Septerna Highlights Business Progress and Reports Third Quarter 2026 Financial Results

11.09.26

Phase 1 Clinical Trial for PTH1R Agonist SEP-479 Ongoing; SAD / MAD Data Expected in Q1 2027

Plans to Initiate Phase 1 Clinical Trial of Newly Selected Oral TSHR NAM Development Candidate SEP-204 in Q1 2027

Cash Position of $565.2 Million Expected to Support Operating Plans at Least into mid-2029

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Septerna, Inc. (Nasdaq: SEPN), a clinical-stage biotechnology company pioneering a new era of G protein-coupled receptor (GPCR) drug discovery, today highlighted pipeline progress and anticipated milestones and reported financial results for the third quarter ended September 30, 2026.

"We are building momentum across our portfolio, with an upcoming important clinical milestone for SEP-479, our oral PTH1R agonist for hypoparathyroidism, and the selection of SEP-204 as our oral TSHR NAM development candidate for Graves' disease and thyroid eye disease," said Jeffrey Finer, M.D., Ph.D., Chief Executive Officer and Co-founder of Septerna. "With Phase 1 data for SEP-479 and the initiation a Phase 1 trial of SEP-204 expected in the first quarter of 2027, we are moving closer to realizing our ambition to translate our GPCR expertise into differentiated oral medicines for patients with significant unmet needs."

Recent Portfolio Progress and Anticipated Milestones

- **SEP-479 PTH1R Agonist for Hypoparathyroidism:**
  - Septerna's Phase 1 single-ascending dose (SAD) and multiple-ascending dose (MAD) clinical trial of SEP-479, an oral small molecule PTH1R agonist in development for hypoparathyroidism, is ongoing in healthy volunteers, with data expected in the first quarter of 2027.
- **SEP-204 TSHR NAM for Graves' Disease and Thyroid Eye Disease:**
  - In conjunction with last week's American Thyroid Association (ATA) annual meeting, Septerna announced the selection of SEP-204 as its oral TSHR negative allosteric modulator (NAM) development candidate as a potential disease-modifying treatment for Graves' disease and thyroid eye disease.
  - Preclinical data presented at ATA demonstrated that SEP-204 potently and selectively inhibited TSHR, restored normal thyroid hormone T4 levels and reduced thyroid enlargement and orbital proptosis in Graves' disease animal models. SEP-204 was generally well tolerated in 28-day GLP toxicology studies and demonstrated a favorable pharmacokinetic profile anticipated to support once-daily oral dosing in humans. Additional details are available in the data release.
  - Following the successful completion of the remaining preclinical development activities, Septerna anticipates initiating a Phase 1 clinical trial for SEP-204 in healthy volunteers in the first quarter of 2027.
- **SEP-631 MRGPRX2 NAM for Mast Cell-Driven Diseases:**
  - Following positive Phase 1 results reported in March 2026, Septerna continues to evaluate capital-efficient, signal-finding clinical studies of SEP-631 in mast cell-driven diseases with high unmet need.
- **Additional Programs:**
  - Under its global collaboration with Novo, initiated in July 2025, Septerna and Novo are advancing oral small molecule programs for obesity, type 2 diabetes and other cardiometabolic diseases. Novo recently assumed responsibility for a development candidate delivered by Septerna's research team and initiated IND-enabling toxicology studies. To date, Septerna has achieved a total of $13 million in research milestones under the collaboration.
  - Septerna also continues to advance wholly owned discovery-stage programs utilizing its Native Complex Platform® across multiple therapeutic areas, including a PTH1R agonist program for osteoporosis.

Corporate Announcements

- In August 2026, Septerna announced the appointment of Rajiv Patni, M.D., as Chief Medical Officer. Dr. Patni is a physician-scientist and accomplished biopharmaceutical executive with more than 25 years of experience leading research, development, regulatory, and medical affairs organizations.

Third Quarter 2026 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled $565.2 million as of September 30, 2026. Septerna expects its existing cash runway to fund operations at least into mid-2029.

- **Revenue:** Revenue was $18.9 million for the quarter ended September 30, 2026, compared to $21.5 million for the quarter ended September 30, 2025. Revenue for the quarter ended September 30, 2026, included the amortization of $2.7 million of the $195.0 million upfront payment from Novo Nordisk, and $5.2 million from the achievement of research milestones, in addition to $11.0 million for research services associated with the collaboration.
- **R&D Expenses:** Research and development (R&D) expenses were $36.6 million for the quarter ended September 30, 2026, compared to $24.3 million for the quarter ended September 30, 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were $9.6 million for the quarter ended September 30, 2026, compared to $7.1 million for the quarter ended September 30, 2025.
- **Net (Loss) Income:** Net loss was $26.6 million for the quarter ended September 30, 2026, compared to net income of $8.2 million for the quarter ended September 30, 2025.

