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

APNIMED, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-43422**	**82-1910611**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Apnimed, Inc.
39 John F. Kennedy Street, 4th Floor
Cambridge, MA 02138
(Address of principal executive offices, including zip code)

(617) 500-8880
(Registrant's telephone number, including area code)

Not Applicable
(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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	**APMD**	**Nasdaq Global Select 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 2.02 Results of Operations and Financial Condition

On November 16, 2026, Apnimed, Inc. issued a press release announcing its financial results for the quarterly period ended September 30, 2026. The full text of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of the Company, dated November 16, 2026
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Apnimed, Inc.

Date: November 16, 2026

By: /s/ Kevin R. Lind

Kevin R. Lind
Chief Executive Officer

Apnimed Reports Third Quarter 2026 Financial Results and Provides Corporate Update

- *New Drug Application ("NDA") for AD109, with a proposed proprietary name Oxnimbi™ (aroxybutynin and atomoxetine) tablets, for oral use, remains under U.S. Food and Drug Administration ("FDA") review with a February 28, 2027, Prescription Drug User Fee Act ("PDUFA") goal date*
- *Commercial readiness activities advance in preparation for a potential U.S. launch*
- *Presented five abstracts at CHEST 2026, including two late-breakers, highlighting AD109 Phase 3 clinical data and the burden of OSA*
- *$351.8 million in cash and cash equivalents as of September 30, 2026, expected to fund the potential U.S. launch of Oxnimbi and operations into the second quarter of 2028*

CAMBRIDGE, Mass., November 16, 2026– Apnimed, Inc. (Nasdaq: APMD) ("Apnimed"), a late-stage clinical pharmaceutical company dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases, today announced its financial results for the third quarter ended September 30, 2026, and provided a corporate update.

"We are in a transformational period at Apnimed," said Kevin Lind, Chief Executive Officer of Apnimed. "With our NDA for AD109 (proposed proprietary name Oxnimbi) under FDA review and a PDUFA goal date of February 28, 2027, we are advancing our launch readiness while continuing to strengthen the clinical story. At CHEST, we presented new analyses in postmenopausal women, on baseline hypoxic burden as a potential marker of blood pressure response, and on patient-reported outcomes. We believe this growing body of evidence is important to establishing the potential role of Oxnimbi for the millions of adults with OSA who remain untreated."

Recent Highlights and Upcoming Milestones

- The NDA for AD109 (proposed proprietary name Oxnimbi) for the treatment of adults with obstructive sleep apnea ("OSA") remains under review by the FDA. The FDA has assigned a PDUFA goal date of February 28, 2027.
- Continued to advance commercial readiness activities, including market access and payer engagement, commercial team and go-to-market build-out, and manufacturing and distribution preparation, to support a potential U.S. launch of Oxnimbi, subject to FDA approval.
- Presented five abstracts at the American College of Chest Physicians' CHEST 2026 Annual Meeting: three featuring Phase 3 AD109 data, including two late-breakers and one on patient-reported outcomes, and two real-world studies on the burden of OSA. The meeting also featured a CHEST-led panel discussion on the results of the Phase 3 SynAIRgy and LunAIRo trials and their potential application to OSA management.
- Completed its upsized initial public offering in August 2026, raising approximately $198.9 million in net proceeds. With $351.8 million in cash and cash equivalents as of September 30, 2026, the Company is well positioned to support commercial readiness and the potential U.S. launch of Oxnimbi, if approved by the FDA.

Third Quarter Financial Results

Cash Position

Apnimed reported cash and cash equivalents of approximately $351.8 million at September 30, 2026.

Research and Development Expenses

Research and development expenses were $11.8 million for the three months ended September 30, 2026, an increase of $2.0 million, or 20%, compared to $9.8 million for the three months ended September 30, 2025. The net increase was primarily due to:

- An increase of $2.1 million in medical affairs expense, driven by increased Key Opinion Leader (“KOL”) engagement in 2026;
- Higher employee-related expenses of $1.3 million; and
- Higher stock-based compensation of $0.6 million.

These increases were partially offset by $2.0 million of lower clinical trial expense related to AD109 (proposed proprietary name Oxnimbi), as we focus on commercial launch.

