prices in active markets for similar assets or other inputs that are observable or can be corroborated by observable market data.

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

5. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Furniture and equipment	$ 2,354	$ 2,025
Leasehold improvements	304	303
Total property and equipment, gross	2,658	2,328
Less: Accumulated depreciation	(2,159)	(1,992)
Total property and equipment, net	$ 499	$ 336

Depreciation expense was $0.2 million and $0.1 million during the years ended December 31, 2025 and 2024, respectively.

6. Other Accrued Expenses

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

	As of December 31,	
	2025	2024
Employee compensation and benefits	$ 8,338	$ 4,092
License milestone	5,000	—
Interest	3,379	—
Consulting and professional fees	2,335	511
Other	1,813	874
Total	$ 20,865	$ 5,477

As of December 31, 2025, and 2024, accounts payable included $0 and $820 of accrued interest, respectively.

7. Commitments

Operating and Finance Leases

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

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 will commence on April 1, 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. As of December 31, 2025, the lease has not commenced and is therefore excluded from the tables below.

When an implicit rate is not provided, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Future minimum lease payments under the Company's Existing Lease consisted of the following (in thousands):

Year Ending December 31,	
2026	$ 74
Thereafter	—
Total minimum lease payments	74
Less: Amount representing interest	(20)
Present value of operating lease liabilities	54
Less: operating lease liabilities, current	(54)
Operating lease liabilities, non-current	$ —

The weighted-average remaining lease term and discount rate under the Company's Existing Lease were as follows:

	As of December 31,	
	2025	**2024**
Weighted-average remaining lease term	0.3 years	1.3 years
Weighted-average discount rate	10.5%	10.5%

The following table presents components of lease costs (in thousands):

	Year Ended December 31,	
	2025	**2024**
Operating lease cost	$ 213	$ 213
Variable lease cost	110	111
Total lease cost	$ 323	$ 324

Clinical Research Studies

The Company enters into contracts in the normal course of business to conduct research and development programs internally and through third-party service providers that include, among others, arrangements with vendors, consultants, contract manufacturing organizations, and contract research organizations. Contracts related to the Company's ongoing clinical trials are generally cancelable with advance notice and the Company's obligations under these contracts are primarily based on services performed through termination dates plus certain cancelation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subject to amendments as a result of any change orders executed. As of December 31, 2025, the Company had $5.5 million of non-cancelable purchase commitments with respect to these arrangements.

Registration Rights Agreement

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

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

The Company accounts for these arrangements in accordance with ASC 825-20, *Registration Payment Arrangements*. As of December 31, 2025, the required registration statement has been timely filed and declared effective by the SEC, and 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

Capital Stock

As of December 31, 2025, the Company's authorized capital stock consisted of 95,000,000 shares of common stock, of which 48,244,960 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 December 31, 2025, no dividends have been declared on the Company's capital stock.

July 2025 Equity Offering

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

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

Each Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of $0.001 per share, or alternatively, at the election of each holder, shares of common stock may be issued through a cashless exercise, with the net number of shares of common stock determined according to the formula set forth in each Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance until all of the Pre-Funded Warrants are exercised. A holder (together with its "attribution parties," as defined in the Pre-Funded Warrant) may not exercise any portion of the Pre-Funded Warrants if immediately after exercise, the holder (together with its attribution parties), would beneficially own in excess of 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise. However, a holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, which increase or decrease shall not become effective until 61 days after notice from the holder to the Company.

Sale and Issuance of Stock

On May 30, 2024, the Company entered into an underwriting agreement with Leerink Partners LLC, TD Securities (USA) LLC and Stifel, Nicolaus & Company, Incorporated as representatives of the several underwriters relating to the issuance and sale of 3,871,000 shares of common stock, at a price to the public of $15.50 per share, generating gross proceeds of $60.0 million. The offering closed on May 31, 2024 and resulted in net proceeds to the Company of $56.3 million after deducting underwriting discounts and other offering expenses payable by the Company.

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

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

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

Common Stock Warrants

As of December 31, 2025, the Company had the following common stock warrants outstanding:

Issue Date	Expiration Date	Warrants Outstanding	Exercise Price	Offering
1/21/2016	1/14/2026	28,716	$ 7.56	Private placement offering – issued to placement agent
5/2/2016	5/2/2026	18,175	7.56	Private placement offering – issued to placement agent
4/28/2017	4/28/2027	32,458	8.42	Private placement offering – issued to placement agent
5/17/2017	5/17/2027	14,969	8.42	Private placement offering – issued to placement agent
4/8/2021	4/8/2031	26,042	14.40	Debt financing – issued to lender
5/30/2024	5/30/2034	84,227	14.84	Debt financing – issued to lender
5/30/2024	5/30/2034	19,649	14.84	Debt financing – issued to lender
9/9/2025	9/9/2035	25,269	14.84	Debt financing – issued to lender
9/9/2025	9/9/2035	25,268	14.84	Debt financing – issued to lender
10/18/2023	N/A	5,747,787	0.001	Private placement offering – issued to investors
7/31/2025	N/A	400,000	0.001	Equity offering – issued to underwriters
Total warrants outstanding		**6,422,560**		

Pre-Funded Warrants

On October 18, 2023, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain investors (the "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, par value $0.001 per share. Each warrant to purchase one share had a purchase price of $8.699 per share, and an exercise price of $0.001 per share for the common stock issuable upon exercise of the warrant.

Each warrant is immediately exercisable and will not expire. Under the terms of the warrants, the Company may not effect the exercise of any such warrant, and a holder will not be entitled to exercise any portion of any warrant, if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder's affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder's or any of the holder's affiliates for purposes of Section 13(d) or Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) would exceed 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the SEC (the "Maximum Percentage"). A holder may reset the Maximum Percentage to a higher percentage (not to exceed 19.99%), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of warrants.

The Securities Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.

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, 2024	11,268,939	$ 4.04
Issued	450,537	1.67
Exercised	(5,282,375)	8.07
Surrendered upon cashless exercise	(14,541)	10.43
Expired	—	—
Outstanding as of December 31, 2025	6,422,560	$ 0.53

During the year ended December 31, 2024, several of the Company's investors exercised 1,827,357 common stock warrants, net of shares withheld for the exercise price, at exercise prices ranging between $8.05 and $9.50 per share, which generated $14.7 million in cash. During the year ended December 31, 2024, 3,544 common stock warrants expired.

Preferred Stock

Series A preferred stock

The Series A preferred stock is non-voting, and each share is convertible at the option of the holder, subject to certain limitations, into 10 shares of common stock. Holders of Series A preferred stock are entitled to receive dividends, on an as-if-converted-to-common stock basis, when, as and if, and in the same form as, dividends are actually paid on the common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or in the event of a Deemed Liquidation Event (as defined in the Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock), the holders of Series A preferred stock are entitled to be paid from assets of the Company available for distribution to its stockholders, before any payment is made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the original issue price ($5.75 on an as-converted-to-common stock basis), plus all accrued and unpaid dividends and (ii) the amount that the holder would have been entitled to receive at such time if the Series A preferred stock were converted into common stock. The Company may not, without the consent of holders of a majority of the outstanding shares of Series A preferred stock, amend its charter in a manner that adversely affects the powers, preferences or rights of the Series A preferred stock or issue or obligate itself to issue shares of any additional class or series of capital stock unless the same ranks junior to the Series A preferred stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company and the payment of dividends.

During the year ended December 31, 2025, 317,577 shares of Series A preferred stock were converted into 3,175,770 shares of common stock. As of December 31, 2025, no shares of Series A preferred stock were outstanding.

9. Stock-Based Compensation

2012 Equity Incentive Plan

In August 2012, the Company adopted the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan provided for options, restricted stock awards, performance stock awards and stock bonuses. The exercise price of each option granted under the 2012 Plan is not less than 100% of the fair market value of one share on the date of grant. The maximum permitted term of options granted under the 2012 Plan is ten years. The Company's board of directors administers the 2012 Plan and determines the provisions of incentive awards, including eligible recipients, number of shares subject to an incentive award, exercise price, vesting schedule, duration of an incentive award and other restrictions an incentive award may be subject to. In September 2017, the 2012 Plan was frozen and no further awards may be made under the 2012 Plan.

2017 Amended and Restated Stock Incentive Plan

In September 2017, the Company adopted the 2017 Amended and Restated Stock Incentive Plan (the "2017 Plan"). The 2017 Plan provides for the grant of options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards and stock bonuses. The exercise price of each option granted under the 2017 Plan is not less than 100% of the fair market value of one share on the date of grant. The maximum permitted term of options granted under the 2017 Plan is ten years. The 2017 Plan is generally administered by the compensation committee of the board of directors, which has the authority to interpret the 2017 Plan, grant awards and make all other determinations necessary for the administration of the 2017 Plan.

The number of shares reserved for issuance under the 2017 Plan will automatically increase on January 1 of each year from 2026 to 2027 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 Company's board of directors may reduce the amount of the increase in any particular year. The number of shares reserved for issuance under the 2017 Plan was automatically increased by 371,432 and 255,060 shares on January 1, 2025 and 2024, respectively.

During the years ended December 31, 2025 and 2024, the board of directors and the stockholders approved additional increases of 3,000,000 and 1,500,000, respectively, to the number of shares reserved for issuance under the 2017 Plan.

As of December 31, 2025, the number of shares available for issuance under the 2017 Plan is 2,591,634.

Stock Options

Options granted under the 2017 Plan are exercisable at various dates as determined upon grant and will expire no more than 10 years from their date of grant. The exercise price of each option shall be determined by the board of directors based on the estimated fair value of the Company's common stock on the grant date. The exercise price shall not be less than 100% of the fair market value of the Company's common stock on the grant date. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years. The 2017 Plan is generally administered by the compensation committee of the board of directors, which has the authority to interpret the 2017 Plan, grant awards and make all other determinations necessary for the administration of the 2017 Plan.

