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

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT

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

Date of Report (Date of earliest event reported): July 14, 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. ☐

EXPLANATORY NOTE

This Current Report on Form 8-K/A (this "Amendment") is being filed to amend the Current Report on Form 8-K filed by Celcuity Inc. (the "Company") with the Securities and Exchange Commission on July 15, 2026 (the "Original Report"). The purpose of filing this Amendment is to correct a clerical error that resulted in the omission of a slide in the presentation furnished as Exhibit 99.2 to the Original Report and to make certain conforming edits to the description of the live webcast and conference call. Exhibit 99.2 to this Amendment hereby supersedes Exhibit 99.2 previously furnished with the Original Report. Except as expressly set forth herein, no other changes have been made to the Original Report.

Item 7.01 Regulation FD Disclosure.

On July 14, 2026, the Company issued a press release announcing U.S. Food and Drug Administration ("FDA") approval of 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 without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. A copy of this press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference. The Company hosted a live webcast and conference call on July 14, 2026, at 4:30 p.m. CT to discuss the FDA approval of REVTORPYK. A copy of the presentation that was provided during the live webcast is furnished as Exhibit 99.2 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 July 14, 2026, the Company issued a press release announcing FDA approval of REVTORPYK for the treatment of patients with HR+/HER2-, 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. The Company anticipates commercial launch of REVTORPYK in late Q3 2026.

The Company plans to submit in Q3 2026 a supplemental New Drug Application ("sNDA") to the FDA for REVTORPYK for the treatment of HR+/HER2-, *PIK3CA* mutated, locally advanced or metastatic breast cancer, following at least one line of endocrine therapy based on results from the mutant cohort of the Phase 3 VIKTORIA-1 trial.

Slide 18 of Exhibit 99.2 to this Current Report on Form 8-K is hereby incorporated by reference into this Item 8.01.

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 relating to 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 gedatolisib, 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 gedatolisib; 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 report 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 gedatolisib; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; 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 report to reflect events or circumstances after the date hereof.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release dated July 14, 2026
99.2	Investor presentation dated July 14, 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: July 15, 2026

CELCUITY INC.

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

Exhibit 99.1

Celcuity Announces FDA Approval of REVTORPYK™ (gedatolisib) for the Treatment of HR+/HER2-, PIK3CA Wild-Type Locally Advanced or Metastatic Breast Cancer

- *REVTORPYK is the first and only FDA-approved therapy that inhibits all class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2*

- *In the Phase 3 VIKTORIA-1 trial, REVTORPYK combined with palbociclib and fulvestrant and REVTORPYK combined with fulvestrant reduced the risk of disease progression or death by 76% and 67%, respectively, compared to fulvestrant among patients with PIK3CA wild-type advanced or metastatic breast cancer*

- *Celcuity to host webcast and conference call today Tuesday, July 14, 2026, at 5:30 p.m. EDT*

MINNEAPOLIS, July 14, 2026 — Celcuity Inc. (Nasdaq: CELC), a biotechnology company focused on developing and commercializing targeted therapies for multiple solid tumor indications, today announced that the U.S. Food and Drug Administration ("FDA") approved 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 without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. REVTORPYK is the only inhibitor of class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2 to receive FDA approval.

"The PI3K/AKT/mTOR, or PAM, pathway is one of the most important targets in cancer, but comprehensively inhibiting it has stymied researchers and drug developers for nearly two decades," said Brian Sullivan, CEO and co-founder of Celcuity. "REVTORPYK addressed this 20-year challenge by becoming the first pan-PI3K, mTORC1/2 inhibitor approved by the FDA. We are thankful for the opportunity to make this important new therapy available to patients with HR+/HER2- locally advanced or metastatic breast cancer."

HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[1] Among this breast cancer subtype, approximately 60% have *PIK3CA* wild-type disease.[2]

"For patients with HR+/HER2- locally advanced or metastatic breast cancer, there is an urgent need for new treatment options that can meaningfully increase the likelihood of survival without disease progression or death," 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, School of Medicine and co-principal investigator for the VIKTORIA-1 trial. "With the approval of REVTORPYK, oncologists now have an effective new treatment option for these patients."

The approval of REVTORPYK is based on positive clinical results from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 trial, an open-label, global, randomized clinical trial evaluating the efficacy and safety of REVTORPYK plus fulvestrant, with or without palbociclib, for the treatment of patients with locally advanced or metastatic HR+/HER2- breast cancer following progression on or after CDK4/6 therapy and an aromatase inhibitor. In the VIKTORIA-1 trial, median progression free survival ("PFS") with the REVTORPYK triplet (REVTORPYK plus palbociclib and fulvestrant) was 9.3 months versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months (HR=0.24; 95% CI: 0.17-0.35; p<0.0001). The objective response rate ("ORR") of the REVTORPYK triplet was 32% compared to 1% with fulvestrant and the median duration of response ("DOR") was 17.5 months. For the REVTORPYK doublet (REVTORPYK plus fulvestrant), the median PFS was 7.4 months versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months (HR=0.33; 95% CI: 0.24-0.48; p<0.0001). The ORR of the REVTORPYK doublet was 28% and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.

"Today's approval of REVTORPYK addresses a significant unmet need for the thousands of patients affected each year by HR+/HER2-, *PIK3CA* wild-type locally advanced or metastatic breast cancer whose disease has progressed after endocrine therapy," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "We are deeply grateful to the patients and their caregivers, investigators and clinical study teams, and Celcuity team members who made this advancement possible."

Celcuity anticipates commercial launch in late Q3 2026. Based on the company's commitment to ensuring broad, affordable, and unrestricted patient access to REVTORPYK, we have designed a comprehensive patient support program. To make REVTORPYK available to patients prior to commercial launch, those who are eligible will be able to enroll in Celcuity's expanded access program.

Celcuity plans to submit in Q3 2026 a supplemental New Drug Application ("sNDA") to the FDA for REVTORPYK for the treatment of HR+/HER2-, *PIK3CA* mutated, locally advanced or metastatic breast cancer, following at least one line of endocrine therapy based on results from the mutant cohort of the Phase 3 VIKTORIA-1 trial. Results for this study were recently presented in a late-breaking abstract oral session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting. Following the sNDA submission, Celcuity intends to submit VIKTORIA-1 data for marketing authorization of gedatolisib to other regulatory authorities around the world.

REVTORPYK is also being studied in the ongoing Phase 3 VIKTORIA-2 clinical trial incorporating two independent studies evaluating two separate patient cohorts with HR+/HER2- locally advanced or metastatic breast cancer who are treatment-naive in the advanced setting.

Webcast and Conference Call Information

The Celcuity management team will host a live webcast and conference call on Tuesday, July 14, 2026, at 5:30 p.m. EDT / 4:30 p.m. CDT to discuss the FDA approval of REVTORPYK. Those who would like to participate may access the live webcast here, or register in advance for the teleconference here. A replay of the webcast will be available on the Celcuity website.

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.[3,4,5]

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 fastingblood 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- locally advanced or metastatic breast cancer ("ABC"), supported FDA approval of REVTORPYK for use in patients without a *PIK3CA* mutation detected. 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 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 gedatolisib, 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 gedatolisib; 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 gedatolisib; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; 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:

