Celcuity

Fact Sheet

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NASDAQ

CELCUITY

QUICK REFERENCE

Celcuity Inc.
Nasdaq: CELC
www.CELCUITY.com

BUSINESS SUMMARY

Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is 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 has completed enrollment and reported topline data for the PIK3CA WT cohort and has completed enrollment of patients for the PIK3CA mutant cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- ABC is currently enrolling patients. 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.

SCIENCE

PAM PATHWAY

Working to comprehensively inhibit the PAM (PI3K/AKT/mTOR) pathway in cancer

Activation of the PAM (PI3K/AKT/mTOR) pathway has been implicated in a wide variety of human cancers, including carcinomas of the breast, prostate, lung, endometrial, colon, and ovary.

Activities associated with this pathway involve the regulation of diverse cellular processes, including cell proliferation, survival, cytoskeletal organization, and glucose transport. Overactivation of the pathway is frequently present in human malignancies and plays a key role in cancer progression.

Each of the 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 also serves as a central regulator of cell metabolism, growth, proliferation, and survival. mTOR is a downstream effector of PI3K and regulated by hormones, growth factors, and nutrients, that is contained in two functionally distinct protein assemblies: mTOR complex 1 (mTORC1) and mTOR complex 2 (mTORC2). In cancer, dysfunctional signaling leads to various constitutive activities of the mTOR complexes, making mTOR an important therapeutic target.

CONTACT INFORMATION

Headquarters
16305 36th Avenue North
Minneapolis, MN 55446

Barwicki Investor Relations
Andrew Barwicki
516-662-9461 / andrew@barwicki.com

Recent Press Releases *(Headlines and Excerpts)*

Celcuity to Present Results from the Pivotal Phase 3 VIKTORIA-1 Trial at the 2025 European Society for Medical Oncology (ESMO) Congress

Sept. 22, 2025 -- Celcuity Inc. announced that a late breaking abstract reporting clinical data from the Phase 3 VIKTORIA-1 trial has been selected for an oral presentation at the upcoming European Society of Medical Oncology (ESMO) Congress, being held October 17-21, 2025. The presentation will provide detailed efficacy and safety data from the PIK3CA wild-type cohort of the VIKTORIA-1 trial.

Late Breaking Oral Presentation Details:

Title: Gedatolisib + fulvestrant ± palbociclib vs fulvestrant in patients with HR+/HER2-/PIK3CA wild-type advanced breast cancer: First results from VIKTORIA-1

Abstract Number: 3535

Session Title: Proffered paper session 1: Breast Cancer, metastatic

Date: October 18, 2025
Time: 10:15 am – 11:45 am CEST
Late-breaking abstracts (LBA) accepted for a Proffered Paper Session at the ESMO Congress 2025 will be published online via the ESMO website on the day of presentation.

Celcuity Announces Upsized Senior Secured Term Loan Facility of $500 Million with Innovatus Capital Partners and Oxford Finance

Sept. 09, 2025 -- Celcuity Inc. announced that it has entered into an amendment to its existing senior secured credit facility with an affiliate of Innovatus Capital Partners, LLC ("Innovatus") and Oxford Finance LLC, and its affiliates (together, "Oxford"). The amendment increases the total term loan facility size to $500 million, including $350 million in committed capital and up to $150 million at the mutual discretion of Celcuity and its lenders. At the closing of the Amendment, the initial funding under the amended credit facility was in a principal amount of $30 million, bringing the total term loan outstanding to $130 million.

Highlights of the amended credit facility include:

- Increased Capital Availability: Adds $170 million in new committed capital, including an additional $50 million for a total of $100 million available upon U.S. Food and Drug Administration ("FDA") approval of gedatolisib in second-line wild-type advanced breast cancer ("ABC") patients post-CDK4/6 inhibitor therapy, and $120 million upon achievement of certain commercial revenue milestones. An additional up to $150 million is also available at the mutual discretion of Celcuity and its lenders.
- Improved Structure and Financial Flexibility: Extends the interest-only period by 14 months, with an additional seven-month extension available upon FDA approval. The maturity date of the facility was also extended by six months.

The amendment significantly enhances Celcuity's financial flexibility and access to capital following the positive topline data from the PIK3CA wild-type cohort of the pivotal VIKTORIA-1 Phase 3 clinical study. The upsized facility strengthens Celcuity's ability to manage its capital structure efficiently while providing additional funding to support the rolling submission to FDA of its New Drug Application ("NDA") via FDA's RTOR program, commercial launch preparations for gedatolisib, and other strategic initiatives.

Celcuity to Initiate NDA Submission of Gedatolisib in PIK3CA Wild-Type Cohort in HR+/HER2- Advanced Breast Cancer Under FDA's Real-Time Oncology Review Program

Aug. 27, 2025 -- Celcuity Inc. announced the U.S. Food and Drug Administration ("FDA") agreed to accept its New Drug Application ("NDA") for gedatolisib in HR+/HER2- advanced breast cancer ("ABC") for review under the Real-Time Oncology Review ("RTOR") program, which facilitates earlier submission of topline efficacy and safety results, prior to the submission of the complete application, to support an earlier start to the FDA's evaluation of the application. Celcuity is expected to initiate in September a rolling submission to the FDA of its NDA for gedatolisib, based on topline data from the PIK3CA wild-type cohort of the Phase 3 VIKTORIA-1 clinical trial. Completion of the NDA submission is targeted for the fourth quarter of 2025.

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Celcuity Inc.

NASDAQ: CELC

www.CELCUITY.com

Barwicki Investor Relations * 30 Wall Street, 8 FL * New York, NY 10005

Deliver to: