Celcuity Inc. Reports Third Quarter 2026 Financial Results and Provides Corporate Update

November 5, 2026

REVTORPYK became commercially available on September 30th for the treatment of patients with HR+/HER2- PIK3CA wild-type locally advanced or metastatic breast cancer

91% of U.S. commercial and Medicare lives are in health plans that cover REVTORPYK

78% of the top 36 strategic accounts, representing ~50% of the total addressable patient population, have prescribed REVTORPYK

Management to host webcast and conference call today, November 5, 2026, at 4:30 p.m. EST

MINNEAPOLIS, Nov. 05, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications, today announced financial results for the third quarter ended September 30, 2026, and other recent business developments.

Celcuity announced on September 30, 2026, that REVTORPYK™ (gedatolisib) became commercially available in the United States for use in combination with fulvestrant, with or without palbociclib, for the treatment of HR+/HER2- locally advanced or metastatic breast cancer ("ABC") without a *PIK3CA* mutation detected following progression on or after at least one line of endocrine therapy in the metastatic setting.

"Our commercial and medical affairs teams have laid the foundation for a strong launch over the past few years, and their efforts are paying off," said Brian Sullivan, CEO and co-founder of Celcuity. "Physicians are enthusiastic and eager to treat their patients with REVTORPYK, and we are pleased with their interest in getting eligible patients on treatment in the initial weeks since we launched."

"We estimate over 90% of commercial and Medicare lives are in health plans that cover REVTORPYK. The unprecedented efficacy results from the wild-type cohort of the pivotal VIKTORIA-1 study, and the preferred Category 1 recommendation in the NCCN Guidelines, provide physicians with a compelling value proposition to address a significant unmet need for the tens of thousands of patients affected each year by HR+/HER2-, *PIK3CA* wild-type advanced breast cancer."

Business Highlights and Other Recent Developments

2nd Line HR+/HER2- ABC – *PIK3CA* wild-type

- **FDA approval**. On July 14, 2026, the US Food and Drug Administration ("FDA") approved REVTORPYK for the treatment of patients with HR+/HER2- ABC without a *PIK3CA* mutation detected following progression on or after at least one line of endocrine therapy in the metastatic setting.
- **NCCN preferred Category 1 recommendation**. On July 30, 2026, NCCN included REVTORPYK as a preferred Category 1 recommendation for second-line and/or subsequent-line therapy for the treatment of patients with HR+/HER2- advanced breast cancer without a *PIK3CA* mutation following progression on or after at least one line of endocrine therapy.
- **Early launch off to a positive start**. 78% of the top 36 strategic accounts, representing ~50% of the total addressable patient population, have ordered REVTORPYK. Over 3,400 sites, many of which are affiliated with one of the top 36 strategic accounts, have directly engaged with Celcuity oncology sales specialists. These sites treat 82% of breast cancer patients. Additionally, over 1,100 health care providers have attended REVTORPYK educational programs.
- **Broad payor coverage and major provider pathway inclusion**. 91% of U.S. commercial and Medicare lives are in health plans that cover REVTORPYK, and REVTORPYK has already been incorporated in 3 of the 4 largest health care provider pathways.

2nd Line HR+/HER2- ABC – *PIK3CA* mutant-type

In October, updated results from the Phase 3 VIKTORIA-1 study were presented in a late breaking rapid oral presentation at the European Society for Medical Oncology ("ESMO") Congress 2026. Key results included:

- Median progression-free survival ("PFS") was 21.5 months with the gedatolisib triplet (gedatolisib + fulvestrant + palbociclib) and 11.5 months with the gedatolisib doublet (gedatolisib + fulvestrant) versus 9.1 months with alpelisib + fulvestrant in patients who had no liver metastases.

- Objective response rate (“ORR”) and median duration of response for patients with evaluable disease were 59% and 19.4 months, respectively, for the gedatolisib triplet and 43% and 27.8 months, respectively, for the gedatolisib doublet, compared to 33% and 7.5 months, respectively, for alpelisib + fulvestrant.
- The discontinuation rate for gedatolisib due to adverse events was 5% and 4% with the gedatolisib triplet and doublet, respectively, compared to 19% for alpelisib + fulvestrant.

Based on the positive data from the *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 study, Celcuity submitted a supplemental New Drug Application (“sNDA”) to the FDA in the third quarter of 2026. Celcuity expects to submit VIKTORIA-1 Phase 3 data for both the wild-type and mutant cohorts to global regulatory authorities later this year or early next year.

