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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 2, 2026

Celcuity Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware	**001-38207**	**82-2863566**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2800 Campus Drive, Suite 140
Minneapolis, Minnesota 55441
(Address of Principal Executive Offices and Zip Code)

(763) 392-0123
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

On June 2, 2026, Celcuity Inc. (the "Company") issued a press release announcing detailed efficacy and safety results from its *PIK3CA* mutant-type ("MT") cohort of its Phase 3 VIKTORIA-1 clinical trial. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 7.01, including the accompanying exhibit, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Item 7.01 shall not be incorporated into any filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On June 2, 2026, the Company announced detailed efficacy and safety results from the *PIK3CA* MT cohort of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib, an investigational pan-PI3K/mTORC1/2 inhibitor, in adults with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), *PIK3CA* MT, locally advanced or metastatic breast cancer ("ABC"), following progression on, or after, treatment with a CDK4/6 inhibitor and an aromatase inhibitor. VIKTORIA-1 is the first Phase 3 clinical trial to compare the efficacy of two PI3K/AKT/mTOR ("PAM") inhibitors in this patient population.

In the trial, the gedatolisib-triplet demonstrated a statistically significant and clinically meaningful improvement in median progression free survival ("PFS") among patients, increasing the likelihood of survival without disease progression or death by two times compared to alpelisib plus fulvestrant (based on a hazard ratio [HR] of 0.50; 95% CI: 0.37-0.68; $p<0.0001$). The median PFS, as assessed by blinded independent central review, was nearly two-times longer, 11.1 months versus 5.6 months, compared to alpelisib plus fulvestrant. The objective response rate ("ORR") of the gedatolisib-triplet was 48.9% compared to 26.0% with alpelisib plus fulvestrant, and the median duration of response ("DOR") for the gedatolisib-triplet was 15.7 months compared to 7.5 months for alpelisib plus fulvestrant.

For the gedatolisib-doublet, the median PFS was more than two-times longer, 11.3 months versus 5.6 months, compared to alpelisib plus fulvestrant (HR=0.51; 95% CI: 0.33-0.79; descriptive $p=0.0013$). The ORR of the gedatolisib-doublet was 35.7%, and the median DOR was 24.2 months.

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

- First Phase 3 trial to demonstrate superiority of one PAM inhibitor versus another.
- The median PFS of 11.1 months for the gedatolisib-triplet is the highest reported by any Phase 3 trial for patients with HR+/HER2- ABC receiving a regimen including endocrine therapy as second-line treatment.
- The ORR of 48.9% for the gedatolisib-triplet is the highest reported by any Phase 3 clinical trial for a regimen including endocrine therapy in second-line HR+/HER2- ABC.

The gedatolisib-triplet and gedatolisib-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, the gedatolisib-doublet, and alpelisib plus fulvestrant groups included neutropenia (58.8%, 0%, and 0.7% of patients, respectively); stomatitis (16.3%, 5.8%, and 5.3% of patients, respectively); rash (6.5%, 5.8%, and 15.1% of patients, respectively); and hyperglycemia (2.6%, 0%, and 14.5% of patients, respectively). TRAEs led to the discontinuation of study treatment in 2.6% of patients in the gedatolisib-triplet group, 3.8% in the gedatolisib-doublet group, and 7.1% in the alpelisib plus fulvestrant group. One Grade 5 TRAE in the gedatolisib-triplet group, which was related to palbociclib, was reported; no Grade 5 TRAEs were reported in the gedatolisib-doublet group, and two Grade 5 TRAEs were reported in the alpelisib plus fulvestrant group.

Overall survival, a key secondary endpoint in VIKTORIA-1, while immature at the time of the analysis, showed promising trends for both the gedatolisib-triplet and the gedatolisib-doublet.

The Company intends to submit these data to the U.S. Food and Drug Administration (the "FDA") as a supplemental New Drug Application ("sNDA") and to submit VIKTORIA-1 data to other regulatory authorities following the sNDA submission.

The Company believes that it is on track to launch gedatolisib commercially, in anticipation of its potential FDA approval in the third quarter of 2026.

The FDA has granted Priority Review of Celcuity's New Drug Application ("NDA") for gedatolisib in patients with HR+/HER2- *PIK3CA* wild-type ("WT") ABC and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026.