1. National Cancer Institute. Surveillance, Epidemiology and End Results Program (Accessed July 2025). https://seer.cancer.gov/statfacts/html/breast-subtypes.html
2. 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.
3. 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
4. Mallon, R., et al. Antitumor efficacy of PKI-587, a highly potent dual PI3K/mTOR kinase inhibitor. Clin Cancer Res, 2011;17(10), 3193-3203. https://doi.org/10.1158/1078-0432.CCR-10-1694
5. 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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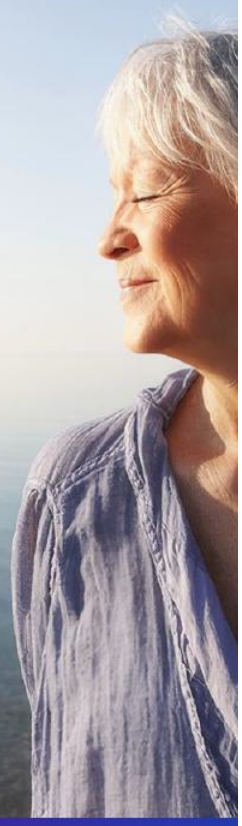
celcuity

REVTORPYK™
gedatolisib 180 mg for injection



FDA Approval

July 14, 2026

Forward-Looking Statements

This presentation contains statements that constitute "forward-looking statements" within the meaning of the Private Securities
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Agenda

Intro and Overview
Brian Sullivan
Chief Executive Offi

REVTORPYK Data
Igor Gorbatchevsk
Chief Medical Office

REVTORPYK: Com
Eldon Mayer
Chief Commercial O

Upcoming Milestor
Brian Sullivan

celcuity

Intro and Overview

Brian Sullivan

Chief Executive Officer and Co-Founder

REVTORPYK Is Now FDA-Approved

REVTORPYK is indicated in combination with fulvestrant, with or without palbociclib, for the treatment of HR+/HER2- locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after ≥ 1 line of endocrine therapy in the metastatic setting

REVTOR
gedatolisib

First and only pan-PI3K, mT
to receive FDA ap

celcuity

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

REVTORPYK is well positioned for near- and long-term success, U.S. market potential across the 1L and 2L+ HR+/HER2- ABC set

BEST-IN-CLASS, FIRST-IN-CLASS PAM INHIBITOR

Inhibits all Class I PI3K isoforms and mTORC1/2

- More potent and cytotoxic than other PAM inhibitors in vitro[1]
  - >300X higher potency
- Only PAM inhibitor equally potent in *PIK3CA* MT and WT cells

TWO POSITIVE PHASE 3 READOUTS IN 2L SETTING

VIKTORIA-1 *PIK3CA* WT and MT patients

- WT: **4.5x PFS** improvement vs. endocrine therapy[2]
- MT: **2x PFS** improvement vs. PI3Kα inhibitor[3]

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Comprehe developr

- Two global F 1L setting in
- **~130,000** population ir

(1) Rossetti, S, et al. njp | Breast Cancer, 2024; (2) Hurvitz, S. et al., JCO, 2026; (3) Hurvitz, S. et al. 2026; (4) Internal estimates using data from National Cancer Institute, SE H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021; Abbreviations: ABC, locally advanced or metastatic breast cancer; WT, wild-type; MT, mutant-type. N REVTORPYK is not currently approved by the FDA for the treatment of patients with PIK3CA mutant tumors or patients in the first-line setting.

celcuity

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

REVTORPYK Label & Supporting Data

Igor Gorbatchevsky, MD

Chief Medical Officer

Overview of REVTORPYK U.S. Prescribing Information

INDICATION:

- REVTORPYK is indicated in combination with fulvestrant, with
  for the treatment of adult patients with HR+/HER2- locally adva
  breast cancer without a *PIK3CA* mutation detected following pr
  treatment with at least one line of endocrine therapy in the meta

DOSAGE & ADMINISTRATION:

- 180 mg intravenously as a 30-minute infusion once weekly on D
  28-day cycle, in combination with fulvestrant ± palbociclib.