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

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term	Aggregate intrinsic value
			(in years)	(in thousands)
Options outstanding as of December 31, 2024	4,306,977	$ 11.13	8.0	$ 13,914
Granted	2,186,593	35.17		
Exercised	(393,301)	8.89		
Forfeited	(257,784)	14.29		
Options outstanding as of December 31, 2025	5,842,485	$ 19.62	7.9	$ 468,191
Options exercisable as of December 31, 2025	2,740,854	$ 11.61	6.6	$ 241,560

In January 2025, the Company modified previously granted stock option awards to 44 employees by reducing the exercise price of these options to the Company's closing common stock price on the modification date. During the year ended December 31, 2025, the incremental compensation expense recognized as a result of these modifications was $0.2 million. The effect of these modifications on stock-based compensation over the remaining service periods will be $0.3 million.

During the year ended December 31, 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 $8.4 million in stock-based compensation expense related to these awards during the year ended December 31, 2025.

During the years ended December 31, 2025 and 2024, the weighted-average grant date fair value of options granted was $25.01 and $11.22 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2025 and 2024, was $35.7 million and $0.6 million, respectively. Upon the exercise of stock options, the Company will issue new shares of its common stock. As of December 31, 2025, the unrecognized compensation cost related to outstanding employee and non-employee options was $52.7 million and is expected to be recognized as expense over a weighted-average period of 1.7 years.

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 option grants issued, were as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	3.6% − 4.7%	3.5% − 4.7%
Expected volatility	74.4% − 82.1%	71.2% − 76.2%
Expected life (years)	5.0 − 10.0	5.3 − 10.0
Expected dividend yield	0%	0%

During the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense for stock options of $20.0 million and $6.6 million, respectively.

Restricted Stock

The following table summarizes restricted stock award and restricted stock unit activity during the year ended December 31, 2025:

	Shares	Weighted-average grant date fair value per share
Outstanding as of December 31, 2024	1,079	$ 14.83
Granted	34,039	89.43
Vested	(1,079)	14.83
Forfeited	(6,600)	98.49
Outstanding as of December 31, 2025	27,439	$ 87.25

As of December 31, 2025, the unrecognized compensation cost related to outstanding restricted stock was $2.3 million and is expected to be recognized over a weighted-average period of 1.9 years. The total fair value of restricted stock vested during the year ended December 31, 2025 was less than $0.1 million.

During the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense for restricted stock of $0.1 million and less than $0.1 million, respectively.

2017 Employee Stock Purchase Plan

In September 2017, the Company adopted the 2017 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides participating employees with an opportunity to purchase shares of the Company's common stock at a discount through payroll deductions. The ESPP is available to all employees unless they are employed for less than 20 hours per week or own 5% or more of the total combined voting power or value of the Company's common stock. The ESPP is administered using overlapping 24 month offering periods (the "Offering Periods"). Each Offering Period has four six-month purchase periods. A new Offering Period and purchase period begin every six months on May 1 and November 1 of each year. Participating employees may purchase common stock, on a voluntary after tax-basis, at a price equal to 85% of the fair market value of a share of common stock on either the offering date or the purchase date, whichever is lower. If the purchase date has a lower price, the employee will automatically be placed in the Offering Period beginning immediately after the purchase date.

The number of shares reserved for issuance under the ESPP automatically increases on January 1 of each year from 2023 to 2027 by the number of shares equal to 0.5% of the aggregate number of outstanding shares of common stock as of the immediately preceding December 31. However, the Company's board of directors may reduce the amount of the increase in any particular year. The number of shares reserved for issuance under the ESPP was automatically increased by 185,716 and 127,530 shares on January 1, 2025 and 2024, respectively.

As of December 31, 2025, the number of shares available for issuance under the ESPP is 469,576.

During the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense related to the ESPP of $1.3 million and $0.3 million, respectively.

Stock-based Compensation

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

	Year Ended December 31,	
	2025	2024
Research and development	$ 8,409	$ 4,405
General and administrative	12,974	2,583
Total	$ 21,383	$ 6,988

10. Debt

July 2025 Convertible Notes Offering

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

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

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

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

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

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

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

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

The issuance costs attributed to the Notes amounted to $6.4 million and were discounted from the Notes. The issuance cost discount is being amortized to interest expense over the term of the Notes based on the effective interest rate method. As of December 31, 2025, the effective interest rate was 3.3%. During the year ended December 31, 2025, interest expense related to the Notes was $2.7 million, including $0.4 million related to discount amortization.

Amended and Restated Loan and Security Agreement

Third Amendment

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

In accordance with the A&R Loan Agreement, a Final Fee equal to 4.5% of the $30.0 million Term D Loan was recognized and an additional $1.4 million was added to debt principal and a corresponding debt discount to be amortized over the life of the loan.

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

Second Amendment

On July 28, 2025, the Company entered into the Second Amendment (the "Second Amendment") to the A&R Loan Agreement with Innovatus, as collateral agent, and the Lenders including Innovatus in its capacity as a Lender and Oxford, pursuant to which Innovatus and Oxford, as Lenders, have agreed to make certain term loans ("Term Loans") to the Company in the aggregate principal amount of up to $180 million. The A&R Loan Agreement was amended to (i) subject to certain terms and conditions, permit the issuance of the Notes discussed above and certain transactions in connection therewith, including the conversion thereof settled solely in common stock (together with cash in lieu of the issuance of any fractional share of common stock), (ii) permit capped call transactions in connection with the pricing of the Notes, (iii) require an amendment fee payable by the Company to Oxford in the amount of less than $0.1 million, which was paid upon execution of the Second Amendment, and (iv) extend to May 9, 2026 the expiration date of Innovatus' right to convert up to 20% of the outstanding principal of the Term A Loan into shares of the Company's common stock at a price per share of $10.00.

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

First Amendment

On May 13, 2025, the Company entered into the First Amendment (the "First Amendment") to the A&R Loan Agreement, pursuant to which the Company agreed to (i) pay Oxford an amendment fee of less than $0.1 million on the effective date of the First Amendment, (ii) extend to March 9, 2026 the expiration date of Innovatus' right to convert up to 20% of the outstanding principal of the Term A Loan into shares of the Company's common stock at a price per share of $10.00, (iii) extend the expiration date of the Term D Draw Period to the earlier of (x) August 31, 2025 and (y) the occurrence of an Event of Default (as defined in the A&R Loan Agreement), (iv) update the liquidity covenant to increase the Minimum Liquidity Percentage (as defined in the First Amendment) to 50% if the Company had failed to achieve the Term D Milestone prior to June 1, 2025 and to decrease the Minimum Liquidity Percentage back to 30% if the Company subsequently achieves the Term D Milestone prior to the end of the Term D Draw Period, and (v) release Innovatus and the Lenders from any and all claims arising out of or related to the A&R Loan Agreement, the First Amendment and related documentation.

May 30, 2024 Amendment and Restatement

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

Funding of the first $100 million under the A&R Loan Agreement occurred on May 30, 2024, including tranche payments of $16.8 million (the "Term A Loan") and $21.5 million (the "Term B Loan") reflecting repayment of the principal amount of loans under the Prior Loan Agreement plus accrued payment-in-kind interest, in addition to $61.7 million of new borrowings (the "Term C Loan"). As described above, the Term D Loan was disbursed to the Company in connection with the Third Amendment. Prior to the Third Amendment, the Company also would have become eligible to draw on a fifth tranche of $50.0 million (the "Term E Loan"), upon achievement of certain clinical trial milestones and satisfaction of certain financial

covenants. The Lenders also could have, in their sole discretion upon the Company's request, made additional term loans to the Company of $45.0 million (the "Term F Loan"). Funding of these additional tranches was also subject to other customary conditions and limits on when the Company could have requested funding for such tranches. Costs associated with the new borrowings were approximately $2.4 million.

Pursuant to the A&R Loan Agreement, the Company is entitled to make interest-only payments for thirty-six months, or up to forty-eight months if certain conditions are met. The Term Loans bear interest at a rate equal to the sum of (a) the greater of (i) the Prime Rate (as defined in the A&R Loan Agreement) or (ii) 7.75%, plus (b) 2.85%, provided that 1.0% of such interest will be payable in-kind by adding an amount equal to such 1.0% of the outstanding principal amount to the then outstanding principal balance on a monthly basis through May 31, 2027. The A&R Loan Agreement is secured by all assets of the Company. Proceeds are being used for working capital purposes and to fund the Company's general business requirements, including the ongoing Phase 3 VIKTORIA-1 clinical trial, the Phase 1b/2 CELC-G-201 clinical trial, and the Phase 3 VIKTORIA-2 clinical trial. The A&R Loan Agreement contains customary representations and warranties and covenants, subject to customary carve-outs, and includes financial covenants related to liquidity and other financial measures. Prior to the Second Amendment, Innovatus also had the right, at its election and until August 9, 2025, to convert up to 20% of the outstanding principal of the Term A Loan into shares of the Company's common stock at a price per share of $10.00. Innovatus will continue to have the right to exercise a previously disclosed warrant granted to it under the Prior Loan Agreement to purchase 26,042 shares of common stock at a price per share of $14.40 through April 8, 2031.

The A&R Loan Agreement contains a Final Fee, which is equal to 4.5% of the initial funding of the agreement and is due on the earliest to occur of (a) the Maturity Date, (b) the acceleration of any Term Loan, and (c) the prepayment of the Term Loans. There is also a contingent non-utilization fee for the Term E Loans. Following the disbursement of the Term D Loan in connection with the Third Amendment, the non-utilization provisions related to the Term D Loan are no longer operative. The Term D Loan shall become due and payable on the earliest of (i) the termination of the Term D Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. If the Company achieves the Term E Milestone and (i) fails to draw the full amount of the Term E Loan during the Term E Draw Period and (ii) fails to notify Collateral Agent, at any time before the date that is four weeks after the Company's achievement of the Term E Milestone, of the Company's intent not to draw the full amount of the Term E Loan, a non-utilization fee with respect to the Term E Loan shall become due and payable on the earliest of (i) the termination of the Term E Draw Period, (ii) the Maturity Date, (iii) the acceleration of any Term Loan, and (iv) the prepayment in whole of the Term Loans. After the 18-month anniversary of the Effective Date, the Company shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under the A&R Loan Agreement, provided the Company (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least seven business days prior to such prepayment, and (ii) pays to Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Fee, plus (D) all other outstanding Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. At May 30, 2024, the Company recognized the Final Fee of $4.5 million as additional debt principal and a corresponding debt discount to be amortized over the life of the loan.

