



Celcuity Inc. Reports Release of Second Quarter 2026 Financial Results and Provides Corporate Update

August 13, 2026

- *REVTORPYK™ (gedatolisib) approved by the U.S. FDA for the treatment of HR+/HER2- PIK3CA Wild-Type locally advanced or metastatic breast cancer on July 14, 2026; on track for commercial launch late third quarter 2026*
- *NCCN® Clinical Practice Guidelines recommended REVTORPYK in combination with fulvestrant, with or without palbociclib, as a preferred Category 1 option for second-line therapy in HR+/HER2- advanced breast cancer*
- *The Phase 3 PIK3CA mutant cohort of the VIKTORIA-1 trial achieved its primary endpoint by doubling the likelihood of survival without disease progression or death compared to alpelisib plus fulvestrant; a supplemental New Drug Application ("sNDA") is planned for submission in the third quarter of 2026*
- *The Phase 3 VIKTORIA-2 trial was expanded to include a second study evaluating gedatolisib as first-line treatment in patients with endocrine-sensitive HR+/HER2- advanced breast cancer*
- *Completed issuance of \$575.0 million convertible note offering, with net proceeds of \$557.2 million*
- *Management to host webcast and conference call today, August 13, 2026, at 4:30 p.m. EDT*

MINNEAPOLIS, Aug. 13, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications, today announced financial results for the second quarter ended June 30, 2026 and other recent business developments.

"Celcuity made monumental progress these past few months, achieving critical clinical and regulatory milestones related to gedatolisib. With the FDA approval of REVTORPYK, positive results from the *PIK3CA* MT cohort of the pivotal VIKTORIA-1 study, and a preferred Category 1 recommendation in the NCCN Guidelines®, we are well positioned to address a significant unmet need for the tens of thousands of patients affected each year by HR+/HER2-, locally advanced or metastatic breast cancer whose disease has progressed after endocrine therapy," said Brian Sullivan, CEO and co-founder of Celcuity. "We are on track to begin shipping REVTORPYK late in the third quarter of 2026, and we look forward to making this important therapy available to patients with locally advanced or metastatic breast cancer."

Mr. Sullivan added, "Based on the positive data from the *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 study, we plan to submit an sNDA to FDA in the third quarter of 2026. Additionally, our VIKTORIA-2 study was expanded to enable evaluation of treatment-naïve patients who have endocrine-sensitive breast cancer, positioning gedatolisib regimens to potentially be available for nearly all patients in the first- and second-line setting, irrespective of their endocrine sensitivity or *PIK3CA* mutation status."

Clinical Highlights

HR+/HER2- Advanced Breast Cancer

2nd Line Setting – *PIK3CA* Wild-Type

Following the unprecedented results from the *PIK3CA* WT cohort of the VIKTORIA-1 Phase 3 clinical trial, on July 14, 2026 Celcuity [announced](#) that the U.S. Food and Drug Administration ("FDA") had approved REVTORPYK, the company's pan-PI3K, mTORC1/2 inhibitor, for the treatment of patients with hormone receptor positive ("HR+"), human epidermal growth factor 2 receptor negative ("HER2-"), locally advanced or metastatic breast cancer ("ABC") without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

Celcuity subsequently [announced](#) that REVTORPYK in combination with fulvestrant, with or without palbociclib, was recommended by the National Comprehensive Cancer Network® ("NCCN®") as a preferred Category 1 second-line and/or subsequent-line therapy for the treatment of patients with HR+/HER2- breast cancer without a *PIK3CA* mutation following progression on or after treatment with at least one line of endocrine therapy.

The build-out of the commercialization infrastructure needed to support a successful launch of REVTORPYK is complete and commercial launch activities for REVTORPYK commenced immediately after approval. Shipments of REVTORPYK are expected to begin late in the third quarter of 2026.

To make gedatolisib available to patients prior to commercial availability of REVTORPYK, last week Celcuity opened an [Expanded Access Program](#) (EAP) to participating physicians on behalf of eligible patients, and we have begun to distribute gedatolisib to those physicians.

2nd Line Setting – *PIK3CA* Mutant-Type

Gedatolisib continued to demonstrate a differentiated clinical profile across different patient populations when combined with fulvestrant, with or without palbociclib. At the 2026 American Society of Clinical Oncology (“ASCO”) Annual Meeting, detailed [results](#) from the *PIK3CA* MT cohort of the global VIKTORIA-1 Phase 3 study were presented at a late-breaking abstract Oral Session. The study demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of progression-free survival (“PFS”) compared with alpelisib plus fulvestrant, with a manageable safety profile.