CONTRAINDICATIONS

- None

SAFETY:

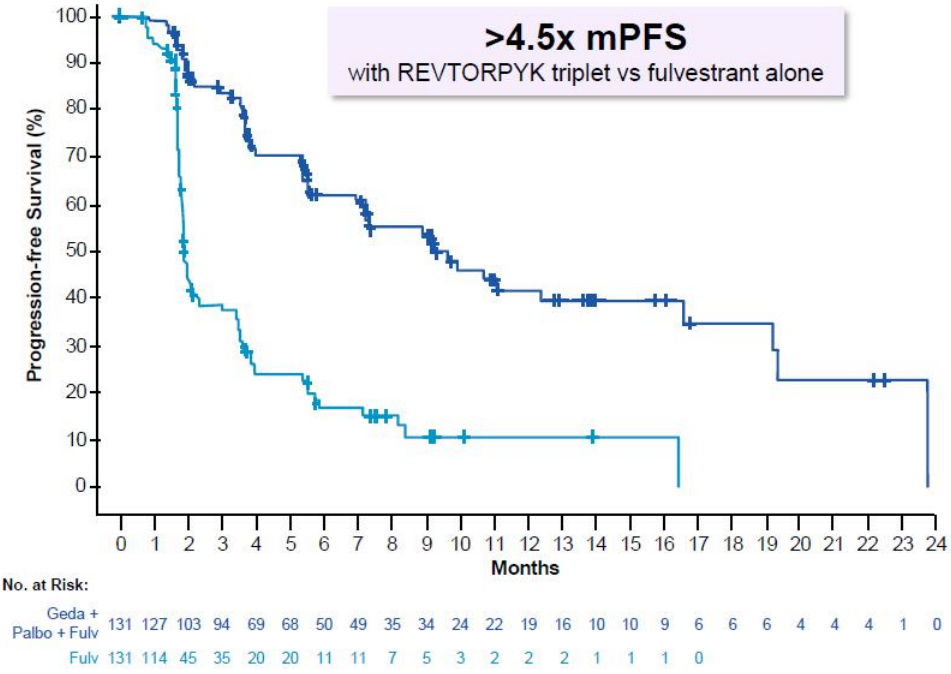
- Warnings & precautions for stomatitis, rash, hyperglycemia, an

Abbreviations HR+ = hormone receptor positive; HER2- = human epidermal growth factor receptor 2 negative

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

Co-Primary Endpoint: PFS of REVTORPYK Triplet vs. Fulve

7.3 months improvement in mPFS



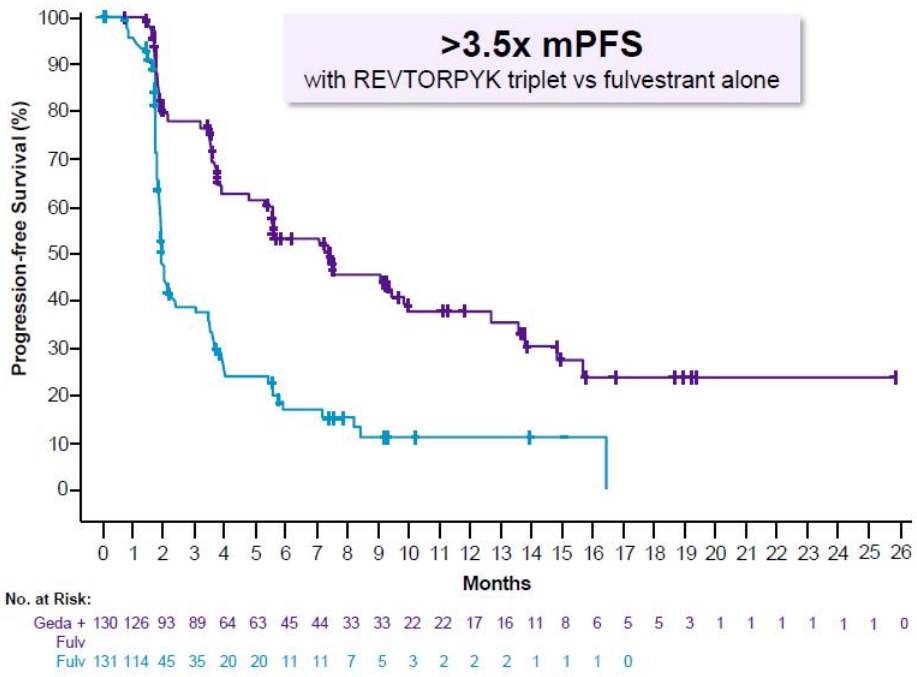
	Geda + fulves (n=1
Median PFS, months (95% CI)	9. (7.2-1
Adjusted HR (95% CI)	(0.1
Objective Response Rate	
Duration of Response	