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

The Company evaluated the change of terms under ASC 470-50, *Debt – Modification and Extinguishment* with respect to the Third Amendment, the Second Amendment, the First Amendment and the A&R Loan Agreement and concluded the change in terms did not result in significant and consequential changes to the economic substance of the debt and thus resulted in a modification of the debt and not an extinguishment of the debt.

Note payable, non-current consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Note payable	$ 130,000	$ 100,000
Add: Final fee	5,850	4,500
Add: PIK interest (added to principal)	1,697	593
Less: unamortized debt issuance costs	(2,619)	(1,614)
Less: unamortized debt discount	(8,401)	(5,752)
Total long-term debt	$ 126,527	$ 97,727

As of December 31, 2025, the fair value of the note payable, which differs from its carrying value, is determined using the Company's estimated discount rate, volatility and risk-free rate, which are considered Level 3 inputs. As of December 31, 2025, the fair value of the note payable was $160.2 million. As of December 31, 2024, the carrying value of the note payable approximates the fair value (Level 3 inputs).

The debt issuance costs and discount will be amortized to interest expense over the term of the Notes based on the effective interest rate method. As of December 31, 2025 and 2024, the effective interest rate was 12.7% and 12.3%, respectively. During the year ended December 31, 2025, interest expense related to the note payable was $14.4 million, including $2.7 million related to discount amortization. During the year ended December 31, 2024, interest expense related to the note payable was $10.3 million, including $1.3 million related to discount amortization.

As of December 31, 2025, future principal payments, including the incurred PIK interest and Final Fee, are as follows (in thousands):

Year Ending December 31,	
2028	$ 43,899
2029	93,648
Total	$ 137,547

As of December 31, 2025, the Company was in full compliance with all financial covenants of the Amended A&R Loan Agreement.

11. License Agreement

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

The Company is also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of $335.0 million. One of these milestone events requires a $5.0 million payment within 60 days following the FDA regulatory filing of a New Drug Application ("NDA") for gedatolisib. The FDA granted the Company's request to submit its NDA via the FDA's Real-Time Oncology Review ("RTOR") program, and the Company completed its final NDA submission to the FDA in November 2025. The Company recorded the $5.0 million NDA filing milestone as research and development expense in June 2025. As of December 31, 2025, this amount was included in other accrued expenses on the Company's balance sheets. Additionally, the Company will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid-teens, which may be subject to deductions for expiration of valid patent claims, amounts due under third-party licenses and generic competition. Unless earlier terminated, the license agreement will expire upon the expiration of all royalty obligations. The royalty period will expire on a country-by-country basis upon the later of (a) 12 years following the date of first commercial sale of such product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such product, or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the license agreement, a valid claim of a licensed patent right.

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

12. Income Taxes

No income tax benefit was recorded during the years ended December 31, 2025 and 2024, due to net losses and recognition of a valuation allowance. The following table, which reflects the Company's retrospective adoption of ASU 2023-09, presents a reconciliation of the U.S. federal statutory rate to the Company's effective tax rate, including the amount (in thousands):

	Year Ended December 31,			
	2025		2024	
	Amount	%	Amount	%
Tax benefit at statutory rate	$ (37,179)	21.0%	$ (23,474)	21.0%
State income tax benefit, net of federal tax effect	(14)	—	(3)	—
Federal change in valuation allowance on deferred tax assets	38,249	(21.6)	23,797	(21.3)
Federal research and development credits	(1,358)	0.8	(982)	0.9
Prior year adjustments	(343)	0.2	(3)	—
Non-deductible items	645	(0.4)	665	(0.6)
Income tax expense (benefit)	$ —	—%	$ —	—%

In July 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, introducing a series of corporate tax changes in the U.S., including 100% bonus depreciation on qualified property and full expensing of domestic research and development expenditures. The impacts of OBBBA are reflected in our results of operations during the year ended December 31, 2025. OBBBA did not have a material impact on the Company's effective income tax rate and its net deferred tax assets as the Company maintains a full valuation allowance.

Deferred tax assets (liabilities) reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, *Income Taxes*, the Company recorded a valuation allowance to fully offset the net deferred tax assets as of December 31, 2025 and 2024, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets. The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets (liabilities) were (in thousands):

	As of December 31,	
	2025	2024
Gross deferred tax assets (liabilities):		
Accrued expenses	$ 253	$ 459
Stock-based compensation	6,056	2,861
Property and equipment	463	420
Right-of-use assets	(11)	(45)
Lease liabilities	12	48
Section 174 expenditures	48,070	30,133
Start-up expenditures	21,955	12,998
Net operating losses and tax credits	23,483	13,340
Deferred tax assets before valuation allowance	100,281	60,214
Valuation allowance	(100,281)	(60,214)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company had federal and state net operating loss carryforwards of $83.3 million and $4.8 million, respectively. The federal and state net operating loss carryforwards for 2017 will begin to expire during the year ending December 31, 2037. The federal net operating loss carryforwards starting in 2018 have no expiration. These deferred tax assets were subject to a full valuation allowance as of December 31, 2025 and 2024.

As of December 31, 2025, the Company had federal and state research and development tax credit carryforwards resulting in deferred tax assets of $4.3 million and $2.0 million, respectively. The federal and state credit carryforwards will begin to expire during the years ending December 31, 2038 and December 31, 2033, respectively. These deferred tax assets were subject to a full valuation allowance as of December 31, 2025 and 2024.

Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may limit in the future the amount of net operating loss carryforwards available to offset future taxable income.

The Company recognizes uncertain tax positions in accordance with ASC 740 on the basis of evaluating whether it is more-likely-than not that the tax positions will be sustained upon examination by tax authorities. For those tax positions that meet the more-likely-than not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement. As of December 31, 2025 and 2024, the Company had no significant uncertain tax positions. There are no unrecognized tax benefits included on the balance sheets that would, if recognized, impact the effective tax rate. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

The Company is no longer subject to U.S. federal income tax examinations for years before 2022, although carryforward attributes that were generated before 2022 may still be adjusted upon examination if used in a future period. State income tax statutes vary by jurisdiction. In most states in which the Company operates, the statute of limitations remains open for four years, and accordingly, the Company is generally no longer subject to state income tax examinations for years before 2021.

The Company's policy is to recognize interest and penalties related to uncertain tax positions as a component of general and administrative expenses. As of December 31, 2025, the Company had no accrued interest or penalties and no amounts were recognized in the statements of operations.

During the years ended December 31, 2025 and 2024, the Company made state tax payments which were deemed immaterial.

13. Subsequent Events

On January 9, 2026, the Company filed a new registration statement and accompanying prospectus supplement, which increased the aggregate offering amount under the Open Market Sale Agreement to $400.0 million.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. 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 December 31, 2025. 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 December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO – 2013") in Internal Control-Integrated Framework. Based on this assessment, our Chief Executive Officer and Chief Financial Officer concluded that our system of internal control over financial reporting was effective as of such date.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to our designation as a small reporting company or SRC and Non-Accelerated filer.

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 December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our system of internal controls over financial reporting.

ITEM 9B. Other Information

Trading Plans

On December 8, 2025, Oncology Diagnostic & Drug Development Consulting LLC, an entity controlled by Richard E. Buller, adopted a 10b5-1 plan for the sale of up to 12,000 shares of Celcuity Inc. common stock beginning March 18, 2026 through December 23, 2026.

During the three months ended December 31, 2025, none of our other 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Information regarding our executive officers is included in Part I, Item 1 of this Annual Report under the caption "Information About Our Executive Officers."

Our board of directors has adopted a Code of Ethical Business Conduct that applies to our directors, officers and employees. In addition, our CEO, CFO and other senior financial officers of the company are subject to a Code of Ethical Business Conduct for Senior Financial Officers. These codes are available on the corporate governance section of our website (which is a subsection of the investor relations section of our website) at the following address: www.celcuity.com. We intend to disclose on our website any amendments or waivers to these codes that are required to be disclosed by SEC or Nasdaq rules.

Additional information required by this Item 10 will be contained in our definitive proxy statement for our 2026 Annual Meeting of Stockholders (the "Definitive Proxy Statement") under the captions "Corporate Governance" and "Meetings and Committees of the Board of Directors" and is incorporated herein by reference.

ITEM 11. Executive Compensation

The information required by this Item 11 will be contained in the Definitive Proxy Statement under the captions "Corporate Governance," "Executive Compensation" and "Director Compensation" and is incorporated herein by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be contained in the Definitive Proxy Statement under the captions "Beneficial Ownership of Common Stock" and "Securities Authorized for Issuance under Equity Compensation Plans" and is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be contained in the Definitive Proxy Statement under the captions "Corporate Governance" and "Certain Relationships and Related Transactions" and is incorporated herein by reference.

ITEM 14. Principal Accountant Fees and Services

The information required by this Item 14 will be contained in the Definitive Proxy Statement under the caption "Proposal No. 2, Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

FINANCIAL STATEMENTS

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FINANCIAL STATEMENT SCHEDULES

None.

EXHIBITS

See Exhibit Index immediately following the signature page hereto, which is incorporated herein by reference.

ITEM 16. Form 10-K Summary

None.

