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 12, 2026

Avalyn Pharma Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-43251**	**45-2463191**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
105 W First Street Boston, Massachusetts		**02127**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (206) 707-0340

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	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, par value $0.001 per share	AVLN	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 12, 2026, Avalyn Pharma Inc. (the "Company") announced its financial results for the quarter ended September 30, 2026. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included under Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto), is intended to be furnished and 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, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Avalyn Pharma Inc. dated November 12, 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.

Avalyn Pharma Inc.

Date: November 12, 2026

By: /s/ Lyn Baranowski

Lyn Baranowski
Chief Executive Officer
(Principal Executive Officer)

Avalyn Reports Third Quarter 2026 Financial Results and Recent Business Highlights

Initiated Phase 1 study of AP03, a fixed dose combination of nebulized pirfenidone and nintedanib, in healthy volunteers

Presented new AP01 data at ERS Congress and published detailed results from AP02 Phase 1 trials in *Respiratory Research;* data support Avalyn's approach of delivering antifibrotic medicines directly to the lungs

Ended the third quarter of 2026 with $386.6 million in cash, cash equivalents and marketable securities; cash runway projected into 2029

BOSTON, MA, November 12, 2026 -- Avalyn Pharma Inc. (Avalyn or the Company, Nasdaq: AVLN), a clinical-stage biopharmaceutical company pioneering inhaled therapies to transform the treatment paradigm of serious, rare respiratory diseases today announced financial results for the third quarter ended September 30, 2026 and recent business highlights.

"As we approach year end, I'm proud of the progress we've made across our portfolio and the strong foundation we've built for what we expect to be a transformational 2027, with data anticipated across all three of our programs," said Lyn Baranowski, Chief Executive Officer of Avalyn. "We remain confident in the potential of inhaled therapies to transform the standard of care for pulmonary fibrosis by delivering effective, well-tolerated treatments both as monotherapies and in combination. With our monotherapy programs advancing through later stages of development, the initiation of our first-in-human study of our combination program, AP03, marks the next step in our portfolio expansion. Backed by a strong balance sheet and dedicated team, we are well-positioned to deliver on our key milestones and continue advancing our mission to address the significant unmet needs of people living with rare respiratory diseases."

Recent Pipeline Progress

AP01 (inhaled pirfenidone)

- *European Respiratory Society (ERS) International Congress 2026*. In September, the Company presented two posters at the ERS Congress in Barcelona, Spain. The first poster highlighted data modeling AP01 distribution throughout the target regions in both healthy and idiopathic pulmonary fibrosis (IPF) lungs, demonstrating robust delivery to sites of fibrotic remodeling and active disease, even in the case of advanced fibrosis. The second poster described patient perspectives on IPF-focused clinical trial design and demonstrated a strong willingness of to participate in clinical trials among survey respondents. The presentations and related distribution modeling videos are accessible on the Company's publications section of the website.

- Results from the MIST study of AP01, a global Phase 2b clinical trial in patients with progressive pulmonary fibrosis (PPF) are anticipated in the second half of 2027.

AP02 (inhaled nintedanib)

- *Phase 1 Data Published in Respiratory Research.* In September, Phase 1 data were published in *Respiratory Research* highlighting AP02's lung-targeted delivery and encouraging tolerability profile. The findings demonstrated AP02's potential to achieve substantially higher lung exposure and markedly lower systemic exposure as compared to oral nintedanib. AP02 was generally well-tolerated across both Phase 1 studies, with no serious adverse events reported. The paper, titled, "Nebulized nintedanib (AP02) for idiopathic pulmonary fibrosis demonstrates favorable safety and lung lining fluid exposures: Results from two Phase 1 safety, tolerability, and pharmacokinetic studies," was published on September 21, 2026, and can be found on the Company's publications section of the website.
- Results from the AURA study of AP02, a global Phase 2 clinical trial in patients with IPF, are anticipated in late 2027.

AP03 (inhaled combination of pirfenidone and nintedanib)

- *Initiated Phase 1 Trial of AP03 in Healthy Volunteers.* The Phase 1 trial is a randomized, double-blinded, placebo controlled, single-center study designed to assess the safety, tolerability, and pharmacokinetics of AP03 in healthy volunteers. It is expected to enroll at least 32 participants and will evaluate single ascending doses (SAD) and multiple ascending doses (MAD). The SAD cohort will begin with a combination dose of 50 mg pirfenidone plus 2 mg nintedanib, with additional doses to follow. Primary endpoints include safety and tolerability. Secondary endpoints will evaluate the pharmacokinetic profile of inhaled pirfenidone and nintedanib following single and multiple-dose administration.
- The study is cleared to proceed in Australia following Human Research Ethics Committee (HREC) and institutional approval, and notification to the Therapeutic Goods Administration under the Clinical Trial Notification (CTN) pathway. More information about the Phase 1 clinical trial ACTRN12626001341314 can be found here.
- Results from the Phase 1 healthy volunteer study of AP03 are anticipated in the second half of 2027.

Recent Corporate Highlights

- *Robert J. Meyer, MD, Appointed to Avalyn's Board of Directors.* In September, we appointed Robert (Bob) J. Meyer, MD, a distinguished pulmonary physician and former senior U.S. Food and Drug Administration leader, to the Company's Board of Directors.