76% red
in risk of disease p

PFS assessed by blinded independent central review. Abbreviations: HR, hazard ratio; mPFS, median progression-free survival

Co-Primary Endpoint: PFS of REVTORPYK Doublet vs. Fulv

5.4 months improvement in mPFS



	Geda + fu (n=1
Median PFS, months (95% CI)	7. (5.5-
Adjusted HR (95% CI)	0.33 (
Objective Response Rate	
Duration of Response	

67% red
in risk of disease p

PFS assessed by blinded independent central review. Abbreviations: HR, hazard ratio; mPFS, median progression-free survival

Safety Highlights from REVTORPYK Prescribing Informatio

SAFETY SUMMARY

- Over 80% of adverse reactions were grade 1 or 2
- No dose reductions or discontinuations of REVTORPYK due to hyperglycemia
- Stomatitis was generally manageable, occurred early and reduced in treatment frequency with each treatment cycle

REVTORPYK triplet

- Most common adverse reactions (≥20%), including laboratory abnormalities: included white blood cell decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, stomatitis, neutropenia, nausea, platelets decreased, glucose increased, fatigue, vomiting, rash, constipation, diarrhea, ALT increased, or AST increased, musculoskeletal pain, sodium decreased, and eosinophils increased.
- Serious adverse reactions in ≥1% of patients included pneumonia (3.8%), thrombosis (3.8%), and stomatitis (1.5%).

REVTORPYK doublet

- Most common adverse reactions (≥20%), inclu stomatitis, glucose increased, eosinophils incre nausea, rash, ALT increased, fatigue, musculos decreased, vomiting, AST increased, pruritus, a
- Serious adverse reactions in ≥1% of patients in thrombosis (2.3%), pleural effusion (1.5%), and

Please see additional important safety information and full Prescribing Information for REVTORPYK here.

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REVTORPYK™ Commercial Overview

Eldon Mayer
Chief Commercial Officer

Positioning REVTORPYK for strong market adoption in the HR+/HER2-/PIK3CA Wild-Type & Mutant advanced breast ca

LARGE POPULATION

37,000 patients with HR+/HER2- ABC receive 2L Rx post- CDK4/6i

60% are *PIK3CA* WT

40% *PIK3CA* MT

SIGNIFICANT UNMET NEED IN HR+/HER2- ADVANCED BREAST CANCER

Significant need for improved efficacy and safety for 2nd line treatments

FDA approvals in both mutant and wild-type indications **would address 100% of market** and provide simplicity of a single *PIK3CA* agnostic treatment

WELL DIFFERENTIATED

Gedatolisib MOA, pharmacokinetics, and IV route of administration **provide a distinct efficacy/safety profile vs. currently available therapies**