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: March 26, 2026

CELCUITY INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Each person whose signature appears below constitutes and appoints Brian F. Sullivan and Vicky Hahne as the undersigned's true and lawful attorneys-in fact and agents, each acting alone, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place and stead, in any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granted unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	Title	Date
/s/ Brian F. Sullivan Brian F. Sullivan	Chairman and Chief Executive Officer (Principal Executive Officer)	March 26, 2026
/s/ Vicky Hahne Vicky Hahne	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2026
/s/ Lance G. Laing Lance G. Laing	Chief Science Officer, Vice President and Secretary, and Director	March 26, 2026
/s/ Richard E. Buller Richard E. Buller	Director	March 26, 2026
/s/ Dave F. Dalvey Dave F. Dalvey	Director	March 26, 2026
/s/ Leo T. Furcht Leo T. Furcht	Director	March 26, 2026
/s/ Polly A. Murphy Polly A. Murphy	Director	March 26, 2026
/s/ Richard J. Nigon Richard J. Nigon	Director	March 26, 2026
/s/ Charles R. Romp Charles R. Romp	Director	March 26, 2026

EXHIBIT INDEX
CELCUITY INC.
FORM 10-K

Exhibit No.	Description
2.1	Form of Plan of Conversion (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
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).
4.1	Specimen Certificate representing shares of common stock of Celcuity Inc. (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
4.2*	Description of Registered Securities.
4.3	Form of Warrant to Purchase Units of Membership Interest issued by Celcuity LLC to Cedar Point Capital, LLC, as placement agent of membership units and unsecured convertible promissory notes of Celcuity LLC (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
4.4	Form of Warrant issued by Celcuity Inc. to Innovatus Life Sciences Lending Fund I, LP in connection with the Loan and Security Agreement dated April 8, 2021 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021).
4.5	Equity Grant Agreement, dated April 7, 2021, between the Company and Pfizer Inc. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021).
4.6	Form of Pre-Funded Warrant to Purchase Common Stock issued by Celcuity Inc. in connection with the Securities Purchase Agreement, dated October 18, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 23, 2023).
4.7	Form of Amendment to Placement Agent's Warrants, dated February 13, 2024 (incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024).
4.8	Form of Amendment to Warrants to Purchase Shares of Common Stock, dated February 13, 2024 (incorporated by reference to Exhibit 4.5 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024).
4.9	Form of Warrant to Purchase Stock issued by Celcuity Inc. in connection with the Amended and Restated Loan Agreement, dated May 30, 2024 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on May 30, 2024).
4.10	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 31, 2025).
4.11	Indenture, dated as of August 1, 2025, between Celcuity Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2025).

Exhibit No.	Description
4.12	First Supplemental Indenture, dated as of August 1, 2025, between Celcuity Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2025).
4.13	Form of Certificate Representing the 2.750% Convertible Senior Notes due 2031 (included as Exhibit A in Exhibit 4.12 above).
4.14	Form of Warrant to Purchase Stock issued by Celcuity Inc. in connection with the Third Amendment to Amended and Restated Loan and Security Agreement, dated September 9, 2025 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 10, 2025).
10.1+	Celcuity Inc. 2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.2+	Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 16, 2025).
10.3+	Amendment to the Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 12, 2023).
10.4+	Form of Stock Option Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.5+	Form of Restricted Stock Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.6+	Form of Restricted Stock Unit Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.7+	Form of Stock Appreciation Rights Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.8+	Celcuity LLC 2012 Equity Incentive Plan, adopted August 10, 2012, as amended by First Amendment to the Celcuity LLC 2012 Equity Incentive Plan, adopted November 12, 2015 (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.9+	Form of Unit Option Agreement pursuant to the Celcuity LLC 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.10	Commercial Lease, dated September 28, 2017, between West Glen Development I, LLC and Celcuity, LLC (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2017).
10.11	Commercial Lease, First Amendment to Lease, dated July 28, 2020, between West Glen Development I, LLC and the Company (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2020).
10.12	Commercial Lease, Second Amendment to Lease, dated July 19, 2021, between West Glen Development I, LLC and the Company (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2021).

Exhibit No.	Description
10.13	Commercial Lease, Third Amendment to Lease, dated July 27, 2022, by and between West Glen Development I, LLC and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2022).
10.14	Commercial Lease, Fourth Amendment to Lease, dated March 13, 2023, by and between West Glen Development I, LLC and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 15, 2023).
10.15	Clinical Trial Agreement, dated May 8, 2017, by and between NSABP Foundation, Inc. and Celcuity LLC (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.16	Amendment No. 1, Clinical Trial Agreement for FB-12 Phase II Study, by and between NSABP Foundation, Inc and the Company, dated October 15, 2020 (incorporated by reference Exhibit 10.15 to the Company's Annual Report on Form 10-K filed with the SEC on February 16, 2021).
10.17+	Confidentiality, Assignment of Inventions and Non-Competition Agreement, dated November 15, 2011, between Celcuity LLC and Brian F. Sullivan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.18+	Confidentiality, Assignment of Inventions and Non-Competition Agreement, dated November 15, 2011, between Celcuity LLC and Lance G. Laing (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.19+	Confidentiality, Non-Compete, and Proprietary Rights Agreement, dated May 17, 2017, between Celcuity LLC and Vicky Hahne (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed with the SEC on August 23, 2017).
10.20	Form of Indemnification Agreement between the Company and each of its officers and directors (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the SEC on September 12, 2017).
10.21†	License Agreement, dated April 8, 2021, by and between the Company and Pfizer Inc. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2021).
10.22†	Amendment No. 1 to License Agreement, dated May 6, 2021, by and between the Company and Pfizer Inc. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2021).
10.23	Open Market Sale Agreement[SM], dated February 4, 2022, by and between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on February 4, 2022).
10.24	Securities Purchase Agreement, dated May 15, 2022, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2022).
10.25	Registration Rights Agreement, dated May 15, 2022, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2022).
10.26	Loan and Security Agreement, dated as of April 8, 2021, by and between the Company and Innovatus Life Sciences Lending Fund I, LP (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2021).

Exhibit No.	Description
10.27	First Amendment to Loan and Security Agreement, dated August 9, 2022, by and among the Company and Innovatus Life Sciences Lending Fund I, LP (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 11, 2022).
10.28	Securities Purchase Agreement, dated October 18, 2023, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 23, 2023).
10.29	Registration Rights Agreement, dated October 18, 2023, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on October 23, 2023).
10.30	Second Amendment to Loan and Security Agreement, dated March 29, 2024, by and among the Company and Innovatus Life Sciences Lending Fund I, LP (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 29, 2024).
10.31+	Amendment to the Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 13, 2024).
10.32+	Amendment to Form of Stock Option Agreement pursuant to Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024).
10.33+	Form of Non-Qualified Stock Option Transfer Agreement pursuant to Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024).
10.34†	Amended and Restated Loan and Security Agreement, dated May 30, 2024, by and among the Company, Innovatus Life Sciences Lending Fund I, LP, as collateral agent, and the Lenders named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 30, 2024).
10.35+	Celcuity Inc. Change in Control and Severance Plan and Summary Plan Description (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025).
10.36+	Form of Stock Option Agreement (Performance-Based) pursuant to Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2025).
10.37	First Amendment to Amended and Restated Loan and Security Agreement, dated May 13, 2025, by and among the Company, Innovatus Life Sciences Lending Fund I, LP, as collateral agent, the Lenders named therein and Oxford Finance LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2025).
10.38	Second Amendment to Amended and Restated Loan and Security Agreement, dated July 28, 2025, by and among the Company, Innovatus Life Sciences Lending Fund I, LP, as collateral agent, the Lenders named therein and Oxford Finance LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2025).
10.39†	Third Amendment to Amended and Restated Loan and Security Agreement, dated September 9, 2025, by and among the Company, Oxford Finance LLC, as collateral agent, the Lenders named therein and Innovatus Life Sciences Lending Fund I, LP (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 10, 2025).
10.40+*	Form of Restricted Stock Unit Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan.

Exhibit No.	Description
19*	Celcuity Inc. Policy to Prohibit Insider Trading.
23.1*	Consent of Boulay PLLP.
24.1*	Power of Attorney (included on the signature page).
31.1*	Certification of principal executive officer required by Rule 13a-14(a).
31.2*	Certification of principal financial officer required by Rule 13a-14(a).
32.1**	Section 1350 Certification of principal executive officer.
32.2**	Section 1350 Certification of principal financial officer.
97	Celcuity Inc. Policy for the Recoupment of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2024).
101	The following information from the Annual Report on Form 10-K of the Company for the year ended December 31, 2025, formatted, in Inline XBRL: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Changes in Stockholders' Equity, (iv) the Statements of Cash Flows, (v) the Notes to Financial Statements, and (vi) the information under Part II, Item 9B "Other Information."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith.
** Furnished herewith.
+ Management contract or compensatory plan.
† Certain portions have been omitted from this exhibit.

Exhibit 4.2

Description of Registrant's Securities
Registered Pursuant to Section 12 of the
Securities Exchange Act of 1934, as amended

The following summary of the terms of our capital stock is subject to and qualified in its entirety by reference to our certificate of incorporation, as amended, and bylaws, copies of which are on file with the SEC as exhibits to previous SEC filings.

As of December 31, 2025, Celcuity Inc. ("we," "us," "our," and the "Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common stock, par value $0.001 per share. In addition, we have certain equity interests outstanding that are convertible into common stock, which are described in more detail below.

As of December 31, 2025, we were authorized to issue 95,000,000 shares of common stock and 2,500,000 shares of preferred stock, $0.001 par value per share.

Common Stock

Fully Paid and Nonassessable

The outstanding shares of our common stock are fully paid and nonassessable.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders.

Dividend Rights

Holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock.

Right to Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. The transfer agent and registrar's address is One State Street Plaza, 30th Floor, New York, NY 10004.

The Nasdaq Capital Market

Our common stock is listed for quotation on The Nasdaq Capital Market under the symbol "CELC".

Preferred Stock

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 2,500,000 shares of preferred stock in one or more series. Our board of directors is authorized to designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors is able to authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes, could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of the Company, which might harm the market price of our common stock. See also "Anti-Takeover Effect of Delaware Law and Certain Charter and Bylaw Provisions" below.

On May 16, 2022, in connection with a Securities Purchase Agreement, dated May 15, 2022, by and among the Company and the Investors named therein (the "2022 Investors," and such Securities Purchase Agreement, the "2022 Securities Purchase Agreement"), the Company filed a Certificate of Designations (the "Certificate of Designations") with the Secretary of State of the State of Delaware, designating 1,850,000 shares out of the authorized but unissued shares of its preferred stock as Series A Convertible Preferred Stock ("Series A Preferred Stock"). No shares of Series A Preferred Stock remained outstanding as of December 31, 2025.

Warrants

2025 Warrants

Under the Third Amendment, dated September 9, 2025 (the "Third Amendment") to the Amended and Restated Loan and Security Agreement (the "A&R Loan Agreement"), by and among the Company, Oxford Finance LLC ("Oxford"), as collateral agent, and the Lenders named therein, including Oxford in its capacity as a Lender and Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), pursuant to which Oxford and Innovatus, as Lenders, have made or agreed to make certain term loans, including the Term D Loan (as such term is defined in the A&R Loan Agreement, as amended by the Third Amendment (the "Amended A&R Loan Agreement")) to the Company, the Company issued to Oxford and Innovatus warrants (the "2025 Warrants") to purchase an aggregate of 50,537 shares of common stock with an exercise price of $14.84 per share. The 2025 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 2025 Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such 2025 Warrant.