Financial Results for Third Quarter 2026

Cash Position: Cash, cash equivalents, and marketable securities were $386.6 million as of September 30, 2026. The Company's current cash, cash equivalents, and marketable securities are projected to be sufficient to fund operations into 2029.

Research & Development (R&D) Expenses: R&D expenses were $25.5 million for the third quarter of 2026, as compared to $22.1 million for the third quarter of 2025. The increase in R&D expenses was primarily driven by the ongoing AP01 and AP02 clinical trials and the AP01 open-label extension study, SAIL.

General & Administrative (G&A) Expenses: G&A expenses were $7.6 million for the third quarter of 2026, as compared to $3.2 million for the third quarter of 2025. The increase in G&A expenses was primarily driven by the increase of G&A headcount and personnel-related expenses, including stock-based compensation.

Net loss: Net loss was $29.7 million for the third quarter of 2026, as compared to $23.6 million for the third quarter of 2025.

About Avalyn Pharma

Avalyn aims to transform the treatment paradigm for pulmonary fibrosis and other serious, rare respiratory diseases. The Company is advancing optimized inhaled formulations of established antifibrotic medicines designed to deliver drug directly to the lungs, enhance local efficacy, and reduce systemic side effects. Avalyn's AP01 program is an optimized inhaled formulation of pirfenidone currently being evaluated in MIST, a global Phase 2b clinical trial in patients with progressive pulmonary fibrosis (PPF). AP01 has indicated encouraging safety and clinical activity across Phase 1b and multi-year open-label extension trials, with long-term data supporting the potential to preserve lung function while improving tolerability relative to historical oral pirfenidone. Avalyn's AP02 program is an optimized inhaled formulation of nintedanib currently being evaluated in AURA, a global Phase 2 clinical trial in patients with idiopathic pulmonary fibrosis (IPF). Avalyn is also advancing AP03, an inhaled fixed-dose combination of pirfenidone and nintedanib, designed to deliver multiple antifibrotic mechanisms through a single lung-targeted platform. By leveraging its proprietary drug-device approach and deep expertise in rare respiratory disease development, Avalyn aims to establish a new standard of care in pulmonary fibrosis through inhaled, lung-targeted therapies. For more information, please visit avalynpharma.com and follow the Company on LinkedIn.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," "will" and "aim" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, implied and express statements about Avalyn's beliefs and expectations regarding: topline data from the MIST Phase 2b trial of AP01 in patients with PPF expected in the second half of 2027; the ongoing enrollment in the AURA Phase 2 trial of AP02 in patients with IPF, including the planned enrollment of 160 patients, and the expected timing of topline data in late 2027; and the anticipation of data in the second half of 2027; the interpretation and potential implications of clinical data; the potential of its product

candidates to address significant unmet needs in the treatment of pulmonary fibrosis and related diseases; the possibility that improved tolerability may translate into clinically meaningful benefit; the potential of AP02 to achieve higher lung exposure and lower systemic exposure than oral nintedanib and to deliver improved efficacy and reduced side effects; the advancement of its pulmonary fibrosis programs; the potential for the treatment paradigm for pulmonary fibrosis to move toward combination therapy; the potential for any of the Company's product candidates to establish or contribute to a new standard of care; Avalyn's expectations regarding having the resources and expertise needed to achieve its anticipated clinical and corporate milestones; and Avalyn's expectations regarding the anticipated timeline of its cash runway and future financial performance.

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: the risk that earlier results may not be indicative of future results; risks related to clinical trial site activation; delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions; risks related to our ability to protect and maintain our intellectual property position or relationships with third-parties; the initiation, timing, progress and results of our current and future research and development programs; nonclinical studies and clinical trials; our ability to successfully complete our clinical trials; our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates; the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates; and risks related to needs for additional financing. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Avalyn's current and future filings with the Securities and Exchange Commission, including those described from time to time under the caption "Risk Factors." In addition, any forward-looking statements represent Avalyn's views only as of today and should not be relied upon as representing its views as of any subsequent date. Avalyn 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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AVALYN PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
OPERATING EXPENSES:				
Research and development	$ 25,491	$ 22,089	$ 73,109	$ 55,290
General and administrative	7,603	3,234	19,184	10,526
Total operating expenses	33,094	25,323	92,293	65,816
LOSS FROM OPERATIONS	(33,094)	(25,323)	(92,293)	(65,816)
OTHER INCOME (EXPENSE):				
Interest income	3,756	1,793	7,577	4,668
Interest expense	(277)	(1)	(647)	(1)
Other expense	(40)	(53)	(96)	(129)
Total other income	3,439	1,739	6,834	4,538
NET LOSS	$ (29,655)	$ (23,584)	$ (85,459)	$ (61,278)

AVALYN PHARMA INC.
CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	September 30, 2026	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 386,598	$ 138,359
Total assets	399,296	148,881
Total liabilities	29,046	15,316
Total stockholders' equity (deficit) and redeemable convertible preferred stock	$ 370,250	$ 133,565