Forward-Looking Statements

This Current Report on Form 8-K (including the exhibit thereto) contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of clinical trial data; the status and timing of the FDA's review of our NDA for gedatolisib, including the PDUFA goal date assigned by the FDA; the ability of our data to support the filing of an sNDA with the FDA and comparable filings with other regulatory authorities; the market opportunity for gedatolisib; our expectations regarding the timing of and our ability to obtain FDA approval to commercialize gedatolisib; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib including future subcutaneous formulations of gedatolisib; our anticipated use of cash; and the strength of our balance sheet. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. The forward-looking statements included in this report are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our clinical results are based on an ongoing analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in our clinical trials or the FDA's review of our NDA for gedatolisib; our ability to obtain and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; the development of therapies and tools competitive with gedatolisib; and our ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2025, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this report to reflect events or circumstances after the date hereof.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release dated June 2, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 2, 2026

CELCUITY INC.

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

Exhibit 99.1

Celcuity's Gedatolisib Combination Regimens Doubled the Likelihood of Survival without Disease Progression or Death Compared to Alpelisib plus Fulvestrant in the PIK3CA Mutant Cohort of the Pivotal Phase 3 VIKTORIA-1 Trial in Patients with HR+/HER2- Advanced Breast Cancer

- *Gedatolisib plus fulvestrant and palbociclib (the "gedatolisib-triplet") reduced the risk of disease progression or death by 50% vs. alpelisib plus fulvestrant (HR=0.50; 95% CI: 0.37–0.68; p<0.0001). Median progression-free survival ("PFS") was 11.1 months with the gedatolisib triplet versus 5.6 months with alpelisib plus fulvestrant*

- *Gedatolisib plus fulvestrant (the "gedatolisib-doublet") reduced the risk of disease progression or death by 49% vs. alpelisib plus fulvestrant (HR=0.51; 95% CI: 0.33–0.79; descriptive p=0.0013). Median PFS was 11.3 months with the gedatolisib-doublet versus 5.6 months with alpelisib plus fulvestrant*

- *Gedatolisib regimens demonstrated robust and durable responses: 48.9% objective response rate ("ORR") and median duration of response ("DoR") of 15.7 months for the gedatolisib-triplet and 35.7% ORR and median DoR of 24.2 months for the gedatolisib-doublet*

- *The safety data and study treatment discontinuation rates for the gedatolisib-triplet and -doublet were consistent with previously reported data from the PIK3CA wild-type cohort of VIKTORIA-1*

MINNEAPOLIS, June 2, 2026 — Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications, today announced detailed efficacy and safety results from the *PIK3CA* mutant ("MT") cohort of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib, an investigational pan-PI3K/mTORC1/2 inhibitor, in adults with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), *PIK3CA* mutated, locally advanced or metastatic breast cancer ("ABC"), following progression on, or after, treatment with a CDK4/6 inhibitor and an aromatase inhibitor. VIKTORIA-1 is the first Phase 3 clinical trial to compare the efficacy of two PI3K/AKT/mTOR ("PAM") inhibitors in this patient population.

The study results will be presented in a late-breaking abstract ("LBA") oral session at the American Society of Clinical Oncology ("ASCO") Annual Meeting today, Tuesday, June 2, 2026, 12:09 p.m. CDT.

The PAM pathway is a key oncogenic driver of HR+/HER2- breast cancer that requires inhibition of multiple molecular components to comprehensively blockade excessive PAM signaling in tumors with or without a PAM variant. Gedatolisib is the first multitarget PAM inhibitor to demonstrate superior efficacy relative to a single-target inhibitor of this pathway. In the PIK3CA MT cohort of the Phase 3 VIKTORIA-1 trial, the gedatolisib-triplet demonstrated a statistically significant and clinically meaningful improvement in median PFS among patients, increasing the likelihood of survival without disease progression or death by two times compared to alpelisib plus fulvestrant (based on a hazard ratio [HR] of 0.50; 95% CI: 0.37-0.68; $p<0.0001$). The median PFS, as assessed by blinded independent central review ("BICR"), was nearly two-times longer, 11.1 months versus 5.6 months, compared to alpelisib plus fulvestrant. The ORR of the gedatolisib-triplet was 48.9% compared to 26.0% with alpelisib plus fulvestrant and the median DOR for the gedatolisib triplet was 15.7 months compared to 7.5 months for alpelisib plus fulvestrant.