General and Administrative Expenses

General and administrative expenses were $22.6 million for the three months ended September 30, 2026, an increase of $16.6 million, or greater than 100%, compared to $6.0 million for the three months ended September 30, 2025. The net increase was primarily related to:

- $8.1 million in professional services incurred related to business consulting and contract negotiations, IT infrastructure, and increased salary and related employee expenses due to increased headcount;
- $4.0 million in infrastructure to prepare the Company, the market, and the Company’s brand for the potential launch of AD109 (proposed proprietary name Oxnimbi), if approved, including key areas such as education on the unmet needs in OSA, pricing strategy, forecast estimates, market access planning, product positioning and stakeholder messaging; and
- $4.4 million in stock-based compensation related to increased headcount and modifications of certain equity awards.

Other Income

Other income was $2.7 million for the three months ended September 30, 2026, an increase of $2.4 million, or greater than 100%, compared to $0.3 million for the three months ended September 30, 2025. The net increase was primarily related to:

- A $1.6 million increase in interest income; and
- A $1.2 million increase in fair value of long-term debt.

These increases were partially offset by a $0.3 million change in fair value of revenue interest liability.

Net Loss

Net loss was $29.5 million for the quarter ended September 30, 2026, compared to a net loss of $10.9 million for the quarter ended September 30, 2025. The increase was primarily attributable to the factors impacting the Company’s expenses and other income described above.

About AD109 / Oxnimbi

AD109 is Apnimed’s investigational drug candidate, with a proposed proprietary name Oxnimbi. The proposed name remains subject to final FDA review and acceptance and may change. AD109 is designed to be the first potential pharmacological treatment to improve oxygenation during sleep and target the neuromuscular root cause of upper airway collapse in adults with OSA. It is a potentially first-in-class combination of aroxybutynin, a novel antimuscarinic, and atomoxetine, a selective norepinephrine reuptake inhibitor. AD109 is intended to be a once-daily oral pill taken at bedtime that is designed to lower the complexity of treating OSA. AD109 may offer an oral solution to help improve oxygenation and health for adults living with OSA. AD109 has completed two Phase 3 clinical trials for the treatment of mild, moderate and severe OSA. Apnimed’s NDA for AD109 is under review by the FDA and was assigned a PDUFA goal

date of February 28, 2027. There can be no assurances that AD109 will be approved by the FDA by the PDUFA goal date, or at all.

About Apnimed

Apnimed is a late-stage clinical pharmaceutical company dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases. Apnimed believes the introduction of once-nightly oral drugs has the potential to expand diagnosis and the reach of treatment for adults with OSA. Apnimed believes that adults with OSA would benefit from having multiple treatment options with differing mechanisms to more fully address the heterogeneity of OSA's disease pathophysiology. Apnimed envisions a new era where novel oral therapies simplify intervention and expand the reach of diagnosis and treatment.

Apnimed is advancing its product candidate, AD109 (proposed proprietary name Oxnimbi), which is designed to improve oxygenation in adults living with OSA. Apnimed believes that Oxnimbi could become the catalyst for a new oral treatment paradigm for OSA, which has historically been limited to devices or invasive surgeries.

Learn more at apnimed.com or follow us on X and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "envisions," "will," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, without limitation, statements regarding our expectations as to commercial readiness activities and launch, the potential approval and commercialization of Oxnimbi, the potential acceptance of Oxnimbi as the proprietary name for AD109, the clinical and therapeutic potential of Oxnimbi (including to address or catalyze a new treatment paradigm for OSA), the size of the commercial opportunity for Oxnimbi, the occurrence and timing of the PDUFA goal date for Oxnimbi, and other statements that are not historical facts. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions.

Forward-looking statements are based on our current expectations, estimates and projections only as of the date of this release and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, the risks inherent in biopharmaceutical product development; our ability to execute on our strategy, including obtaining the requisite regulatory approvals on the expected timeline, if at all; risks related to our financial condition and the need for substantial additional funding in order to complete development activities and commercialize Oxnimbi; risks related to the competitive landscape for OSA products; our ability to attract, integrate and retain key personnel; risks related to regulatory developments and approval processes of the FDA and comparable foreign regulatory authorities; and risks related to establishing and maintaining our intellectual property protections. These and other risks and uncertainties concerning our business and operations are described more fully in the section titled "Risk Factors" of our most recent periodic report filed with the U.S. Securities and Exchange Commission ("SEC"). Forward-looking statements contained in this announcement are made as of this date, and Apnimed undertakes no duty to update such information except as required under applicable law.