2025 Pre-Funded Warrants

Under the Underwriting Agreement, dated July 30, 2025, by and among the Company, and Jefferies LLC, TD Securities (USA) LLC, and Leerink Partners LLC as representatives (the "Underwriting Agreement"), the Company issued pre-funded warrants (the "2025 Pre-Funded Warrants") to purchase up to 400,000 shares of common stock. Each 2025 Pre-Funded Warrant to purchase one share was sold for a purchase price of $37.999 per 2025 Pre-Funded Warrant and has an exercise price of $0.001 per share (for aggregate consideration equating to $38.00 per share of common stock issuable upon exercise of the 2025 Pre-Funded Warrants).

Each 2025 Pre-Funded Warrant may be exercised on a cashless basis and is immediately exercisable and will not expire. Under the terms of the 2025 Pre-Funded Warrants, the Company may not effect the exercise of any such 2025 Pre-Funded Warrant, and a holder will not be entitled to exercise any portion of any 2025 Pre-Funded Warrant, if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder's affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder's or any of the holder's affiliates for purposes of Section 13(d) or Section 16 of the Exchange Act) would exceed 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission (the "Maximum Percentage"). A holder may reset the Maximum Percentage to a higher or lower percentage (not to exceed 19.99%), effective 61 days after written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of 2025 Pre-Funded Warrants.

2024 Warrants

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

2023 Pre-Funded Warrants

Under the Securities Purchase Agreement, dated October 18, 2023, by and among the Company and the Investors named therein (the "2023 Investors," and such Securities Purchase Agreement, the "2023 Securities Purchase Agreement"), the Company issued pre-funded warrants (the "2023 Warrants") to purchase 5,747,787 shares of common stock. Each 2023 Warrant to purchase one share was sold for a purchase price of $8.699 per Warrant and has an exercise price of $0.001 per share (for aggregate consideration equating to $8.70 per share of common stock issuable upon exercise of the 2023 Warrants).

Each 2023 Warrant is immediately exercisable and will not expire. Under the terms of the 2023 Warrants, the Company may not effect the exercise of any such 2023 Warrant, and a holder will not be entitled to exercise any portion of any 2023 Warrant, if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder's affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder's or any of the holder's affiliates for purposes of Section 13(d) or Section 16 of the Exchange Act) would exceed the Maximum Percentage. A holder may reset the Maximum Percentage to a higher percentage (not to exceed 19.99%), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of 2023 Warrants.

Registration Rights Agreement

2023 Registration Rights Agreement

In connection with the 2023 Securities Purchase Agreement, the Company entered into a Registration Rights Agreement (the "2023 Registration Rights Agreement") with the 2023 Investors, pursuant to which the Company agreed to register for resale the Registrable Securities (the "2023 Registrable Securities"), which include: (i) the shares of common stock then issued or issuable upon exercise of the 2023 Warrants (assuming the 2023 Warrants are exercisable in full without regard to any exercise limitation therein) (the "2023 Warrant Shares"), and (ii) any other securities issued or issuable with respect to, in exchange for or in replacement of, the 2023 Warrant Shares issued and sold pursuant to the 2023 Securities Purchase Agreement. Under the 2023 Registration Rights Agreement, the Company agreed to file a registration statement covering the resale by the 2023 Investors of the 2023 Registrable Securities no later than 30 days following the Closing Date (as defined in the 2023 Registration Rights Agreement). The Company agreed to use commercially reasonable efforts to cause the registration statement to become effective and to keep such registration statement effective until such time as there are no longer 2023 Registrable Securities held by the 2023 Investors. The Company agreed to be responsible for all fees and expenses incurred in connection with the registration of the 2023 Registrable Securities. The Company filed a registration statement on Form S-3 registering for resale the 2023 Registrable Securities, which was declared effective on November 28, 2023.

The Company granted the 2023 Investors customary indemnification rights in connection with the registration statement, including for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"). The 2023 Investors also granted the Company customary indemnification rights in connection with the registration statement.

2022 Registration Rights Agreement

In connection with the 2022 Securities Purchase Agreement, the Company entered into a Registration Rights Agreement (the "2022 Registration Rights Agreement") with the 2022 Investors, pursuant to which the Company agreed to register for resale the Registrable Securities (the "2022 Registrable Securities"), which include: (i) the common stock, (ii) the shares of common stock then issued or issuable upon conversion of the Series A Preferred Stock (assuming on such date the shares of Series A Preferred Stock are convertible in full without regard to any conversion limitations in the Certificate of Designations), and (iii) the common stock then issued or issuable upon exercise of the 2022 Warrants (assuming the 2022 Warrants are exercisable in full without regard to any exercise limitations therein). Under the 2022 Registration Rights Agreement, the Company agreed to file a registration statement covering the resale by the 2022 Investors of the 2022 Registrable Securities no later than 30 days following (i) the Closing Date (as defined in the 2022 Registration Rights Agreement) and (ii) the date the Company obtained the necessary stockholder approval to increase the aggregate authorized number of shares of capital stock and the number of shares of common stock such that the Company had available, and had reserved, such number of its duly authorized but unissued shares of common stock as shall be sufficient to effect the conversion of all shares of Series A Preferred Stock then outstanding or available for issuance upon the exercise of the 2022 Warrants. The Company agreed to use commercially reasonable efforts to cause the registration statement to become effective and to keep such registration statement effective until such time as there are no longer 2022 Registrable Securities held by the 2022 Investors. The Company agreed to be responsible for all fees and expenses incurred in connection with the registration of the 2022 Registrable Securities. The Company filed a registration statement on Form S-3 registering for resale the 2022 Registrable Securities, which was declared effective on January 11, 2023.

The Company granted the 2022 Investors customary indemnification rights in connection with the registration statement, including for liabilities arising under the Securities Act. The 2022 Investors also granted the Company customary indemnification rights in connection with the registration statement.

The representations, warranties and covenants contained in each of the 2025 Warrants, the 2025 Pre-Funded Warrants, the 2024 Warrants, the 2023 Warrants, the Third Amendment, the A&R Loan Agreement, the Underwriting Agreement, the 2023 Securities Purchase Agreement, the 2022 Securities Purchase Agreement, the 2023 Registration Rights Agreement and the 2022 Registration Rights Agreement were made solely for the benefit of the parties thereto and may be subject to limitations agreed upon by the contracting parties.

Anti-Takeover Effect of Delaware Law and Certain Charter and Bylaw Provisions

Our certificate of incorporation, as amended, and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our Company. A summary of these provisions is as follows:

- ***Board of directors vacancies.*** Our bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors will be permitted to be set only by a resolution adopted by our board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- ***Advance notice requirements for stockholder proposals and director nominations.*** Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

- ***No cumulative voting.*** The Delaware General Corporation Law, or DGCL, provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our certificate of incorporation, as amended, does not provide for cumulative voting.

- ***Stockholder action; special meetings of stockholders.*** Our certificate of incorporation, as amended, provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Further, our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, or our Chief Executive Officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- ***Issuance of undesignated preferred stock.*** We have 650,000 shares of undesignated preferred stock. Our board of directors has the authority, without further action by the stockholders, to issue this preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- ***Amendment of charter and bylaw provisions.*** The affirmative vote of stockholders representing at least two-thirds of the voting power of all then-outstanding capital stock is required to amend, alter or repeal certain provisions of our certificate of incorporation, as amended, including the provision noted above regarding stockholders not being able to act by written consent. A majority of our board of directors has authority to adopt, amend or repeal provisions of our bylaws. Stockholders also have the authority to adopt, amend or repeal provisions of our bylaws, but only with the affirmative vote of stockholders representing at least two-thirds of the voting power of all then-outstanding capital stock.

We are subject to the provisions of Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who owns 15% or more of the voting stock of a corporation, or any affiliate or associate of a corporation who, within three years prior, did own 15% or more of the voting stock of that corporation.

Exhibit 10.40

CELCUITY INC.
2017 STOCK INCENTIVE PLAN

RESTRICTED STOCK UNIT AGREEMENT

THIS RESTRICTED STOCK UNIT AGREEMENT ("Agreement") is entered into as of the "Grant Date" set forth below, by and between Celcuity Inc., a Delaware corporation (the "Company") and the person named below (the "Participant"). The Award granted hereby is granted under the Celcuity Inc. 2017 Stock Incentive Plan (the "Plan"). Unless otherwise defined herein, terms used in this Agreement that are defined in the Plan will have the meanings given to them in the Plan.

1. Grant of Award. The Company hereby grants to the Participant a restricted stock unit award (the "Award") for the number of restricted stock units (the "Units") set forth below, on the terms and conditions set forth herein, and subject to the terms and conditions of the Plan, which is incorporated herein by reference. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Agreement, the terms and conditions of the Plan will prevail.

Grant Number:	RSU-_____
Participant:	_____
Grant Date:	_____
Vesting Commencement Date:	_____
Total Number of Restricted Stock Units Subject to the Award:	_____ Units

Each Unit represents the right to receive one share of the Company's Common Stock ("Shares"). The Units granted to the Participant will be credited to an account in the Participant's name maintained by the Company. This account shall be unfunded and maintained for book-keeping purposes only, with the Units simply representing an unfunded and unsecured obligation of the Company. The Units subject to this Award will be subject to the restrictions set forth in Section 2 of this Agreement and will be subject to forfeiture for the period and on the terms and conditions set forth in Section 3 of this Agreement.

2. Non-Transferability. Neither this Award nor the Units subject to this Award may be sold, transferred, assigned, pledged or otherwise encumbered or disposed of other than by will or by the laws of descent or distribution. The Units and the Participant's right to receive Shares in Settlement of the Units will be subject to forfeiture as provided in Section 3.

3. Vesting of Restricted Stock Units.

(a) Vesting. The Units will remain subject to forfeiture until vested as provided herein. The Units will vest, and the risk of forfeiture will lapse, *[insert vesting schedule]*; *provided*, *however*, that if the Participant ceases to provide services to the Company before this Award has become vested with respect to all of the Units, no additional Units will vest after the termination of such services.