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$6 billion total addres

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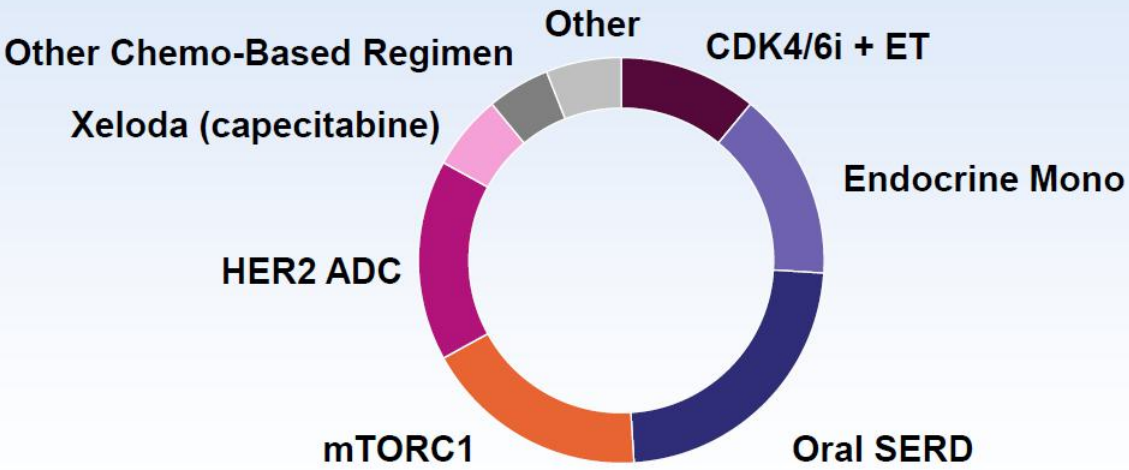
NOTE: REVTORPYK is not currently approved by the FDA for the treatment of patients with PIK3CA mutant tumors.
Please see additional important safety information and full Prescribing Information for REVTORPYK here.

Fragmented market with no “Go To” option for PIK3CA Wild HR+HER2- ABC patients after progressing on initial endocr

Current Treatments Used in 2L PIK3CA Wild-Type ABC



Source: Celcuity Demand Study (n=100), 70 community and 30 academic, fielded in Dec 2025

Entering Launch with Market and Organizational Momentun

ENGAGED KEY STAKEHOLDERS

- >1,500 KOLs & Community Breast Cancer Experts
- Over 200 Health System Accounts
- Major Oncology Organizations
- Patient Advocacy Groups
- KOL Advisory Boards

PAM PATHWAY & REVTORPYK AWARENESS/ ADVOCACY

- "PAMpathway.com" unbranded Marketing campaign
- CME & 3rd Party Insights Programs & Regional Events

LAUNCH PLAN TACTICS IN PLACE

- Promotional Materials & Programs
- Digital Media Campaign
- Speaker Bureau / Peer-to-peer promotional programs
- National and Regional oncology conferences

D

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-
-
-
-

Access for REVTORPYK is Designed to Offer Patients and Provi Rapid Access with Seamless Support Solutions

100% of top Payer Pathways were engaged pre-approval

100% of top 36 Strategic Accounts were engaged pre-approval

>90% of US medical benefit lives covered through pre-approval engagements

3 Access Field Teams
- Directors of National Payer Accounts & Field Reimbursement
- Directors of Strategic Accounts
- Director Value & Outcomes Liaison