1st Line HR+/HER2- ABC

- **VIKTORIA-2.** Enrollment is ongoing in the Phase 3 VIKTORIA-2 clinical trial that is evaluating gedatolisib combined with palbociclib and fulvestrant in the first-line setting for patients with endocrine resistant HR+/HER2- ABC (Study 1) or gedatolisib combined with palbociclib and letrozole in the first-line setting for patients with endocrine sensitive HR+/HER2- ABC (Study 2).

Metastatic Castration-Resistant Prostate Cancer (“mCRPC”)

Updated data from a Phase 1b/2 study evaluating gedatolisib plus darolutamide in men with mCRPC were presented at a poster session at the ESMO Congress 2026. Key results included:

- Median radiographic progression free survival (“rPFS”) was 15.7 months and the six-month rPFS rate (“rPFS6”) was 82.2% in patients with prior exposure to abiraterone. Median rPFS was 9.1 months and rPFS6 was 62.5% in patients with prior exposure to enzalutamide.
- Prostate-specific antigen (“PSA”) ≥50% decreases from baseline were observed across all dose levels; response rates were 36%, 47% and 67% at the 120-, 180-, and 240-mg gedatolisib dose levels, respectively, in patients with prior exposure to either abiraterone or enzalutamide.
- Gedatolisib plus darolutamide demonstrated a manageable safety profile across the evaluated dose levels (120 mg, 180 mg, 240 mg) with one dose-limiting toxicity (Grade 3 rash), no Grade 4/5 treatment-related adverse events (“TRAEs”), and no TRAEs leading to treatment discontinuation or death. Grade 3 TRAEs occurred in 9 patients with only rash and pruritus occurring in more than one patient..
- The randomized Phase 2 study to evaluate the efficacy and safety of, and determine the recommended Phase 3 dose level of, gedatolisib in combination with darolutamide in patients with prostate cancer is expected to begin in the first half of 2027.

New Senior Management

Byron Robinson, Ph.D., J.D., joined Celcuity as Chief Strategy Officer to support development of strategic clinical and business development plans. Byron has served for more than 30 years in a variety of executive roles with responsibility for drug discovery, global clinical development, program leadership, portfolio strategy, market intelligence and competitive analytics. His experience includes senior executive roles at both small and large biotech and pharma companies including Janux Therapeutics, Merck KGaA, Bayer AG, and Amgen.

Third Quarter 2026 Financial Results

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

Net loss for the third quarter of 2026 was $73.3 million, or $1.33 per share, compared to a net loss of $43.8 million, or $0.92 per share, for the prior year period. Non-GAAP adjusted net loss for the third quarter of 2026 was $66.8 million, or $1.21 per share, compared to non-GAAP adjusted net loss of $37.2 million, or $0.78 per share, for the prior year period. Non-GAAP adjusted net loss excludes stock-based compensation expense, non-cash interest expense and non-cash investment income. 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.

Shipments of REVTORPYK commenced on September 30, 2026. We recognize revenue when control of REVTORPYK transfers to the healthcare providers or pharmacies, which generally occurs upon delivery. Because no product was received by the healthcare providers or pharmacies until after September 30, 2026, we did not recognize any product revenue during the third quarter ended September 30, 2026.

Total operating expenses were $77.3 million for the third quarter of 2026, compared to $42.8 million for the prior year period.

Research and development (“R&D”) expenses were $37.5 million for the third quarter of 2026, compared to $30.4 million for the

prior year period. The $7.1 million increase in R&D expenses was primarily due to a $5.3 million increase in employee-related and consulting expenses, of which $1.5 million related to stock-based compensation, and a $2.1 million increase in manufacturing and other costs. These increases were partially offset by a $0.3 million decrease in clinical trial costs.

Selling, general and administrative ("SG&A") expenses were $39.8 million for the third quarter of 2026, compared to $12.4 million for the prior year period. The $27.4 million increase in SG&A expenses was primarily due to a $14.4 million increase in employee-related expenses, of which $1.7 million related to stock-based compensation. The increase in employee-related expenses was primarily driven by the hiring of additional personnel to support the commercialization of REVTORPYK. The remaining $13.0 million increase was primarily due to an $11.1 million increase in costs to support the commercialization of REVTORPYK, including consulting expenses and expanding infrastructure costs, and a $1.9 million increase in other administrative expenses. In the aggregate, $25.3 million of the $27.4 million SG&A increase related to commercial headcount additions and other activities to support the commercialization of REVTORPYK.