For the gedatolisib-doublet, the median PFS was more than two-times longer, 11.3 months versus 5.6 months, compared to alpelisib plus fulvestrant (HR=0.51; 95% CI: 0.33-0.79; descriptive p=0.0013). The ORR of the gedatolisib-doublet was 35.7% and the median DOR was 24.2 months.

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

- First Phase 3 trial to demonstrate superiority of one PAM inhibitor versus another.
- The median PFS of 11.1 months for the gedatolisib-triplet is the highest reported by any Phase 3 trial for patients with HR+/HER2- ABC receiving a regimen including endocrine therapy as second-line treatment.
- The objective response rate of 48.9% for the gedatolisib-triplet is the highest reported by any Phase 3 clinical trial for a regimen including endocrine therapy in second-line HR+/HER2- ABC.

"Therapies that target only PI3Kα or AKT typically offer modest benefit for patients with *PIK3CA* mutant HR+/HER2- advanced breast cancer whose disease has progressed while on or after treatment with a CDK4/6 inhibitor," said Sara Hurvitz, MD, Senior Vice President, Clinical Research Division, Fred Hutchinson Cancer Center, Smith Family Endowed Chair in Women's Health and Professor and Head, Division of Hematology and Oncology, University of Washington, Department of Medicine and co-principal investigator for the trial. "By comprehensively blocking the PI3K/AKT/mTOR, or PAM, pathway, gedatolisib combined with fulvestrant, with or without palbociclib, showed it can offer these patients two times the likelihood of survival without disease progression or death relative to a single-target inhibitor of the PAM pathway. With these results, the gedatolisib regimens, if approved, represent a new potential standard of care for patients with HR+, HER2-negative, *PIK3CA* mutant advanced breast cancer whose disease progressed on or after treatment with a CDK4/6 inhibitor."

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, the gedatolisib-doublet, and alpelisib plus fulvestrant groups included neutropenia (58.8%, 0%, and 0.7% of patients, respectively); stomatitis (16.3%, 5.8%, and 5.3% of patients, respectively); rash (6.5%, 5.8%, and 15.1% of patients, respectively); and hyperglycemia (2.6%, 0%, and 14.5% of patients, respectively). TRAEs led to the discontinuation of study treatment in 2.6% of patients in the gedatolisib-triplet group, 3.8% in the gedatolisib-doublet group, and 7.1% in the alpelisib plus fulvestrant group. [1]One Grade 5 TRAE in the gedatolisib-triplet group, which was related to palbociclib, was reported, no Grade 5 TRAE's were reported in the gedatolisib-doublet group, and two Grade 5 TRAE's were reported in the alpelisib plus fulvestrant group.

"Both gedatolisib regimens were well-tolerated with few VIKTORIA-1 patients discontinuing treatment due to an adverse event," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "These safety results compare very favorably to those from the patient group treated with alpelisib and fulvestrant, which we believe reflects the benefit of gedatolisib's multi-target mechanism of action, pharmacokinetic profile, and intravenous administration."

Overall survival, a key secondary endpoint in VIKTORIA-1, while immature at the time of the analysis, showed promising trends for both the gedatolisib-triplet and -doublet.

Celcuity intends to submit these data to the U.S. Food and Drug Administration ("FDA") as a supplemental New Drug Application ("sNDA") and to submit VIKTORIA-1 data to other regulatory authorities following the sNDA submission.

"It is rare in oncology for a targeted therapy to offer both improved efficacy and better safety results relative to another drug in its class," said Brian Sullivan, CEO and co-founder of Celcuity. "This second positive Phase 3 data readout further underscores the broad potential of multi-target PAM inhibition and increases our excitement about our two Phase 3 trials in the first-line setting for HR+/HER2- advanced breast cancer. We are on track to launch gedatolisib commercially, in anticipation of its potential FDA approval in the third quarter of 2026, and we look forward to the possibility of bringing this important therapy to physicians treating patients with advanced breast cancer."

