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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 16, 2026

CERENOME, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34375**	**33-0827593**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6420 LEVIT GREEN BOULEVARD
Suite 310
Houston, Texas **77021**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (737) 255-7194

(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, par value $0.001 per share	CNSY	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On November 16, 2026, Cerenome, Inc. issued a press release regarding its report of interim ReSPECT-LM data at the 2026 Society for Neuro-Oncology Annual Meeting. The press release contains statements intended as "forward-looking statements" which are subject to the cautionary statements about forward-looking statements set forth therein. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 16, 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.

CERENOME, INC.

Date: November 16, 2026

By: /s/ Marc H. Hedrick, M.D.
Name: Marc H. Hedrick, M.D.
Title: President and Chief Executive Officer

Cerenome Reports Interim ReSPECT-LM Data Supporting Repeat Dosing of REYOBIQ™ in Leptomeningeal Metastases at the 2026 SNO Annual Meeting

No dose-limiting toxicities in the first 10 patients; consistent and reliable dosing of a targeted radiopharmaceutical; early disease control signal in line with existing data

HOUSTON, November 16, 2026 (GLOBE NEWSWIRE) — Cerenome, Inc. (Nasdaq: CNSY) ("Cerenome" or the "Company"), a CNS oncology company advancing an integrated platform that combines precision diagnostics, targeted radiopharmaceuticals, and artificial intelligence, today announced interim data from its ongoing ReSPECT-LM study of repeated intraventricular dosing of REYOBIQ™ (rhenium Re186 obisbemeda) in patients with leptomeningeal metastases (LM). The data were presented as a poster on November 13, 2026, during the Society for Neuro-Oncology (SNO) 31st Annual Meeting and Education Day.

The poster reports treatment exposure, safety, dosimetry, LM progression status, and cerebrospinal fluid (CSF) tumor-cell findings for the first 10 patients treated. No dose-limiting toxicities or adverse events leading to treatment discontinuation have been reported. To date, one patient has received three 26.4 mCi doses, for a total administered activity of 79.2 mCi. This exceeds the highest activity given as a single administration in the prior single-dose ReSPECT-LM study (75 mCi). Furthermore, imaging showed the radiation dose delivered to the LM compartment was consistent from one treatment to the next within each patient, varying by a median of 8%. These levels are consistent with previously reported Phase 1 single-dose data. Dose escalation is ongoing.

No LM progression was documented by the three- and six-month landmarks among evaluable patients (0/5 at each landmark), and progression was documented in 1 of 4 evaluable patients by nine months.

"These interim findings support the feasibility and early tolerability of fractionated REYOBIQ dosing as a way to deliver a higher cumulative radiation dose to the LM compartment," said Eric J. Daniels, M.D., Cerenome's Chief Operating Officer. "The LM progression findings among evaluable patients are encouraging, alongside the absence of dose-limiting toxicities to date and consistent radiation delivery across repeat administrations. Our focus now is on continued dose escalation and enrollment to define recommended multiple-dose regimens in support of a future randomized study."

Interim ReSPECT-LM Findings

Of the 10 patients, six received 13.2 mCi per administration and four received 26.4 mCi per administration. Primary cancers included melanoma (4), breast cancer (3), non-small cell lung cancer (1), ovarian cancer (1), and neuroendocrine cancer (1). Nine patients had received prior LM therapy, and three were receiving concurrent systemic treatment.

- **Safety:** No dose-limiting toxicities or adverse events leading to discontinuation have been observed. One patient had Grade 3 treatment-related nausea, which resolved within five days. The only serious adverse event, shortness of breath occurring in a single subject, was considered unrelated to treatment. All 10 patients had at least one treatment-emergent adverse event; the most common were nausea (60%), headache (40%), decreased lymphocyte count (40%), and decreased white blood cell count (40%).
- **Landmark LM progression findings:** No LM progression was documented by three or six months among evaluable patients (0/5 at each landmark). By nine months, LM progression was documented in 1 of 4 evaluable patients. Evaluability was determined by principal investigator review of available records, based on documented progression on or before the landmark or adequate disease-assessment follow-up establishing LM status through that landmark. Patients with insufficient follow-up, or who died from primary disease before the landmark without prior LM progression, were excluded. These descriptive findings are not progression-free survival estimates.
- **CSF tumor-cell findings:** Serial monitoring with Cerenome's CNSide® documented tumor-cell reductions in individual patients. Three patients with detectable tumor cells at baseline later had samples with zero tumor cells/mL. Two of them remained at zero tumor cells/mL at their latest assessments, 9.2 and 2.3 months after the first dose, respectively. The third later had a rise in tumor-cell counts and MRI-confirmed LM progression, nearly 4 months after the third dose of REYOBIQ.

- **High cumulative absorbed doses:** The first patient to complete three administrations at 26.4 mCi per dose received an estimated cumulative LM compartment absorbed dose of 207 Gy, with no dose-limiting toxicities. Five patients completing three administrations at the lowest dose level, 13.2 mCi per dose, received cumulative LM compartment absorbed doses of 85–137 Gy, again consistent with previously observed Phase 1 data.
- **Consistent repeat-dose delivery:** In patients who received repeat administrations, the absorbed dose per mCi varied little from dose to dose (median within-patient coefficient of variation, 8%), as did the CSF effective half-life (12%). Dosimetry was consistent with the prior single-dose ReSPECT-LM experience, supporting the feasibility of repeat dosing. SPECT/CT imaging in the patient who completed three 26.4 mCi administrations showed a similar distribution of activity after each dose.