Net cash used in operating activities for the third quarter of 2026 was $66.2 million, compared to $44.8 million for the prior year period. In addition, we made a $50.0 million payment to Pfizer triggered by receipt of FDA approval for REVTORPYK per our exclusive global license agreement for gedatolisib. Cash, cash equivalents and short-term investments were $642.7 million at the end of the third quarter of 2026. We expect that our current cash, cash equivalents and short-term investments will finance our operations through 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://viavid.webcasts.com/starthere.jsp?ei=17786&tp_key=e66abcfe8a. 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

Celcuity is a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. Celcuity's first FDA-approved product is REVTORPYK™ (gedatolisib), a potent pan-PI3K and mTORC1/2 inhibitor that comprehensively blocks the PI3K/AKT/mTOR (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. Celcuity's Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib plus fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, supported FDA approval of REVTORPYK for use in adult 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 the VIKTORIA-1 clinical trial have been released.

Celcuity's 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 plus palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. Celcuity's Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib plus 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, Minnesota. 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 FDA's review of the Company's supplemental New Drug Application ("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 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 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.

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Celcuity Inc.
Condensed Balance Sheets
(in thousands)

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 178,165	$ 165,703
Investments	464,538	275,794
Inventory	1,476	—
Prepaid clinical trial costs	19,669	18,896
Other current assets	10,108	5,266
Total current assets	673,956	465,659
Property and equipment, net	901	499
Intangible assets, net	50,000	—
Operating lease right-of-use assets	1,061	51
Other non-current assets	951	349
Total assets	$ 726,869	$ 466,558
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 12,407	$ 6,407
Accrued clinical trial costs	11,277	16,826
Other accrued expenses	22,159	20,865
Operating lease liabilities, current	259	54
Total current liabilities	46,102	44,152
Operating lease liabilities, non-current	848	—
Convertible notes	753,958	195,324
Note payable	—	126,527
Total liabilities	800,908	366,003
Total stockholders' equity (deficit)	(74,039)	100,555
Total liabilities and stockholders' equity (deficit)	$ 726,869	$ 466,558

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development[(1)]	$ 37,519	$ 30,425	$ 101,659	$ 96,598
Selling, general and administrative[(1)]	39,800	12,424	92,285	26,393
Total operating expenses	77,319	42,849	193,944	122,991
Loss from operations	(77,319)	(42,849)	(193,944)	(122,991)
Other (expense) income:				
Interest expense	(2,691)	(4,595)	(14,199)	(10,982)
Interest income	6,673	3,640	14,578	7,904
Loss on debt extinguishment	—	—	(11,477)	—
Other (expense) income, net	3,982	(955)	(11,098)	(3,078)
Net loss before income taxes	(73,337)	(43,804)	(205,042)	(126,069)
Income taxes	—	—	—	—
Net loss	$ (73,337)	$ (43,804)	$ (205,042)	$ (126,069)
Net loss per share, basic and diluted	$ (1.33)	$ (0.92)	$ (3.74)	$ (2.81)
Weighted average common shares outstanding, basic and diluted	54,143,356	47,589,731	54,810,032	44,785,236

(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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
GAAP net loss	$ (73,337)	$ (43,804)	$ (205,042)	$ (126,069)
Adjustments to net loss:				
Stock-based compensation				
Research and development[1, 2]	3,038	1,478	7,390	3,904
Selling, general and administrative[1, 3]	6,984	5,301	14,861	8,023
Non-cash interest expense[4]	(62)	1,050	2,986	2,639
Non-cash investment income[5]	(3,471)	(1,180)	(4,022)	(840)
Loss on debt extinguishment[6]	—	—	11,477	—
Non-GAAP adjusted net loss	$ (66,848)	$ (37,155)	$ (172,350)	$ (122,343)
GAAP net loss per share - basic and diluted	$ (1.33)	$ (0.92)	$ (3.74)	$ (2.81)
Adjustments to net loss:				
Stock-based compensation				
Research and development[1, 2]	0.06	0.03	0.13	0.09
Selling, general and administrative[1, 3]	0.13	0.11	0.27	0.18
Non-cash interest expense[4]	—	0.02	0.05	0.06
Non-cash investment income[5]	(0.07)	(0.02)	(0.06)	(0.03)
Loss on debt extinguishment[6]	—	—	0.21	—
Non-GAAP adjusted net loss per share - basic and diluted	$ (1.21)	$ (0.78)	$ (3.14)	$ (2.51)
Weighted average common shares outstanding, basic and diluted	55,143,356	47,589,731	54,810,032	44,785,236

(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, net for amortization of debt issuance costs and discount, payment-in-kind interest and change in accrued interest related to the convertible notes and note payable.

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

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