The FDA has granted Priority Review of Celcuity's New Drug Application ("NDA") for gedatolisib in patients with HR+/HER2-/*PIK3CA* wild-type ("WT") ABC and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026.

About HR+/HER2- Breast Cancer

Breast cancer is the second most common cancer and one of the leading causes of cancer-related deaths worldwide.[1] More than two million breast cancer cases were diagnosed globally in 2022.[1] While survival rates are high for those diagnosed with early breast cancer, only approximately 30% of patients who are diagnosed with or who progress to metastatic disease are expected to live five years after their diagnosis.[2] HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[2]

Three interconnected signaling pathways, estrogen, cyclin D1-CDK4/6, and the PAM pathway , are primary oncogenic drivers of HR+/HER2- ABC.[3] Therapies inhibiting these pathways are approved and used in various combinations for ABC. Currently approved inhibitors of the PAM pathway for breast cancer target a single PAM pathway component, such as PI3Kα, AKT, or mTORC1.[4,5,6,7] However, resistance to CDK4/6 inhibitors and current endocrine therapies develops in many patients with advanced disease.[8] Optimizing the inhibition of the PAM pathway is an active area of focus for breast cancer research.

About the VIKTORIA-1 Phase 3 Trial

VIKTORIA-1 is 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 progressed on or after prior CDK4/6 therapy in combination with an aromatase inhibitor. The trial enrolled 701 subjects regardless of *PIK3CA* status while enabling separate evaluation of subjects according to their *PIK3CA* status. Detailed results from the *PIK3CA* WT cohort of VIKTORIA-1 have been previously reported. For the *PIK3CA* MT cohort, 350 subjects who met eligibility criteria and had confirmed *PIK3CA* mutations were randomly assigned (3:3:1) to receive a regimen of either the gedatolisib-triplet, alpelisib and fulvestrant, or the gedatolisib-doublet.

About Gedatolisib

Gedatolisib is an investigational, multi-target PAM inhibitor that potently targets all four class I PI3K isoforms, mTORC1, and mTORC2 to induce comprehensive blockade of the PAM pathway.[9,10,11] As a multi-target PAM inhibitor, gedatolisib's mechanism of action is highly differentiated from currently approved single-target inhibitors of the PAM pathway.[11] Inhibition of only a single PAM component gives tumors an escape mechanism through cross-activation of the uninhibited targets. Gedatolisib's comprehensive PAM pathway inhibition ensures full suppression of PAM activity by eliminating adaptive resistance cross-activation that occurs with single-target inhibitors. Unlike single-target inhibitors of the PAM pathway, gedatolisib has demonstrated equal potency and comparable cytotoxicity in *PIK3CA*-mutant and -wild-type breast tumor cells in nonclinical studies and early clinical data.[11,12]

About Celcuity

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 PI3K/AKT/mTOR ("PAM") pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. The company's Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, has reported detailed results for Study 1, which evaluated patients with *PIK3CA* WT tumors, and for Study 2, which evaluated patients with *PIK3CA* MT tumors. Our Phase 3 clinical trial, VIKTORIA-2, is ongoing and incorporates two independent studies, Study 1 and Study 2, evaluating two separate cohorts of patients with ABC who are treatment-naive in the advanced setting. Study 1 is evaluating gedatolisib combined with palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib combined with palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is ongoing. More detailed information about Celcuity's active clinical trials can be found at ClinicalTrials.gov. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com. Follow us on LinkedIn and X.

Forward Looking Statements

This press release contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of clinical trial data; the status and timing of the FDA's review of our NDA for gedatolisib, including the PDUFA goal date assigned by the FDA; the ability of our data to support the filing of an sNDA with the FDA and comparable filings with other regulatory authorities; the market opportunity for gedatolisib; our expectations regarding the timing of and our ability to obtain FDA approval to commercialize gedatolisib; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; and other expectations with respect to gedatolisib including future subcutaneous formulations of gedatolisib. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. The forward-looking statements included in this press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our clinical results are based on an ongoing analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in our clinical trials or the FDA's review of our NDA for gedatolisib; our ability to obtain and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; the development of therapies and tools competitive with gedatolisib; and our ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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