



Septerna Reports Third Quarter 2024 Financial Results and Recent Business Highlights

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Deep Pipeline of GPCR Programs Focused Initially on Indications in Endocrinology, Immunology and Inflammation, and Metabolic Diseases

Phase 1 Clinical Trial Ongoing for SEP-786, Oral Small Molecule for Hypoparathyroidism, with Data Expected in Mid-2025

Well-Capitalized with Balance Sheet to Support a Planned Operating Runway into Second Half of 2027

SOUTH SAN FRANCISCO, Calif., Nov. 20, 2024 (GLOBE NEWSWIRE) -- [Septerna, Inc.](#) (Nasdaq: SEPN), a clinical-stage biotechnology company pioneering a new era of G protein-coupled receptor (GPCR) drug discovery, today reported financial results for the third quarter ended September 30, 2024 and provided a portfolio overview and business highlights.

“At Septerna, we recently celebrated two major milestones: our transition to a clinical-stage company with the initiation of our Phase 1 clinical trial for SEP-786, and our debut as a public company following a successful IPO,” said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. “Our Native Complex Platform™ has yielded a deep pipeline of oral small molecule programs, each offering a unique product profile, early clinical biomarker readouts, and substantial market potential. Leading our pipeline is SEP-786, which we believe could transform hypoparathyroidism treatment by providing full-day calcium control with a convenient, disease-modifying oral therapy. With a talented team, a pioneering platform, a robust pipeline, and a strong balance sheet, we believe we are well positioned to deliver multiple novel GPCR medicines with the potential to meaningfully improve patients’ lives.”

Septerna’s proprietary [Native Complex Platform™](#) is uniquely designed to enable targeting of GPCRs with a wide spectrum of pharmacologies to affect GPCR signaling in different ways to achieve desired therapeutic effects. Using this platform, Septerna aims to discover and develop a portfolio of oral small molecule GPCR-targeted medicines with novel mechanisms to treat diseases across multiple therapeutic areas.

Portfolio Overview

SEP-786 PTH1R Agonist Advancing in Phase 1 Clinical Trial:

- SEP-786 is an oral small molecule Parathyroid Hormone 1 Receptor (PTH1R) agonist in development for the treatment of hypoparathyroidism. In preclinical studies, SEP-786 has been observed to be generally well-tolerated and has demonstrated potent and selective activation of PTH1R in cell-based models, and in a preclinical animal model of hypoparathyroidism, SEP-786 controlled serum calcium levels within the normal range over a 28-day dosing period.
- In September 2024, [Septerna initiated a Phase 1](#) randomized, placebo-controlled, single-ascending dose (SAD) and multiple-ascending dose (MAD) trial to assess preliminary safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of SEP-786 in up to 180 healthy adult participants. Data from both the SAD and MAD portions of the trial are expected in mid-2025.

SEP-631 MRGPRX2 Negative Allosteric Modulator (NAM) in IND-Enabling Studies:

- SEP-631 is a selective oral small molecule Mas-related G protein-coupled receptor X2 (MRGPRX2) NAM in development for the treatment of chronic spontaneous urticaria (CSU), an inflammatory skin disease. In preclinical studies, SEP-631 demonstrated potent and long-lasting inhibition of MRGPRX2, which is a highly and uniquely expressed receptor on mast cells and, when activated, is believed to be a key driver of CSU.
- SEP-631 is currently being evaluated in Investigational New Drug (IND)-enabling studies in anticipation of submitting for regulatory clearance to initiate a Phase 1 clinical trial. Due to MRGPRX2’s expression on mast cells, SEP-631 has the potential to treat other mast cell-driven diseases beyond CSU, including allergic asthma, atopic dermatitis, and prurigo nodularis.

TSHR NAM Program for Endocrine Disorders:

- Septerna is advancing an oral small molecule thyroid stimulating hormone receptor (TSHR) NAM program designed to be a disease-modifying treatment for Graves’ disease and thyroid eye disease (TED). In a novel mouse model of Graves’ disease, the TSHR NAMs have demonstrated the ability to reverse hyperthyroidism and proptosis (eye bulging effect from TED), and in cell-based assays using primary human cells, these TSHR NAMs inhibited several Graves’ disease patient TSHR autoantibodies.
- Septerna is progressing several TSHR NAM lead compounds towards selection of a development candidate for future

IND-enabling studies.

Incretin Receptor (GLP-1R, GIPR, GCGR) Program for Metabolic Diseases:

- Septerna is advancing a next-generation incretin receptor program aimed at discovering and developing oral small molecules as selective single- or multi-acting GLP-1, GIP, or glucagon receptor agonists for the treatment of metabolic diseases, including obesity and type 2 diabetes. Preclinical data from incretin agonist compounds with distinct single- or multi-acting profiles have demonstrated differential potency and selectivity in activating GIPR, GLP-1R, and GCGR-induced intracellular signaling. In addition, the company's mono-GIPR agonists have shown favorable PK properties and the ability to control glucose and induce weight loss in various mouse models.
- Septerna is progressing several incretin receptor agonist lead compounds towards selection of one or more development candidates for future IND-enabling studies.

Business Highlights

- In October 2024, Septerna [completed its upsized initial public offering \(IPO\)](#), in which it raised net proceeds of approximately \$302.6 million, after deducting underwriting discounts and commissions and other offering expenses.
- In September 2024, Jae Kim, M.D., was appointed as chief medical officer [to lead an expanded team](#) with the company's transition to a clinical-stage organization.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled \$137.5 million as of September 30, 2024. Together with net proceeds from the company's IPO, Septerna expects its current cash position to support its planned operations into the second half of 2027.
- **R&D Expenses:** Research and development (R&D) expenses were \$17.8 million for the third quarter of 2024.
- **G&A Expenses:** General and administrative (G&A) expenses were \$4.9 million for the third quarter of 2024.
- **Net Loss:** Net loss totaled \$20.5 million for the third quarter of 2024.

About Septerna

Septerna, Inc. is a clinical-stage biotechnology company pioneering a new era of GPCR oral small molecule drug discovery powered by its proprietary Native Complex Platform™. Its industrial-scale platform aims to unlock the full potential of GPCR therapies and has led to the discovery and development of its deep pipeline of product candidates focused initially on treating patients in three therapeutic areas: endocrinology, immunology and inflammation, and metabolic diseases. Septerna was launched by preeminent drug discovery company builders and scientific leaders in the biochemistry, structural biology, and pharmacology of GPCRs. For more information, please visit www.septerna.com.

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 continued development and advancement of Septerna's oral small molecule GPCR-targeted programs, including the ongoing clinical trial of SEP-786 and the timing of clinical updates for SEP-786 in mid-2025; the initiation, timing, progress, and results of conducting its research and development programs and its current and future preclinical studies and anticipated clinical trials, and the release of data related thereto; its ability to demonstrate, and the timing of, preclinical proof-of-concept *in vivo* and *ex vivo* for multiple programs; its ability to advance any product candidates that it may identify and successfully complete any clinical studies; the potential of its proprietary Native Complex Platform™; its expectations regarding the implementation of its business model, and strategic plans for its business, product candidates, and technology; and the accuracy of its estimates regarding expenses and capital requirements, including its expected cash runway through the second half of 2027. 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: uncertainties related to Septerna's product candidates entering clinical trials; the authorization, initiation, and conduct of preclinical and IND-enabling studies and other development requirements for potential product candidates, including uncertainties related to opening INDs and obtaining regulatory approvals; risks related to the development and optimization of new technologies, the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the scope of protection Septerna is able to establish and maintain for intellectual property rights covering its Native Complex Platform™; Septerna's ability to identify and enter into future license agreements and collaborations; and general economic, industry and market conditions. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Septerna's most recent Quarterly Report on Form 10-Q, 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,	
	2024	2023	2024	2023
Revenue	\$ 176	\$ 33	\$ 863	\$ 33
Operating expenses:				
Research and development	17,832	9,281	46,020	25,653
General and administrative	4,894	2,792	10,948	6,622
Total operating expenses	<u>22,726</u>	<u>12,073</u>	<u>56,968</u>	<u>32,275</u>
Loss from operations	<u>(22,550)</u>	<u>(12,040)</u>	<u>(56,105)</u>	<u>(32,242)</u>
Interest and other income, net	1,891	1,095	4,637	1,528
Benefit for income taxes	136	—	338	—
Net loss attributable to common stockholders	<u>\$ (20,523)</u>	<u>\$ (10,945)</u>	<u>\$ (51,130)</u>	<u>\$ (30,714)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (8.40)</u>	<u>\$ (5.45)</u>	<u>\$ (21.87)</u>	<u>\$ (16.49)</u>
Weighted-average shares outstanding, basic and diluted	<u>2,443,678</u>	<u>2,007,620</u>	<u>2,337,891</u>	<u>1,862,036</u>

SEPTERNA, INC.
Condensed Balance Sheets
(In thousands, except for share and per share data)
(Unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 137,512	\$ 88,483
Working capital ⁽¹⁾	120,180	105,764
Total assets	174,281	130,867
Total liabilities	37,532	20,026
Convertible preferred stock	224,157	149,215
Accumulated deficit	(97,706)	(46,576)
Total stockholders' deficit	(87,408)	(38,374)

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, 2024 for further details regarding our current assets and current liabilities.