(b) Treatment Upon a Change in Control. In the event of a Change in Control of the Company, the Committee administering the Plan may take any of the actions described in Section 14 of the Plan with respect to this Award.

(c) Accelerated Vesting upon Death or Disability. If the Participant ceases to provide services to the Company by reason of the Participant's death or Disability before this Award has become vested with respect to all of the Units, all unvested Units will vest as of such termination date.

(d) Termination of Service Relationship. If the Participant ceases to provide services to the Company for any reason other than death or disability before this Award has become vested with respect to all of the Units, the Participant will immediately forfeit all unvested Units without any payment therefor.

4. Settlement of Units. After any Units vest pursuant to Section 3, the Company will, as soon as practicable, and no later than the March 15 of the year following the year that such Units vest, cause to be issued and delivered to the Participant, or to the Participant's designated beneficiary or estate in the event of the Participant's death, one Share in payment and settlement of each vested Unit. Delivery of the Shares will be effected by issuance of one or more stock certificates issued in the Participant's name, by a book-entry in the Participant's name with the Company's transfer agent, or by the electronic delivery of the Shares to a brokerage account designated by the Participant, and shall be subject to the tax withholding provisions of Section 5 and shall be in complete satisfaction and settlement of such vested Units.

5. Tax Consequences and Withholding. No Shares will be delivered to the Participant in settlement of vested Units unless the Participant has made arrangements acceptable to the Company for payment of any federal, state, local or foreign withholding taxes that may be due as a result of the delivery of the Shares ("Withholding Taxes"). Specifically, pursuant to the Grant Notice and this Section 5, Participant hereby agrees to a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "FINRA Dealer") as Participant's agent (the "Agent") whereby the Agent is irrevocably authorized to sell a portion of the Shares to be issued on a vesting date necessary to satisfy the Withholding Taxes and whereby the FINRA Dealer will forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company. If, for any reason, such "same day sale" commitment pursuant to this Section 5 does not result in sufficient proceeds to satisfy the Withholding Taxes or would be prohibited by applicable law at the applicable time, Participant authorizes the Company to satisfy the obligations with regard to all Withholding Taxes by one or a combination of the following: (a) withholding from any compensation otherwise payable to Participant by the Company; (b) causing Participant to tender a cash payment (which may be in the form of a check, electronic wire transfer or other method permitted by the Company); or (c) withholding a number of whole Shares having a fair market value, as determined by the Company as of the date on which the Withholding Taxes obligations arise.

6. Section 409A. This Award is intended to be exempt from Section 409A of the Code under the short-term deferral exception specified in Treas. Reg. §1.409A-l(b)(4), and to the maximum extent permitted this Agreement will be interpreted and administered in accordance with this intent. Each amount to be paid or benefit to be provided under this Agreement shall be construed as a separate and distinct payment for purposes of Section 409A.

7. No Shareholder Rights. The Units subject to this Award do not entitle the Participant to any rights of a shareholder of the Company's Common Stock. The Participant will not have any of the rights of a shareholder of the Company in connection with the grant of Units subject to this Agreement unless and until Shares are issued to the Participant upon settlement of the Units as provided in Section 4.

8. NO GUARANTEE OF CONTINUED SERVICE. THE PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF UNITS PURSUANT TO THE VESTING SCHEDULE IN THIS AGREEMENT IS EARNED ONLY BY CONTINUING AS AN EMPLOYEE, DIRECTOR, OR CONSULTANT AT THE WILL OF THE COMPANY (AND NOT THROUGH THE ACT OF BEING HIRED OR BEING GRANTED AN AWARD). THE PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS AN EMPLOYEE, DIRECTOR, OR CONSULTANT FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND WILL NOT INTERFERE WITH THE PARTICIPANT'S RIGHT OR THE COMPANY'S RIGHT TO TERMINATE THE PARTICIPANT'S RELATIONSHIP (A) AS AN EMPLOYEE AT ANY TIME, WITH OR WITHOUT CAUSE; (B) AS A CONSULTANT PURSUANT TO THE TERMS OF THE PARTICIPANT'S AGREEMENT WITH THE COMPANY OR AN AFFILIATE; OR (C) AS A DIRECTOR PURSUANT TO THE BYLAWS OF THE COMPANY AND ANY APPLICABLE PROVISIONS OF THE CORPORATE LAW OF THE STATE OR OTHER JURISDICTION IN WHICH THE COMPANY IS DOMICILED, AS THE CASE MAY BE.

9. Entire Agreement; Governing Law. The Plan is incorporated herein by reference. The Plan and this Agreement constitute the entire agreement of the parties regarding the acquisition of stock in the Company and supersede in their entirety all prior oral and written undertakings and agreements of the Company and the Participant on that subject, with the exception of any other Awards previously granted and delivered to the Participant under the Plan or any similar plan maintained by the Company or its Affiliates. This Agreement may not be modified adversely to the Participant's interest except by means of a writing signed by the Company and the Participant. This Agreement is governed by the internal substantive laws but not the choice of law rules of the State of Minnesota.

* * * * *

[Signature page follows]

Signature page to Restricted Stock Unit Agreement

By the Participant's signature and the signature of the Company's representative below, the Participant and the Company agree that this Award is granted under and governed by the terms and conditions of the Plan and this Agreement. The Participant has reviewed the Plan and this Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands all provisions of the Plan and Agreement. The Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board of Directors (or any Committee to whom the Board has delegated administration of the Plan) upon any questions relating to the Plan and this Agreement.

As a condition to acceptance of this Award, to the fullest extent permitted under the Plan, Section 5 of this Agreement and applicable law, Participant acknowledges that Withholding Taxes will be satisfied through the sale of a number of Shares issued on the settlement of vested Units and the remittance of the cash proceeds to the Company. The Company is authorized and directed by the Participant, to make payment from the cash proceeds of this sale directly to the appropriate taxing authorities in an amount equal to the taxes required to be withheld. The mandatory sale of Shares to cover Withholding Taxes is imposed by the Company on the Participant in connection with the receipt of this Award, and it is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and be interpreted to meet the requirements of Rule 10b5-1(c).

The Participant further agrees to notify the Company of any change in the Participant's residence address indicated below.

PARTICIPANT:	**CELCUITY INC.**
_____	By: _____
(Signature)	Title: _____
_____	_____
(Print Name)	(Print Name)
Address:	Address:
_____	Celcuity Inc.
_____	16305 36th Avenue N., Suite 100
_____	Minneapolis, MN 55446

Exhibit 19

CELCUITY INC.

POLICY TO PROHIBIT INSIDER TRADING

As Amended & Restated February 12, 2026

Executive Summary

This Policy to Prohibit Insider Trading (the "**Insider Trading Policy**" or the "**Policy**") provides guidelines for directors, officers, employees, or other representatives of Celcuity Inc. ("**Celcuity**" or the "**Company**") who may have access to material non-public information about the Company or its customers, suppliers and other business partners.

Both federal securities laws and Company policy prohibit transactions in Company Securities at a time when you may be in possession of material information about the Company that has not been publicly disclosed. "**Company Securities**" means the Company's common stock, options to purchase common stock, or any other type of securities that the Company may issue, including (but not limited to) preferred stock, convertible debentures and warrants, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's Securities.

You are similarly prohibited from buying or selling securities of Company customers, suppliers or other business partners when you have received, through your employment or other relationship with the Company, material non-public information about such customers, suppliers or business partners. These prohibitions also apply to members of your household as well as all others whose transactions may be attributable to you. Anyone who violates these prohibitions can face severe civil and criminal penalties.

"**Material information**" is any information that a reasonably prudent investor would consider to be important in making a decision to buy or sell a security. It specifically includes any information that would affect the public market price for the Company's common stock. Either positive or negative information may be material. Once a public announcement has been made of the material information, you should wait at least 24 hours following the announcement before engaging in any market trade of Company stock (e.g., announcement at 10:00 a.m. on Monday, trade after 10:00 a.m. on Tuesday; announcement at 2:00 p.m. on Friday, trade after 2:00 p.m. on Monday), assuming at the time of the transaction you do not have other material information that has not been made public.

Securities laws and Company policy also prohibit disclosure of material non-public information except on a need-to-know basis. Even if you are not engaging in any stock trading activity, you must not disclose material information to others, especially to those outside the Company. This information is owned by the Company and must be protected as such. **Any questions from brokers, securities analysts or the media regarding the Company should be directed to the Chief Executive Officer, the Chief Financial Officer, or the General Counsel.**

This is only a summary. Please refer to the entire Insider Trading Policy set forth below for additional restrictions and requirements. If you have any questions about this Policy or your ability to share information or engage in a transaction involving Company Securities, please contact our General Counsel.

Insider Trading Policy

The Need for an Insider Trading Policy: The Company's stock is publicly-traded; therefore, the Company is required to take active steps to prevent violations of insider trading laws by Company personnel, and members of the Board of Directors (each, a "**Director**"). Although insider trading has long been illegal, over the years Congress has expanded the enforcement authority of the Securities and Exchange Commission (the "**SEC**") and the Justice Department, increased substantially the penalties for insider trading, and created potential liability for companies and other "controlling persons," such as directors and managers, for violations by anyone under their supervision, influence or control. We are adopting this Insider Trading Policy to protect the Company and its Directors and personnel from liability and reputational harm, and to avoid even the appearance of improper conduct on the part of anyone employed by or associated with Celcuity (because anyone with material non-public information could be considered an "insider"). We cannot afford to have our reputation for integrity and ethical conduct damaged.

The Consequences: The consequences of insider trading violations can be severe. For individuals who trade on inside information (or tip information to others), the consequences can include a civil penalty of up to three times the profit gained or loss avoided, a criminal penalty (no matter how small the profit) of up to $5 million, and a prison sentence of up to 20 years. For a company (as well as possibly any supervisory person) that fails to take appropriate steps to prevent illegal trading, the consequences can include a civil penalty of the greater of $1 million or three times the profit gained or loss avoided as a result of the individual's violation, and a criminal penalty of up to $25 million. In addition, any employee or consultant who violates this Policy faces discipline or even termination of employment for cause.