- **Low estimated bone marrow exposure:** The median blood-derived marrow absorbed dose was 0.023 Gy per administration (range, 0.010–0.41 Gy). This low level of blood exposure is important to avoid potential cytopenias and further supports continued investigation of local LM compartmental delivery.

“The lack of documented LM progression among evaluable patients at the three- and six-month landmarks is early and encouraging, particularly in a population in which most patients had received prior LM therapy,” said Andrew J. Brenner, M.D., Ph.D., Professor of Medicine at Mays Cancer Center at UT Health San Antonio and lead author of the poster. “The ability to deliver substantial cumulative radiation doses with consistent repeat-dose delivery and low estimated marrow exposure supports further evaluation. These findings remain preliminary, and continued enrollment and follow-up are needed to determine the clinical activity of this regimen.”

These preliminary findings come from an ongoing, open-label dose-escalation study. Patients had different primary cancers, treatment histories, and lengths of follow-up, and some received concurrent systemic therapy. The landmark analyses include only patients evaluable at each time point and do not establish a progression-free or overall survival benefit.

As previously announced, Cerenome is targeting a Phase 2 randomized study in 2027, subject to continued clinical progress and regulatory alignment.

Poster Presentation

Abstract Code	CTNI-40
Poster Title	Repeated Intraventricular Rhenium-186 Obisbemeda (186RNL) in Leptomeningeal Metastases: Interim Dosimetry, Safety, and CSF Tumor Cell Response From the ReSPECT-LM Multiple-Dose Study
Date and Time	Friday, November 13, 2026, 7:30-9:30 p.m. ET
Location	Exhibit Hall D & E, Pennsylvania Convention Center, Philadelphia

About ReSPECT-LM
ReSPECT-LM (NCT07098806) is an open-label, multicenter Phase 1 study of repeated intraventricular administration of REYOBIQ in adults with LM from solid tumors. REYOBIQ is delivered into the LM compartment through an Ommaya reservoir. The study is evaluating three dose levels (13.2, 26.4 and 44.1 mCi) and three dosing intervals (every 14, 28 or 56 days) across eight planned cohorts, with three administrations per participant. It is designed to assess safety, dosimetry and activity, and to identify a recommended multiple-dose regimen.

About REYOBIQ™
REYOBIQ (rhenium Re186 obisbemeda) is an investigational injectable radiotherapeutic in which the radioisotope rhenium-186 is chelated and trapped inside a nanoliposome. It is designed to deliver targeted, high-dose beta radiation directly to tumors through local delivery, such as convection-enhanced delivery or an intraventricular (Ommaya) catheter, while keeping exposure to the rest of the body low.

REYOBIQ is being evaluated for the treatment of leptomeningeal metastases, recurrent glioblastoma, and pediatric brain cancers in the ReSPECT-LM, ReSPECT-GBM, and ReSPECT-PBC clinical trials, respectively.

Results from the multicenter Phase 1 ReSPECT-GBM trial were published in Nature Communications in 2025 (Brenner AJ, et al. Nat Commun. 2025;16:2079). REYOBIQ is investigational and has not been approved by the U.S. Food and Drug Administration or any other regulatory authority for any use. ReSPECT-GBM is supported by an award from the National Cancer Institute (NCI), part of the U.S. National Institutes of Health (NIH), and ReSPECT-LM is funded by a $17.6 million grant from the Cancer Prevention & Research Institute of Texas (CPRIT). The Company's ReSPECT-PBC clinical trial for pediatric brain cancer is supported by a $3 million grant from the U.S. Department of Defense's Peer Reviewed Cancer Research Program.

About Cerenome
Cerenome (Nasdaq: CNSY) is a CNS oncology company advancing an integrated platform that combines precision diagnostics, targeted therapeutics, and artificial intelligence to improve outcomes for patients with central nervous system cancers. The CNSide® CSF diagnostics platform combines cellular and molecular testing to support the detection, characterization, and longitudinal assessment of cancers involving the CNS.

Its lead therapeutic platform, REYOBIQ™ (rhenium Re186 obisbemeda), is being evaluated in clinical trials for leptomeningeal metastases, recurrent glioblastoma, and pediatric brain cancers. The data & artificial intelligence platform is designed to integrate diagnostic, molecular, imaging, and clinical data into actionable insights that support precision oncology and therapeutic innovation.

By integrating commercial diagnostics, targeted therapeutics, proprietary longitudinal data, and artificial intelligence within a single organization, Cerenome is building a differentiated CNS oncology platform designed to improve patient care while creating long-term shareholder value. For more information, visit https://www.cerenome.com.

Forward-Looking Statements

This press release contains statements that may be deemed “forward-looking statements” within the meaning of U.S. securities laws, including statements regarding commercialization, clinical trials and upcoming developments. All statements in this press release other than statements of historical fact are forward-looking statements. These forward-looking statements may be identified by future verbs, as well as terms such as “expected,” “planning,” “future,” “targeting,” “continue,” and similar expressions or the negatives thereof. Such statements are based upon certain assumptions and assessments made by management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These statements include, without limitation, statements regarding the development and clinical utility of the ReSPECT-LM study and future randomized studies regarding ReSPECT-LM.

Investor Contact
CORE IR
IR@cerenome.com