1 Tailored Distribution Model to optimize access

Comprehensive & Simple Pa

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REVTORPYK Launch Priorities

DRIVE AWARENESS

Rapid engagement of core REVTORPYK customers

9,000+

Academic and Community HCPs

2,000 Core Prescribers

RAPID ADOPTION

Unique MOA, Strong Efficacy, Tolerable AE profile

88

Oncology Sales Specialists

24 Years Industry Experience

362 President's Club Awards

DELIV

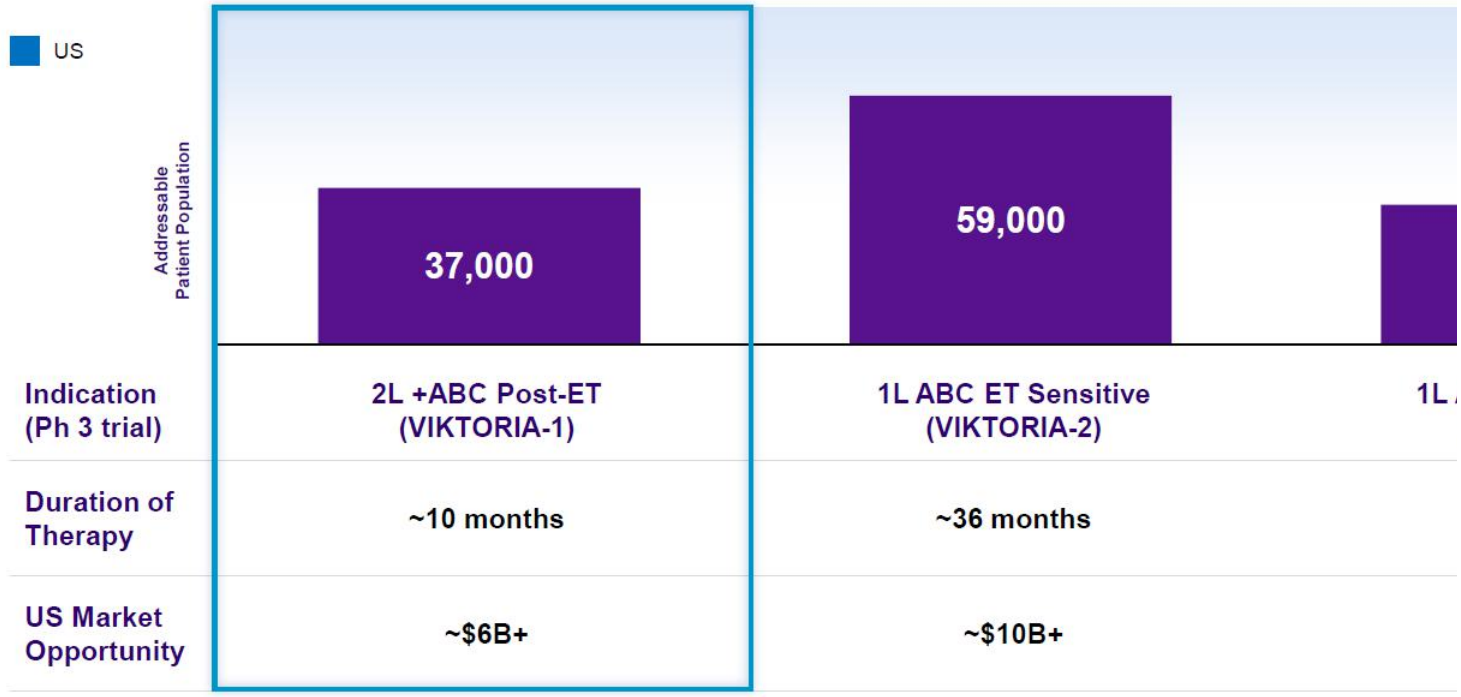
Broad pay world-clas

Alig

- Field Sales
- Market Acc

DEMONSTRATE CELCUITY TO BE A TRUSTED LONG-TERM PAR IN BREAST CANCER

REVTORPYK FDA approval lays foundation for multiple potentia indications 1L and 2L+ setting for HR+/HER2- advanced breast c



Indication (Ph 3 trial)	**2L +ABC Post-ET (VIKTORIA-1)**	**1L ABC ET Sensitive (VIKTORIA-2)**	**1L**
Duration of Therapy	**~10 months**	**~36 months**	
US Market Opportunity	**~$6B+**	**~$10B+**	

Sources: Patient populations are derived from internal estimates using data from National Cancer Institute, SEER, 2024; Pan, H, NEJM, 2017;377:1836-46; Dowsett, M 2009; Salvo, E. M. et al. 2021; Dat George, D. J. et al. 2022; Duration of therapy is based on the actual average mPFS reported in a Phase 3 study or the mPFS assumed in the clinical study. Market opportunity assumes REVTORPYK pric newly launched therapies for breast cancer patients. Abbreviations: HR, hormone receptor; ABC, advanced breast cancer, ET, endocrine therapy; NOTE: REVTORPYK is not currently approved by the F mutant tumors or patients in the first-line setting.