About Septerna

Septerna, Inc. is a clinical-stage biotechnology company with a world-class team of GPCR experts and drug developers advancing cutting-edge science to unlock the full potential of GPCR therapies for patients with significant unmet needs. The company's proprietary Native Complex Platform® is designed to enable new approaches to GPCR drug discovery and has led to the development of a diverse pipeline of novel oral small molecule drug candidates. Septerna is advancing programs in endocrinology, immunology and inflammation, metabolic diseases and additional therapeutic areas, both independently and with partners. For more information, please visit www.septerna.com. Septerna intends to use its Investor Relations website and LinkedIn as means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Septerna's Investor Relations website and follow https://www.linkedin.com/company/septernainc on LinkedIn, in addition to following Septerna's press releases, SEC filings, public conference calls, presentations, and webcasts.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements about Septerna's beliefs and expectations regarding: the translating of SEP-479, SEP-204, SEP-631 and any future preclinical data into similar clinical findings; the availability of SEP-479 Phase 1 clinical data; SEP-479's potential as a differentiated once-daily oral therapy for patients with hypoparathyroidism; advancing SEP-204 into a Phase 1 clinical trial and timing thereof; SEP-204's potential as a disease-modifying treatment for Graves' disease and thyroid eye disease; continuing to advance programs under the Novo collaboration and achieving milestones thereunder; the potential of its proprietary Native Complex Platform®; the continued advancement of SEP-631, including plans to evaluate development strategies for capital-efficient, signal-finding clinical trials; the role of MRGPRX2 in mast cell-driven diseases; SEP-631's potential to provide a convenient oral treatment option for patients with mast cell-driven diseases; the advancement of its discovery-stage programs across multiple therapeutic areas; the size and growth potential of the markets for its current and future product candidates; its strategic plans for its business, product candidates, and technology; its uses of capital, expenses and financial results, including its expected cash runway at least into mid-2029; and the scope of protection it is able to establish and maintain for intellectual property rights covering its Native Complex Platform® and its product candidates; among others. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: Septerna's product candidates successfully entering and advancing through clinical trials (including those for SEP-479, SEP-204 and SEP-631) including uncertainties related to opening investigational new drug applications (INDs) and obtaining other regulatory approvals; risks related to clinical development outcomes including unexpected safety or efficacy findings; the results of preclinical studies including the long-term toxicology studies for SEP-479, SEP-204, and SEP-631, or preclinical studies or clinical trials not being predictive of future clinical outcomes; risks related to the timing of initiating clinical studies and future availability of clinical data; the scope of protection Septerna is able to establish and maintain for intellectual property rights covering its Native Complex Platform® and its product candidates; and Septerna's ability to identify and enter into future license agreements and collaborations; and general economic, industry and market conditions; among others. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Septerna's Quarterly Report on Form 10-Q for the three months ended September 30, 2026, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Septerna's views only as of today and should not be relied upon as representing its views as of any subsequent date. Septerna explicitly disclaims any obligation to update any forward-looking statements subject to any obligations under applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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SEPTERNA, INC.
Condensed Statements of Operations
(In thousands, except for share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue	$ 18,881	$ 21,495	$ 72,150	$ 21,833
Operating expenses (income):				
Research and development	36,556	24,264	101,223	65,723
General and administrative	9,554	7,117	28,292	20,884
Gain on sale of non-financial asset	—	(12,500)	—	(12,500)
Total operating expenses	46,110	18,881	129,515	74,107
(Loss) income from operations	(27,229)	2,614	(57,365)	(52,274)
Interest income and other expense, net	5,260	5,559	15,035	14,133
Provision for income taxes	(4,621)	—	(5,931)	—
Net (loss) income	$ (26,590)	$ 8,173	$ (48,261)	$ (38,141)
Net (loss) income per share, basic	$ (0.57)	$ 0.18	$ (1.06)	$ (0.86)
Net (loss) income per share, diluted	$ (0.57)	$ 0.18	$ (1.06)	$ (0.86)
Weighted-average shares outstanding, basic	46,914,946	44,343,085	45,579,174	44,150,041
Weighted-average shares outstanding, diluted	46,914,946	45,602,099	45,579,174	44,150,041

SEPTERNA, INC.
Condensed Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2026	**December 31, 2025**
Cash, cash equivalents and marketable securities	$ 565,188	$ 548,658
Working capital [1]	402,486	324,033
Total assets	619,404	596,187
Total liabilities	191,475	214,261
Additional paid-in capital	645,441	548,517
Accumulated deficit	(215,514)	(167,253)
Total stockholders' equity	$ 427,929	$ 381,926

1. Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes thereto included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 for further details regarding our current assets and current liabilities.