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 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: 49% objective response rate (“ORR”) and median duration of response (“DoR”) of 15.7 months for the gedatolisib-triplet and 36% ORR and median DoR of 24.2 months for the gedatolisib-doublet.

The safety data for the gedatolisib-triplet and -doublet were consistent with previously reported data from the *PIK3CA* wild-type cohort of VIKTORIA-1. Analyses of the treatment discontinuation rate due to an adverse event for gedatolisib and alpelisib in the *PIK3CA* MT cohort were updated using the same methodology that determined the discontinuation rate due to an adverse event for the *PIK3CA* WT cohort presented in the REVTORPYK label. For patients who received the gedatolisib triplet and gedatolisib doublet, 5.2% and 3.8% of patients discontinued gedatolisib due to an adverse event, respectively. For patients who received alpelisib, 19.1% discontinued treatment with alpelisib due to an adverse event.

Celcuity intends to submit these data to the FDA in the third quarter as an sNDA and to submit VIKTORIA-1 data to other regulatory authorities outside the U.S. following the sNDA submission.

Analyses of the mean number of gedatolisib treatment cycles patients received in the *PIK3CA* WT and MT cohorts of the VIKTORIA-1 Phase 3 trial were also updated as of August 2, 2026, with a median follow-up period of approximately 21 months and 17 months for the *PIK3CA* WT and MT cohorts, respectively. For patients who received the gedatolisib-triplet, the mean number of treatment cycles on gedatolisib was 9.0 and 10.0 cycles in the *PIK3CA* WT and MT cohorts, respectively, with 12% (16) and 22% (34) of patients still receiving gedatolisib therapy in each cohort, respectively. For patients who received the gedatolisib-doublet, the mean number of treatment cycles on gedatolisib was 9.7 and 11.3 cycles in the *PIK3CA* WT and MT cohorts, respectively, with 12% (15) and 19% (10) of patients still receiving gedatolisib therapy in each cohort, respectively.

Celcuity expects to provide further updates to results from both the *PIK3CA* MT and WT cohorts of VIKTORIA-1 at medical conferences in the fourth quarter.

1st Line Setting

Celcuity continues to advance gedatolisib combined with palbociclib and endocrine therapy in the first-line setting for patients with HR+/HER2- ABC through its ongoing Phase 3 VIKTORIA-2 clinical trial. The VIKTORIA-2 trial was expanded in the second quarter 2026 to include a second study (Study 2) evaluating the efficacy and safety of gedatolisib in combination with palbociclib and letrozole in patients with treatment-naïve endocrine-sensitive HR+/HER2- ABC. Study 1 of the VIKTORIA-2 trial is evaluating gedatolisib in combination with palbociclib and fulvestrant in patients with treatment-naïve endocrine-resistant HR+/HER2- ABC.

Metastatic Castration-Resistant Prostate Cancer (“mCRPC”)

Development of gedatolisib in combination with darolutamide continues to advance. In the dose finding portion of Celcuity’s Phase 1b study, evaluation of a 240 mg dose of gedatolisib was completed. No adverse events led to treatment discontinuation of gedatolisib and dose limiting toxicity criteria for dose reduction were not met. Evaluation of a 300 mg dose is ongoing. Once the Phase 1/1b portion of the study is completed, Celcuity expects to select the recommended phase 2 dose level(s) and control arm options for the randomized Phase 2 portion of the study. The company expects to provide updated clinical data and additional visibility into its mCRPC development strategy during the fourth quarter of 2026.

Other Recent Developments

In June 2026, the Company conducted a public offering of 0.250% convertible senior notes due 2032. The net proceeds from the offering were \$557.2 million, after deducting underwriting discounts and commissions and the Company’s estimated offering expenses. The Company utilized \$137.0 million of the net proceeds to prepay term loan debt.

Celcuity’s advancement of a subcutaneous gedatolisib formulation is ongoing with the goal of demonstrating clinical equivalence to the current intravenous formulation of gedatolisib. The subcutaneous formulation is aimed to support potential future indications for gedatolisib regimens that may result in duration of treatment periods greater than several years.

Second Quarter 2026 Financial Results

Unless otherwise stated, all comparisons are for the second quarter ended June 30, 2026, compared to the second quarter ended June 30, 2025.

Net loss for the second quarter of 2026 was \$78.9 million, or \$1.44 per share, compared to a net loss of \$45.3 million, or \$1.04 per share, for the prior year period. Non-GAAP adjusted net loss for the second quarter of 2026 was \$58.7 million, or \$1.07 per share, compared to non-GAAP adjusted net loss of \$40.5 million, or \$0.93 per share, for the prior year period. Non-GAAP adjusted net loss excludes stock-based compensation expense, non-cash interest expense, non-cash investment (income) expense and loss on debt extinguishment. Because these items have no impact on Celcuity's cash position, management believes non-GAAP adjusted net loss better enables Celcuity to focus on cash used in operations. For a reconciliation of financial measures calculated in accordance with generally accepted accounting principles in the United States ("GAAP") to non-GAAP financial measures, please see the financial tables at the end of this press release.