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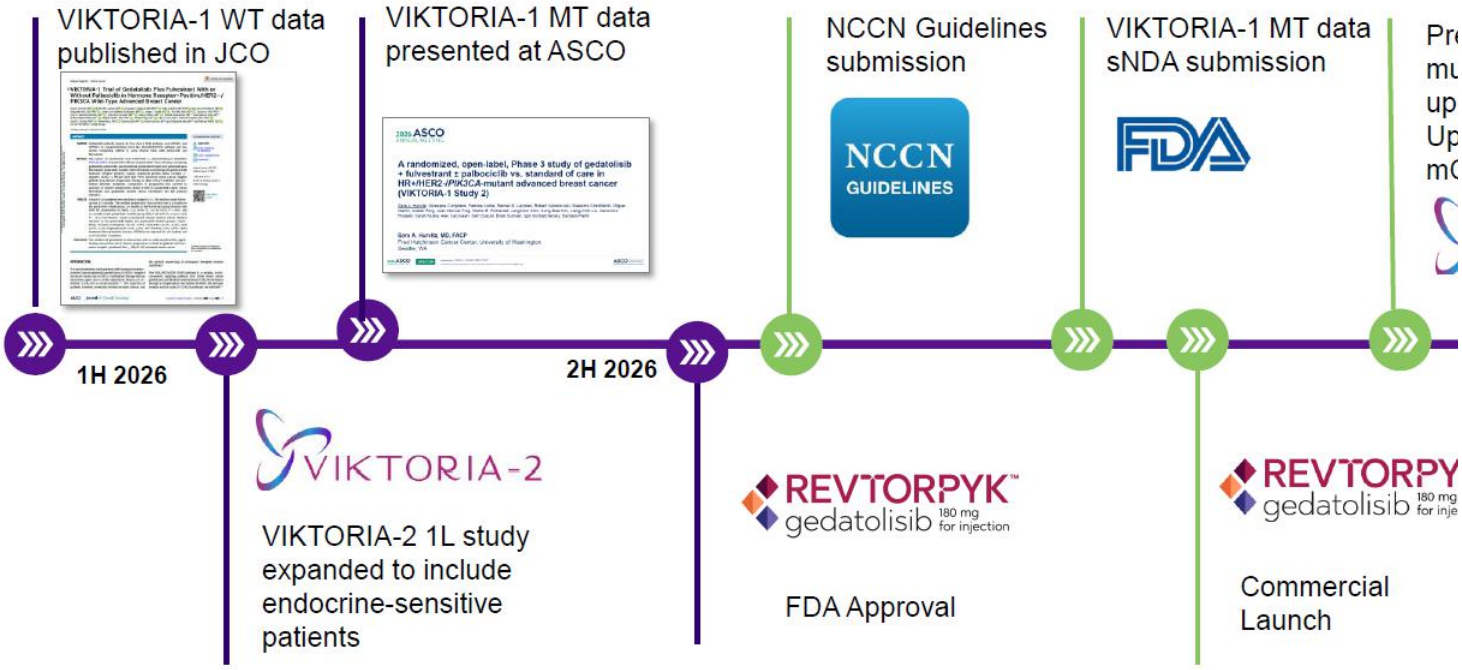
Upcoming Milestones

Brian Sullivan
Chief Executive Officer and Co-Founder

Key Milestones Achieved and Upcoming in 2026-2027



Abbreviations: MAA – Marketing Authorization Application; NDA - New Drug Application; PDUFA - Prescription Drug User Fee Act; mCRPC, metastatic castration resistant prostate

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Unlocking the Potential of Treating Cancers That Involve the PI3K/AKT/mTOR Pathway

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Thank You

... to the numerous patients and their families who participated in our clinical dev

... to the clinical investigators, nurses, site coordinators, and countless support s

... to the Celcuity team continuously working to deliver this important medicine to