Media Contact:
media@apnimed.com

Investor Contact:
ir@apnimed.com

APNIMED, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 351,826	$ 41,890
Prepaid research and development costs	1,881	1,541
Accounts receivable	588	959
Prepaid expenses and other current assets	6,661	665
Total current assets	360,956	45,055
PROPERTY AND EQUIPMENT, NET	46	66
ASSETS HELD FOR SALE	—	26,893
CONTINGENT ASSET	9,812	—
OPERATING LEASE RIGHT-OF-USE ASSET	652	835
OTHER ASSETS	24	24
TOTAL ASSETS	$ 371,490	$ 72,873
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 4,326	$ 1,788
Accrued expenses and other current liabilities	15,068	11,026
Operating lease liability	273	250
Short-term deferred revenue	17,296	97,812
Total current liabilities	36,963	110,876
LONG TERM LIABILITIES:		
Operating lease liability, net of current	414	623
Convertible notes	—	40,646
Debt	39,059	—
Revenue interest liability	10,297	—
Deposit liability	—	57,120
Deferred revenue	—	15,244
TOTAL LIABILITIES	86,733	224,509
COMMITMENTS AND CONTINGENCIES (NOTE 7)		
Convertible Preferred Stock, $0.00001 par value, no shares and 25,934,116 shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares and 25,934,116 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively. Liquidation preference of $0 and $224,518 as of September 30, 2026 and December 31, 2025, respectively.	—	221,147
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $0.00001 par value, 10,000,000 and no shares authorized as of September 30, 2026 and December 31, 2025, respectively; no shares issued or outstanding as of either date.	—	—
Common stock, $0.00001 par value, 500,000,000 shares authorized as of September 30, 2026 and 45,627,228 (42,481,983 Class A, 2,948,668 Class B, and 196,577 Class C) shares authorized as of December 31, 2025; 41,630,779 shares issued and outstanding as of September 30, 2026 and 4,781,256 (1,832,588 Class A, 2,752,091 Class B, and 196,577 Class C) shares issued and outstanding as of December 31, 2025.	1	1
Additional paid-in capital	517,970	24,560
Accumulated deficit	(233,214)	(397,344)
Total stockholders' equity (deficit)	284,757	(372,783)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 371,490	$ 72,873

APNIMED, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED 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
REVENUE - RELATED PARTY	$ 2,480	$ 8,802	$ 99,374	$ 29,043
OPERATING EXPENSES:				
Research and development	11,812	9,754	29,816	49,179
General and administrative	22,628	6,045	41,808	16,868
Cost of services - related party	245	1,987	3,615	5,028
Total operating expenses	34,685	17,786	75,239	71,075
INCOME (LOSS) FROM OPERATIONS	(32,205)	(8,984)	24,135	(42,032)
OTHER INCOME (EXPENSES):				
Interest income	1,814	263	3,002	1,003
Gain on reversal of deposit liability	—	—	57,120	—
Change in fair value of long-term debt	1,208	—	(451)	—
Change in fair value of revenue interest liability	(260)	—	(720)	—
Change in fair value of convertible notes	—	—	1,315	—
Other expense	(81)	—	(2,819)	—
Total other income	2,681	263	57,447	1,003
NET INCOME (LOSS) FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(29,524)	(8,721)	81,582	(41,029)
Income tax expense	—	—	—	—
NET INCOME (LOSS) FROM CONTINUING OPERATIONS	(29,524)	(8,721)	81,582	(41,029)
Gain on sale of equity method investment	—	—	85,380	—
Loss from discontinued operations	—	(2,189)	(2,832)	(68,001)
NET INCOME (LOSS) FROM DISCONTINUED OPERATIONS	—	(2,189)	82,548	(68,001)
NET INCOME (LOSS)	$ (29,524)	$ (10,910)	$ 164,130	$ (109,030)
Net income (loss) per share - Basic:				
Continuing operations	$ (1.05)	$ (1.83)	$ 6.46	$ (8.62)
Discontinued operations	$ —	$ (0.46)	$ 6.54	$ (14.29)
Basic net income (loss) per share	$ (1.05)	$ (2.29)	$ 13.00	$ (22.91)
Net income (loss) per share - Diluted:				
Continuing operations	$ (1.05)	$ (1.83)	$ 4.75	$ (8.62)
Discontinued operations	$ —	$ (0.46)	$ 4.88	$ (14.29)
Diluted net income (loss) per share	$ (1.05)	$ (2.29)	$ 9.63	$ (22.91)
Weighted average common shares outstanding, basic	28,019,494	4,768,110	12,621,882	4,756,996
Weighted average common shares outstanding, diluted	28,019,494	4,768,110	16,903,129	4,756,996