Total operating expenses were \$66.1 million for the second quarter of 2026, compared to \$44.0 million for the prior year period.

Research and development ("R&D") expenses were \$31.1 million for the second quarter of 2026, compared to \$36.4 million for the prior year period. The \$5.3 million decrease in R&D expenses was primarily due to a \$7.0 million decrease in clinical trial costs, which was primarily driven by decreased costs for the VIKTORIA-1 Phase 3 clinical trial, and a \$5.0 million decrease in license milestone costs. These decreases were partially offset by a \$3.8 million increase in employee-related and consulting expenses, of which \$0.9 million related to stock-based compensation, and a \$2.9 million increase in manufacturing and other costs.

Selling, general and administrative ("SG&A") expenses were \$35.0 million for the second quarter of 2026, compared to \$7.6 million for the prior year period. The \$27.4 million increase in SG&A expenses was primarily due to a \$14.5 million increase in employee-related expenses, of which \$3.3 million related to stock-based compensation. The increase in employee-related expenses was primarily driven by the hiring of additional personnel within our commercial function to support the anticipated launch of REVTORPYK. The remaining \$12.9 million increase was primarily due to a \$10.8 million increase in costs to support pre-commercial launch activities, including consulting expenses, professional fees and expanding infrastructure costs, and a \$2.1 million increase in other administrative expenses. In the aggregate, \$23.4 million of the \$27.4 million SG&A increase related to commercial headcount additions and other launch-related activities.

Net cash used in operating activities for the second quarter of 2026 was \$55.4 million, compared to \$36.2 million for the prior year period. Cash, cash equivalents and short-term investments were \$754.0 million at the end of the second quarter of 2026. We expect that our current cash, cash equivalents and short-term investments will finance our operations at least into 2029.

Webcast and Conference Call Information

To participate in the teleconference, domestic callers should dial 1-800-717-1738 and international callers should dial 1-646-307-1865.

A live webcast presentation can also be accessed using this weblink: https://viaid.webcasts.com/starthere.jsp?ei=1767665&tp_key=7e57f2ab18. A replay of the webcast will be available on the Celcuity website following the live event.

About REVTORPYK (gedatolisib)

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.

Please click [here](#) for Important Safety Information and Full Prescribing Information for REVTORPYK.

About Celcuity

We are a biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. Our 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. Our Phase 3 clinical trial, VIKTORIA-1, evaluated gedatolisib in combination with fulvestrant, with or without palbociclib, for the treatment of patients with HR+/HER2- ABC. Data from this trial is the basis for FDA approval of REVTORPYK for use in adult 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. Results for the *PIK3CA* mutant cohort of the VIKTORIA-1 study have been released. Our Phase 3 clinical trial, VIKTORIA-2, is an ongoing trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib in combination with palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib in combination 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 and its products, including important safety information and full prescribing information 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 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 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 gedatolisib; 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:

1. 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

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Celcuity Inc. Condensed Balance Sheets (in thousands)

	June 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 182,049	\$ 165,703
Investments	571,995	275,794
Prepaid clinical trial costs	12,996	18,896
Other current assets	8,801	5,266
Total current assets	775,841	465,659
Property and equipment, net	611	499
Intangible assets, net	50,000	—
Operating lease right-of-use assets	1,107	51
Other non-current assets	661	349
Total assets	<u>\$ 828,220</u>	<u>\$ 466,558</u>
Liabilities and stockholders' equity (deficit)		

Current liabilities:		
Accounts payable	\$ 8,093	\$ 6,407
Accrued clinical trial costs	7,942	16,826
Accrued license milestone	50,000	5,000
Other accrued expenses	20,581	15,865
Operating lease liabilities, current	257	54
Total current liabilities	86,873	44,152
Operating lease liabilities, non-current	893	—
Convertible notes	753,235	195,324
Note payable	—	126,527
Total liabilities	841,001	366,003
Total stockholders' equity (deficit)	(12,781)	100,555
Total liabilities and stockholders' equity (deficit)	\$ 828,220	\$ 466,558

