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): August 26, 2026

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

Delaware	**001-38207**	**No. 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 August 26, 2026, Celcuity Inc. (the "Company") issued a press release announcing the submission of its supplemental New Drug Application (“sNDA”) to the U.S. Food and Drug Administration (“FDA”) for REVTORPYK™ (gedatolisib) for the treatment of patients with hormone receptor-positive (“HR+”), human epidermal growth factor receptor 2-negative (“HER2-”), locally advanced or metastatic breast cancer ("ABC") with a PIK3CA mutation, following progression on or after treatment with at least one line of endocrine therapy. A copy of this 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 exhibits, 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 August 26, 2026, the Company issued a press release announcing the submission of its sNDA to the FDA for REVTORPYK for the treatment of patients with HR+/HER2- ABC with a PIK3CA mutation, following progression on or after treatment with at least one line of endocrine therapy.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release dated August 26, 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: August 26, 2026

CELCUITY INC.

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

Exhibit 99.1

celcuity

Celcuity Submits sNDA to FDA for REVTORPYK™ (gedatolisib) for HR+/HER2-, PIK3CA Mutant Locally Advanced or Metastatic Breast Cancer

- *If approved, REVTORPYK would be the first and only therapy for advanced breast cancer with a PIK3CA mutation that inhibits all class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2*

MINNEAPOLIS, August 26, 2026— Celcuity Inc. (Nasdaq: CELC), a biotechnology company focused on developing and commercializing targeted therapies for multiple solid tumor indications, today announced the submission of its supplemental New Drug Application ("sNDA") to the U.S. Food and Drug Administration ("FDA") for REVTORPYK™ (gedatolisib) for the treatment of patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), locally advanced or metastatic breast cancer ("ABC") with a *PIK3CA*mutation, following progression on or after treatment with at least one line of endocrine therapy.

"This submission allows us to potentially make REVTORPYK available to all patients with HR+/HER2- locally advanced or metastatic breast cancer, regardless of *PIK3CA*mutation status," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "In the *PIK3CA* mutant cohort of the VIKTORIA-1 trial, REVTORPYK demonstrated compelling safety and efficacy results. Pending regulatory approval, we believe REVTORPYK has the potential to become an important treatment option in this indication."

The application to the FDA is supported by positive results from the *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 clinical trial. In the trial, REVTORPYK plus fulvestrant and palbociclib (the "REVTORPYK-triplet") reduced the risk of disease progression or death by 50% versus 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 REVTORPYK-triplet versus 5.6 months with alpelisib plus fulvestrant. REVTORPYK plus fulvestrant (the "REVTORPYK-doublet") reduced the risk of disease progression or death by 49% versus alpelisib plus fulvestrant (HR=0.51; 95% CI: 0.33–0.79; descriptive p=0.0013). Median PFS was 11.3 months with the REVTORPYK-doublet versus 5.6 months with alpelisib plus fulvestrant. The REVTORPYK regimens demonstrated robust and durable responses: 49% objective response rate ("ORR") and median duration of response ("DOR") of 15.7 months for the REVTORPYK-triplet and 36% ORR and median DOR of 24.2 months for the REVTORPYK-doublet. The safety data for both regimens were generally consistent with previously reported data from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 trial.

REVTORPYK in combination with fulvestrant, with or without palbociclib, was approved by the FDA on July 14, 2026, for the treatment of patients with HR+/HER2- ABC without a PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

"The recent FDA approval of REVTORPYK marked an important milestone for Celcuity and for patients with *PIK3CA* wild-type HR+/HER2- advanced breast cancer," said Brian Sullivan, CEO and co-founder of Celcuity. "We are deeply committed to expanding the availability of REVTORPYK to a broader population of patients. We look forward to working collaboratively with the FDA on this application to potentially bring this treatment to patients with *PIK3CA*mutated locally advanced or metastatic breast cancer."

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] Among this breast cancer subtype, approximately 40% have *PIK3CA* mutations.[3]

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* wild-type cohort of VIKTORIA-1 have been previously reported. For the *PIK3CA* mutant 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 REVTORPYK (gedatolisib)

REVTORPYK is a kinase inhibitor of class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2, resulting in downstream inhibition of multiple effectors, including AKT.[4,5,6]

REVTORPYK is in development for the first-line treatment of HR+/HER2- locally advanced or metastatic breast cancer and for the second-line treatment of metastatic castration resistant prostate cancer.