Any of the above consequences, even an SEC investigation that does not result in prosecution, can tarnish one's reputation and irreparably damage a career. Regulators use sophisticated surveillance techniques to identify transactions that may appear illegal, so you should assume that any suspicious trading activity, even if it is through foreign accounts or family members or friends or relates to only a small number of shares, will be detected and vigorously prosecuted.

Administration of the Policy: Our General Counsel will administer the Policy, provided that with respect to the General Counsel, the Chief Financial Officer will administer the Policy. All determinations by such individuals will be final and not subject to further review.

Our Policy: It is the policy of the Company that no Director, employee or other Company personnel (including contractors) who is aware of material non-public information relating to the Company (so-called "inside" information of a nature which could affect the Company's stock price or affect an investor's decision to buy or sell the Company Securities) may, directly or indirectly through family members or other persons or entities:

- Engage in any transaction in Company Securities (including sales, purchases and bona fide gifts), unless this Policy provides a specific exception;

- Recommend that others engage in transactions in Company Securities;

- Disclose material non-public information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to anyone; or

- Engage in any other action to take advantage of material non-public information, including assisting anyone engaged in the above activities.

Small transactions, and transactions that may be necessary or justifiable for independent reasons (such as the need to sell Company stock to raise money for an emergency expenditure), are no exception. The securities laws do not recognize any mitigating circumstances, and even the appearance of an improper transaction must be avoided to preserve our reputation for adhering to the highest standards of conduct.

- Material Information. Material information is any information that a reasonable investor would consider important in a decision to buy, hold or sell securities. In short, any information that could reasonably affect a company's stock is deemed to be "material."

- Examples. Common examples of information that will frequently be regarded as material are: projections of future earnings or losses; changes in projections which have been made public, news of a pending or proposed merger, acquisition, or tender offer; news of a significant product development or clinical trial results; changes in dividend policies, the declaration of a stock split or the offering of additional securities; changes in management; impending bankruptcy or financial liquidity problems; significant licensing or collaboration agreements; significant cybersecurity incidents or other significant disruptions in our business, reputation or assets; and the gain or loss of a substantial customer, supplier or other business partner. This is not an exhaustive list. Either positive or negative information may be material.

- "Non-public" Information. As you can appreciate, it is also improper for Company personnel to enter a trade immediately after Celcuity has made a public announcement of material information, including earnings releases. Because Company stockholders and the investing public should be afforded the time to receive the information and act upon it, as a general rule you should not engage in any transactions until at least 24 hours after the information has been released. Thus, if an announcement is made at 10:00 a.m. on Monday, after 10:00 a.m. on Tuesday generally would be the first time you should trade, assuming you do not have other material information that has not been made public. If an announcement is made at 2:00 p.m. on Friday, the first time trading would be permitted would generally be after 2:00 p.m. on the following Monday.

- 20/20 Hindsight. Remember, if your securities transactions become the subject of scrutiny, they will be viewed after-the-fact with the benefit of hindsight. As a result, before engaging in any securities transaction, you should carefully consider how regulators and others might view your transaction in hindsight.

- Transactions by Dependents & Household Members. This Policy also applies to anyone living in your household (other than an unrelated person who the applicable Administrator of this Policy determines should not be covered by this Policy) and anyone financially dependent upon you or whose transactions in Company Securities are directed by you or are subject to your influence or control, even if they do not live in your household (such as parents, siblings or adult children who consult with you before they trade in Company Securities). Company personnel are expected to be responsible for compliance by their dependents and personal household, and you should treat all transactions by such persons as if the transactions were for your own account.

  This Policy does not, however, apply to personal securities transactions of family members, financial dependents, or household members where the purchase or sale decision is made by a third party not controlled by, influenced by, or related to you or your family members.

- Transactions by Entities That You Influence or Control. This Policy applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "**Controlled Entities**"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account. However, nothing in this Policy is intended to limit the ability of a venture capital partnership or other similar entity with which a director is affiliated to distribute Company Securities to its partners, members or other similar persons. It is the responsibility of each affected Director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

- Disclosing Information to Others. Whether the information is proprietary information about the Company or one of its customers, suppliers or other business partners, or information that could have an impact on the market price of the Company's or its customer's, supplier's or other business partner's stock, Company personnel must not pass the information on to others. The above penalties apply whether or not you derive any benefit from another's actions. In order to prevent unintentional disclosure, all inquiries and requests for information regarding the Company or the Company's customers, suppliers or other business partners (e.g., from the media, stockbrokers or securities analysts) should be referred to our General Counsel.

This Policy also applies to information relating to any other organization, including our customers, suppliers, and other business partners, and organizations that are involved in a potential transaction or business relationship with the Company, obtained in the course of your employment or other relationship with Celcuity. For example, you must keep information about that other company confidential and cannot engage in transactions in that other company's securities if you are aware of non-public information that is material to that company. Note that what constitutes "material non-public information" differs by company. Information that is not material to Celcuity may be material to another company. Please consult with our General Counsel if you have any questions.

Exceptions: This Policy does not apply to the following transactions, except as specifically noted:

- The exercise of stock options, except this Policy **does apply** to both the cashless exercise of such options and open market sales of shares acquired through the exercise of any options. Furthermore, stock option exercises are subject to the terms of the Company's governing stock option plans and any agreements entered into between the Company and the holders of such options.

- The purchase of Company Securities under the Company's employee stock purchase plan resulting from the periodic contribution of money to the plan pursuant to a payroll deduction election, including any decision to terminate contributions made during any pay period, except that this Policy **does apply** to the sale of Company Securities purchased pursuant to the employee stock purchase plan.

- The initial election to participate in the employee stock purchase plan for any enrollment period or any modifications following such initial election (i.e., to increase or decrease the contributions made during any pay period), if such election or modification was made at a time when the Covered Person does not possess material non-public information.

- The purchase of Company Securities in the Company's 401(k) plan resulting from the periodic contribution of money to the plan pursuant to a payroll deduction election. This Policy **does apply**, however, to certain elections you may make under the 401(k) plan, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company Securities fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Company Securities fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Company Securities fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in the allocation of loan proceeds to the Company stock fund. It should be noted that sales of Company Securities from a 401(k) account are also subject to Rule 144, and therefore "affiliates" of the Company (typically officers and Directors) should ensure that a Form 144 is filed when required.

- Any other purchase of Company Securities from the Company or sales of Company Securities to the Company.

Additional Prohibited Transactions: Celcuity prohibits Company personnel from engaging in any of the following activities with respect to Company Securities:

- Trading in Company Securities on a short-term basis. Any Company stock purchased in the open market must be held for a minimum of six months. Subject to the terms of the applicable awards, stock received from the Company as a compensatory equity award that is registered with the SEC on a Form S-8 need not be held for six months and can be sold at any time, assuming you do not have any material non-public information.

- Margin accounts and pledged securities. This Policy prohibits holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan.

- Hedging Transactions. This Policy prohibits engaging in any hedging transactions with respect to Company Securities. Hedging transactions include transactions for which the value of the trade is tied to the value of Company Securities. Examples are put options, call options, and other derivative and financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such transactions may permit a director, officer or employee to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer or employee may no longer have the same objectives as the Company's other shareholders.

- Short Sales. This Policy prohibits short sales of Company Securities. Short sales (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. Section 16(c) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), also prohibits officers and directors from engaging in short sales.

- Standing and Limit Orders. Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as described below) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer or other employee is in possession of material non-public information. The Company therefore discourages placing standing or limit orders on Company Securities. If a person subject to this Policy determines that they must use a standing order or limit order, the order should be

limited to short duration and should otherwise comply with the restrictions and procedures outlined below under the heading "Trading Windows and Advance Notice Procedure for Directors, Executive Officers and Certain Other Key Employees." In addition, if you are a Covered Person under this Policy, you should inform any broker with whom you place a standing or limit order of that designation at the time the order is placed.

Trading Windows and Advance Notice Procedure for Directors, Executive Officers and Certain Other Key Employees: Because the Company's directors, executive officers and certain other key employees listed below (the "**Covered Persons**") have regular access to material non-public information, this Policy requires that such persons comply with the trading window and advance notice procedures described below for all transactions in Company Securities. A "**Covered Person**" is any of the following persons subject to this Policy: (a) all executive officers and Directors of Celcuity Inc., (b) all administrative assistants supporting executive officers, (c) all members of the senior management team of Celcuity, (d) those persons within Celcuity identified by the Company's General Counsel as a Covered Person for purposes of this Insider Trading Policy, and (e) if they are otherwise subject to this Policy, the household members, dependents and Controlled Entities of the individuals identified in (a), (b), (c), or (d) of this sentence. The Company may amend the list from time to time as it deems necessary to add or subtract from the list of Covered Persons.

The trading window and advance notice procedures are not applicable to employees other than the Covered Persons. However, even if you are not subject to these additional restrictions, you should exercise caution when engaging in transactions outside of the trading window because of the heightened risk that those transactions will attract regulatory scrutiny and may expose you to accusations of improper behavior.

Trading Window: Transactions in Company Securities by Covered Persons will be restricted to certain window periods following the end of each quarter. The window during which trades generally will be permitted, provided such trades comply with advance notice procedures (see below) and provided you possess no material non-public information, will begin 24 hours (not including weekends and other non-business days) after the public release of all material information with respect to the financial results of the most recently completed quarter and will end at the close of market on the 15th day of the third month following the end of the most recent fiscal quarter.

Event-Specific Restricted Periods: From time to time, there may be a material event that is known only to certain Covered Persons. In such instances, to avoid the appearance of impropriety, the General Counsel, together with the Chief Financial Officer, may not allow any Covered Persons to engage in transactions in Company Securities, regardless of whether the trading window is open. The General Counsel also has discretion to close the trading window early in any particular quarter. In either of these situations, the General Counsel may notify Covered Persons that they should not trade in Company Securities, without disclosing the reason for the restriction. The existence of an event-specific restricted period or shortening of the trading window will not be announced to the Company as a whole and should not be communicated to any other person. Even if the General Counsel has not designated you as a person who should not trade due to an event-specific restriction, you should not trade while aware of material non-public information.