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development ⁽¹⁾	\$ 31,077	\$ 36,415	\$ 64,140	\$ 66,174
Selling, general and administrative ⁽¹⁾	35,041	7,594	52,485	13,968
Total operating expenses	66,118	44,009	116,625	80,142
Loss from operations	(66,118)	(44,009)	(116,625)	(80,142)
Other (expense) income:				
Interest expense	(5,423)	(3,204)	(11,508)	(6,387)
Interest income	4,154	1,945	7,905	4,264
Loss on debt extinguishment	(11,477)	—	(11,477)	—
Other expense, net	(12,746)	(1,259)	(15,080)	(2,123)
Net loss before income taxes	(78,864)	(45,268)	(131,705)	(82,265)
Income taxes	—	—	—	—
Net loss	\$ (78,864)	\$ (45,268)	\$ (131,705)	\$ (82,265)
Net loss per share, basic and diluted	\$ (1.44)	\$ (1.04)	\$ (2.41)	\$ (1.90)
Weighted average common shares outstanding, basic and diluted	54,816,437	43,663,364	54,640,608	43,359,748

(1) Certain prior period amounts have been reclassified from research and development expenses to selling, general and administrative expenses to conform to the current period presentation.

Cautionary Statement Regarding Non-GAAP Financial Measures

This press release contains references to non-GAAP adjusted net loss and non-GAAP adjusted net loss per share. Management believes these non-GAAP financial measures are useful supplemental measures for planning, monitoring, and evaluating operational performance as they exclude stock-based compensation expense, non-cash interest expense, non-cash investment (income) expense and loss on debt extinguishment from net loss and net loss per share. Management excludes these items because they do not impact Celcuity's cash position, which management believes better enables Celcuity to focus on cash used in operations. However, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share are not recognized measures under GAAP and do not have a standardized meaning prescribed by GAAP. As a result, management's method of calculating non-GAAP

adjusted net loss and non-GAAP adjusted net loss per share may differ materially from the method used by other companies. Therefore, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may not be comparable to similarly titled measures presented by other companies. Investors are cautioned that non-GAAP adjusted net loss and non-GAAP adjusted net loss per share should not be construed as alternatives to net loss, net loss per share or other statements of operations data (which are determined in accordance with GAAP) as an indicator of Celcuity's performance or as a measure of liquidity and cash flows.

Celcuity Inc.
Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and
GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share
(unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
GAAP net loss	\$ (78,864)	\$ (45,268)	\$ (131,705)	\$ (82,265)
Adjustments to net loss:				
Stock-based compensation				
Research and development ^{(1), (2)}	2,240	1,261	4,352	2,425
Selling, general and administrative ^{(1), (3)}	4,664	1,443	7,877	2,723
Non-cash interest expense ⁽⁴⁾	1,471	789	3,048	1,589
Non-cash investment (income) expense ⁽⁵⁾	332	1,286	(551)	340
Loss on debt extinguishment ⁽⁶⁾	11,477	—	11,477	—
Non-GAAP adjusted net loss	<u>\$ (58,680)</u>	<u>\$ (40,489)</u>	<u>\$ (105,502)</u>	<u>\$ (75,188)</u>
GAAP net loss per share - basic and diluted	\$ (1.44)	\$ (1.04)	\$ (2.41)	\$ (1.90)
Adjustments to net loss:				
Stock-based compensation				
Research and development ^{(1), (2)}	0.04	0.03	0.08	0.06
Selling, general and administrative ^{(1), (3)}	0.08	0.03	0.14	0.06
Non-cash interest expense ⁽⁴⁾	0.03	0.02	0.06	0.04
Non-cash investment (income) expense ⁽⁵⁾	0.01	0.03	(0.01)	0.01
Loss on debt extinguishment ⁽⁶⁾	0.21	—	0.21	—
Non-GAAP adjusted net loss per share - basic and diluted	<u>\$ (1.07)</u>	<u>\$ (0.93)</u>	<u>\$ (1.93)</u>	<u>\$ (1.73)</u>
Weighted average common shares outstanding, basic and diluted	<u>54,816,437</u>	<u>43,663,364</u>	<u>54,640,608</u>	<u>43,359,748</u>

(1) Certain prior period amounts have been reclassified from research and development expenses to selling, general and administrative expenses to conform to the current period presentation.

(2) To reflect a non-cash adjustment to operating expenses for research and development stock-based compensation.

(3) To reflect a non-cash adjustment to operating expenses for selling, general and administrative stock-based compensation.

(4) To reflect a non-cash adjustment to other (expense) income for amortization of debt issuance costs and discount and payment-in-kind interest related to the issuance of the convertible notes and note payable.

(5) To reflect a non-cash adjustment to other (expense) income for accretion on investments and change in accrued interest income.

(6) To reflect a non-cash adjustment to other (expense) income for loss on extinguishment related to the repayment of the note payable.