Indication Statement

REVTORPYK (gedatolisib) is a kinase inhibitor indicated in combination with fulvestrant, with or without palbociclib, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Stomatitis: REVTORPYK can cause severe stomatitis, including ulcers and oral mucositis. Stomatitis occurred in 72% of patients treated with REVTORPYK with fulvestrant and palbociclib, including Grade 3 events in 22% of patients. Stomatitis occurred in 58% of patients treated with REVTORPYK with fulvestrant, including Grade 3 events in 12% of patients. Initiate a steroid-containing, alcohol-free mouthwash prior to starting treatment with REVTORPYK and continue prophylactically during treatment. Monitor patients for signs and symptoms of stomatitis. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Dermatologic Adverse Reactions: REVTORPYK can cause severe rash. Rash occurred in 30% of patients treated with REVTORPYK in combination with fulvestrant and palbociclib, including Grade 3 events in 6% of patients. Rash occurred in 40% of patients treated with REVTORPYK with fulvestrant, including 5% of patients with Grade 3 events. Monitor patients for rash and infectious sequelae. Instruct patients to limit sun exposure during REVTORPYK treatment. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Hyperglycemia: REVTORPYK can cause severe hyperglycemia. Monitor fasting glucose prior to initiating treatment with REVTORPYK and periodically during treatment. Monitor HbA1c level if clinically indicated. Increased fasting glucose occurred in 46% of patients receiving REVTORPYK in combination with fulvestrant and palbociclib (Grade 3: 0.9%) and in 57% of patients receiving REVTORPYK in combination with fulvestrant (Grade 3: 1.8%). The safety of REVTORPYK has not been established in patients with Type 1 or uncontrolled Type 2 diabetes mellitus. Patients with well-controlled Type 2 diabetes may require intensified antihyperglycemic therapy and close monitoring of fasting glucose. Manage hyperglycemia with antihyperglycemic medications as clinically indicated. Evaluate fasting blood glucose and HbA1c levels prior to starting and at regular intervals during treatment. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Embryo-Fetal Toxicity: Based on its mechanism of action, REVTORPYK can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with REVTORPYK and for 2 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose.

Advise women not to breastfeed during treatment with REVTORPYK and for 2 weeks after the last dose. When REVTORPYK is used in combination, advise patients to use effective contraception during treatment and for the longest post-treatment duration recommended in the Prescribing Information of any of the individual products. Verify the pregnancy status of females of reproductive potential prior to initiating treatment.

ADVERSE REACTIONS

REVTORPYK in Combination with Fulvestrant and Palbociclib: The most common (≥20%) adverse reactions, including laboratory abnormalities when given in combination with fulvestrant and palbociclib were decreased white blood cells, decreased neutrophils, decreased hemoglobin, decreased lymphocytes, stomatitis, nausea, decreased platelets, increased fasting glucose, fatigue, vomiting, rash, constipation, diarrhea, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), musculoskeletal pain, decreased sodium, and increased eosinophils.

REVTORPYK in Combination with Fulvestrant: The most common (≥20%) adverse reactions, including laboratory abnormalities when given in combination with fulvestrant were stomatitis, glucose increased, eosinophils increased, hemoglobin decreased, nausea, rash, ALT increased, fatigue, musculoskeletal pain, lymphocytes decreased, vomiting, AST increased, pruritus, and diarrhea.

USE IN SPECIFIC POPULATION

Lactation: Advise women not to breastfeed during treatment with REVTORPYK and for 2 weeks after the last dose. When used in combination, advise patients not to breastfeed during treatment and for the longest post-treatment duration recommended in the Prescribing Information of any of the individual products.

Infertility: Advise females and males of reproductive potential that REVTORPYK may impair fertility.

Please see full Prescribing Information, including Patient Information, for REVTORPYK.

You may report side effects related to Celcuity products to Celcuity Medical Information at 1-877-4-CELCUITY (1-877-423-5284) or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Celcuity

Celcuity is a biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. The company's first FDA-approved product is REVTORPYK (gedatolisib), a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades 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. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, supported FDA approval of REVTORPYK for use in patients without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. Results for the *PIK3CA* mutant cohort of VIKTORIA-1 have been released. VIKTORIA-2 is an ongoing Phase 3 clinical trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naive in the advanced setting. Study 1 is evaluating gedatolisib plus palbociclib plus fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib plus letrozole as first-line treatment for patients with endocrine- sensitive HR+/HER2- ABC. A Phase 1/2 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 REVTORPYK and the potential therapeutic benefits of gedatolisib; the size, design and timing of the Company's clinical trials; the Company's interpretation of clinical trial data; the status and timing of the submission, and the FDA's review, of the Company's sNDA for REVTORPYK, and for making comparable filings with other regulatory authorities outside the U.S.; the market opportunity for gedatolisib; the Company's expectations regarding the timing of and its ability to commercialize REVTORPYK; the Company's strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib, including subcutaneous formulations to support potential future indications for gedatolisib regimens; the Company's anticipated use of cash; and the strength of its 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 press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that the Company's topline clinical results are based on an ongoing analysis of 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 the Company's clinical trials or the submission, and FDA's review of, its sNDA for REVTORPYK; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize REVTORPYK in the U.S. and obtain regulatory approval of gedatolisib outside the U.S., and the market acceptance of REVTORPYK; the development of therapies and tools competitive with gedatolisib; and the Company's ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in its 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 the Company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

References:

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2. National Cancer Institute. Surveillance, Epidemiology and End Results Program (accessed July 2025). https://seer.cancer.gov/statfacts/html/breast-subtypes.html
3. Anderson, E. et al. A Systematic Review of the Prevalence and Diagnostic Workup of PIK3CA Mutations in HR+/HER2– Metastatic Breast Cancer, Int J Breast Cancer. 2020 Jun 20;2020:3759179
4. Venkatesan, A. M., et al. Bis(morpholino-1,3,5-triazine) derivatives: potent adenosine 5'-triphosphate competitive phosphatidylinositol-3-kinase/mammalian target of rapamycin inhibitors: discovery of compound 26 (PKI-587), a highly efficacious dual inhibitor. J Med Chem, 2010;53(6), 2636-2645. https://doi.org/10.1021/jm901830p
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6. Rossetti, S., et al. Gedatolisib shows superior potency and efficacy versus single-node PI3K/AKT/mTOR inhibitors in breast cancer models. NPJ Breast Cancer, 2024;10(1), 40. https://doi.org/10.1038/s41523-024-00648-0

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