Pre-Clearance of Transactions: To provide assistance in avoiding even the appearance of an improper transaction (which could result, for example, where a person engages in a trade while unaware of a pending major development), all transactions in Company Securities by "Covered Persons" (as defined above) must notify the General Counsel of the proposed transaction by submitting the Transaction Pre-Clearance Form set forth in Attachment 1, as updated from time to time by the Company, and await pre-clearance from the General Counsel. The pre-clearance request should be submitted at least two business days in advance of the proposed transaction and must be effected within five business days of receipt of pre-clearance, unless an exception is granted. Covered Persons should also notify the General Counsel once the pre-cleared transaction is completed.

The pre-clearance will serve only to confirm the status of the trading window. Even if you receive pre-clearance of an open trading window from the General Counsel, you are still prohibited under this Policy from effecting the transaction if you possess material non-public information or it would violate any other provision of this Policy or any applicable securities law or regulation. Pre-clearance is not a defense to a claim of insider trading and does not excuse you from otherwise complying with securities laws or this Policy. You may want to consult outside counsel regarding the proposed transaction. Transactions by the General Counsel must receive pre-clearance by the Chief Financial Officer.

Rule 10b5-1 Plans and Exceptions: The trading window restrictions and pre-clearance procedures set forth above do not apply to the transactions to which this Policy does not apply, as described under the heading "Exceptions." Further, the trading window restrictions, event-specific restricted periods, and pre-clearance procedures do not apply to transactions conducted pursuant to a binding contract, written plan or specific instruction that is adopted and operated in compliance with Rule 10b5-1(c) of the Exchange Act and is adopted at a time when such Covered Person does not possess material non-public information, so long as the underlying contract, instruction or plan also complies with the Company's Rule 10b5-1 Plan Guidelines set forth in Attachment 2 ("**Rule 10b5-1 Plan Guidelines**"). Any adoption, modification or termination of a Rule 10b5-1 Plan must be submitted to the General Counsel for approval, at least five business days prior to entering into, modifying or terminating the Rule 10b5-1 Plan.

In addition, Covered Persons who enter into any written contract, plan, instruction or arrangement, including holders of certain Company equity awards, such as restricted stock units, where the plan or instruction authorizes an agent to sell only such shares as are necessary to satisfy the Company's tax withholding obligations arising exclusively from the vesting of the equity award, at a time that such Covered Person is not aware of material non-public, which (i) specifies the amount of Company Securities to be purchased or sold and the price at which and the date on which they are to be purchased or sold, or (ii) includes a written formula or algorithm to determine those transactions, or (iii) does not permit the Covered Person to exercise any subsequent influence over the transactions, must also (x) submit a request for approval at least five business days prior to entering into, modifying or terminating the contract, plan, instruction or arrangement, even if it does not meet the specific criteria of Rule 10b5-1(c) or the Company's Rule 10b5-1 Plan Guidelines, or (y) with respect to certain Company equity awards, otherwise comply with the process established by the Company's equity plan administrator for such plan or instruction.

Post-Termination Transactions: This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material non-public information when his or her service terminates, that individual may not engage in transactions in Company Securities until that information has become public or is no longer material.

Certification: Company personnel may be required from time to time to re-certify their understanding of and intent to comply with this Policy.

Company Assistance: Any person who has any general questions about this Policy or questions about specific transactions should contact the General Counsel. Remember, however, the ultimate responsibility for adhering to this Policy and avoiding improper transactions rests with you. In this regard, it is imperative that you use your best judgment and consult with your legal and financial advisors, as needed. We advise you to seek assistance if you have any questions at all. The rules relating to insider trading can be complex, and a violation can carry severe consequences.

ATTACHMENT 1

CELCUITY INC.
TRANSACTION PRE-CLEARANCE FORM

Name of Covered Person: _____

Date of Notice: _____

Anticipated Date of Transaction: _____

Please describe the proposed transaction, including the type of transaction (purchase, sale, option exercise, gift, etc.), the number of shares, and any third parties involved in the transaction:

Please list any transactions in the securities of Celcuity Inc. ("Celcuity") in which you have engaged during the six months prior to the date of this notice, including, but not limited to, purchases or sales in the open market, exercises of options or warrants, gifts, or receipt of grants of restricted stock or other equity, OR if you have not had any such transactions in the preceding six months, please so indicate by checking this box. ☐

Date _____ Type of Transaction _____

Please check the following box to indicate that you are not in possession of material non-public information regarding Celcuity. ☐

_____
Signature of Covered Person

NOTICE: This Form relates only to certain aspects of Celcuity's Policy to Prohibit Insider Trading. Pre-clearance by the Company only indicates that a trading window is open. It does not indicate whether the transaction is allowable under applicable securities laws or Celcuity policies. YOU are responsible for compliance with all applicable securities laws and Celcuity policies. You are encouraged to consult outside counsel before engaging in the proposed transaction. Failure to receive pre-clearance at all or on a timely basis shall not give rise to any claims against the General Counsel, Chief Financial Officer, Chief Executive Officer or Celcuity.

To be completed by the Company:

Pre-cleared this ____ day of _____, 20___.

Signature: _____
Title: General Counsel

ATTACHMENT 2

CELCUITY INC.
RULE 10B5-1 PLAN GUIDELINES

Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), provides a defense from insider trading liability if transactions occur pursuant to a plan that complies with the conditions set forth in Rule 10b5-1(c) of the Exchange Act (a "**Rule 10b5-1 Plan**"). If the plan meets the requirements of Rule 10b5-1, transactions in Company Securities may occur without regard to certain insider trading restrictions. In order to avoid a violation of securities laws and to comply with the Celcuity Inc. Policy to Prohibit Insider Trading (the "**Policy**"), any person subject to the Policy that intends to use a Rule 10b5-1 Plan must comply with these Rule 10b5-1 Guidelines. Please note that brokers may apply additional procedures, which may be more stringent.

In general, a Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material non-public information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The Rule 10b5-1 Plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

As specified in the Policy, a Rule 10b5-1 Plan must be approved by the General Counsel and meet the requirements of Rule 10b5-1 and these Guidelines. Any Rule 10b5-1 Plan must be submitted for approval five business days prior to entering into, modifying or terminating the Rule 10b5-1 Plan. Following approval of entry into the Rule 10b5-1 Plan, no further pre-approval of transactions conducted under the Rule 10b5-1 Plan will be required.

The following guidelines apply to all Rule 10b5-1 Plans:

- You may enter into, modify or terminate a Rule 10b5-1 Plan only during a trading window. In addition, you may not enter into, modify or terminate a Rule 10b5-1 Plan during an event-specific restricted period or otherwise while you are aware of material non-public information.

- Unless otherwise determined by the General Counsel, all Rule 10b5-1 Plans must have a duration of at least 6 months and no more than 2 years.

- For officers and directors, no transaction may take place under a Rule 10b5-1 Plan until the later of (a) 90 days after adoption or modification (as specified in Rule 10b5-1) of the Rule 10b5-1 Plan or (b) two business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the fiscal quarter (the Company's fourth fiscal quarter in the case of a Form 10-K) in which the Rule 10b5-1 Plan was adopted or modified (as specified in Rule 10b5-1). In any event, the cooling-off period is subject to a maximum of 120 days after adoption of the plan.

- For persons other than officers and directors, no transaction may take place under a Rule 10b5-1 Plan until 30 days following the adoption or modification (as specified in Rule 10b5-1) of a Rule 10b5-1 Plan.

- Subject to certain limited exceptions specified in Rule 10b5-1, you may not enter into more than one Rule 10b5-1 Plan at the same time.

- Subject to certain limited exceptions specified in Rule 10b5-1, you are limited to only one "single trade" Rule 10b5-1 Plan during any 12-month period (i.e., a Rule 10b5-1 Plan designed to effect an open market purchase or sale of the total amount of securities subject to the Rule 10b5-1 Plan as a single transaction).

- You must act in good faith with respect to a Rule 10b5-1 Plan. A Rule 10b5-1 Plan cannot be entered into as part of a plan or scheme to evade the prohibition of Rule 10b-5. Therefore, although modifications to an existing Rule 10b5-1 Plan are not prohibited, a Rule 10b5-1 Plan should be adopted with the intention that it will not be amended or terminated prior to its expiration.

- Officer and directors must include a representation in the Rule 10b5-1 Plan at the time of its adoption or modification that (i) the person is not aware of material non-public information about the Company or Company Securities and (ii) the person is adopting the plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5.

The Company and the Company's officers and directors must make certain disclosures in SEC filings concerning Rule 10b5-1 Plans. Officers and directors of the Company must undertake to provide any information requested by the Company regarding Rule 10b5-1 Plans for the purpose of providing the required disclosures or any other disclosures that the Company deems to be appropriate under the circumstances. Each director, officer and other Section 16 insider understands that the approval or adoption of a pre-planned selling program in no way reduces or eliminates such person's obligations under Section 16 of the Exchange Act, including such person's disclosure and short-swing trading liabilities thereunder. If any questions arise, such person should consult with their own counsel in implementing a Rule 10b5-1 Plan.

[For use outside of Veeva.]

CERTIFICATION

The undersigned hereby certifies that they have read and understand, and agree to comply with, Celcuity Inc.'s Policy to Prohibit Insider Trading.

Date: _____

_____
Signature

_____
Name (please print)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 26, 2026, with respect to the financial statements included in the Annual Report of Celcuity Inc. on Form 10-K for the year ended December 31, 2025. We hereby consent to the incorporation by reference in the Registration Statements of Celcuity Inc. on Form S-8 (Reg. Nos. 333-287766, 333-279556, 333-271976, 333-270238, 333-265328, 333-256500, 333-253940, 333-238787, and 333-221117) and on Form S-3 (Reg. No. 333-292646, 333-281887 and 333-275551).

Minneapolis, Minnesota
March 26, 2026

Exhibit 31.1

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian F. Sullivan, certify that:

1. I have reviewed this annual report on Form 10-K of Celcuity Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2026

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

Exhibit 31.2

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vicky Hahne, certify that:

1. I have reviewed this annual report on Form 10-K of Celcuity Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 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 Annual Report on Form 10-K for the year ended December 31, 2025 (the "Report") by Celcuity Inc. (the "Registrant"), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

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

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

Date: March 26, 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 Annual Report on Form 10-K for the year ended December 31, 2025 (the "Report") by Celcuity Inc. (the "Registrant"), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

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

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

Date: March 26, 2026

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