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): June 03, 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 June 3, 2026, Avalyn Pharma Inc. (the "Company") announced its financial results for the quarter ended March 31, 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 June 3, 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: June 3, 2026

By: /s/ Lyn Baranowski

Lyn Baranowski
Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Avalyn Reports First Quarter 2026 Financial Results and Recent Business Highlights

On track to complete enrollment of MIST Phase 2b trial of AP01 in progressive pulmonary fibrosis (PPF) in mid-2026, with newly presented long term open-label extension clinical data that support favorable tolerability profile

Enrollment underway in AURA Phase 2 trial of AP02 in patients with idiopathic pulmonary fibrosis (IPF) with topline data anticipated by the end of 2027

Upsized initial public offering (IPO) gross proceeds of $345.0 million, together with approximately $123.1 million in cash, cash equivalents, and marketable securities as of March 31, 2026, projected to be sufficient to fund operations into 2029

BOSTON, June 3, 2026 -- Avalyn Pharma Inc. (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 first quarter ended March 31, 2026 and recent business highlights.

“Our recent IPO marks a transformative moment for Avalyn, providing the capital to advance three potentially paradigm-shifting programs in pulmonary fibrosis, a disease where current oral antifibrotics are limited by tolerability challenges that prevent many patients from receiving the full benefit of treatment," said Lyn Baranowski, CEO of Avalyn Pharma. "By delivering inhaled therapies directly to the lungs through nebulization, our programs are designed to address the urgent gap in treatments for these deadly diseases. The combination of anti-fibrotic activity seen in our clinical trials to date, together with the open-label extension data to be presented at EULAR in patients with PPF, reinforce our conviction that improved tolerability can unlock the potential for extended duration of treatment and clinical benefit. With clinical readouts across each of our three programs expected in 2027, we are executing with focus and discipline as we work to redefine the standard of care for patients living with this devastating disease."

Recent Pipeline Progress

AP01 (inhaled pirfenidone)

- *MIST Phase 2b Trial On-Track to Complete Enrollment Mid-2026, with Multiple Recent Presentations Supporting its Clinical Profile.*
    - MIST is an ongoing Phase 2b randomized, double blind, placebo-controlled trial evaluating two doses of AP01 in patients with PPF. This 375-patient, 52-week trial is designed to assess safety and efficacy of AP01 with a primary endpoint of change in lung function measured by FVC. Enrollment is on-track to be completed mid-2026 with topline data anticipated in the second half of 2027.
    - On June 6, 2026, the Company will present data from the PPF compassionate use cohort of its ATLAS open-label extension study at the European Alliance for Associations for Rheumatology (EULAR) Conference. Patients in this compassionate use cohort had late stage disease with no other treatment options. Study results indicate that after four years, AP01 remains generally well

tolerated in these patients with PPF, with an adverse event profile consistent with that observed in the ATLAS Phase 1b trial. Though this study was not designed for efficacy, a favorable trend in lung function trajectory as measured by FVC was seen out to 48 months compared with published data. These AP01 data, combined with previously reported long-term extension data in patients with IPF, suggest the potential for AP01 to impact disease progression and survival in patients with pulmonary fibrosis.

- In May 2026, Avalyn presented two posters at the American Thoracic Society (ATS) Annual Meeting in Orlando, FL, demonstrating its commitment to patients, and both hearing and addressing their concerns. Posters summarized how patient, care partner, and physician input informed improvements in instruction materials for the eFlow® Nebulizer System for AP01, and described the importance of healthcare communication from the patient perspective.

AP02 (inhaled nintedanib)

- *Enrollment Underway in AURA Phase 2 Trial.* In March 2026, Avalyn announced first patient dosing in its AURA trial of AP02**.** AURA is a Phase 2 randomized, double-blind trial evaluating two doses of AP02 administered twice daily in patients with IPF. The 12-week study is designed to enroll 160 patients to assess safety and efficacy, as measured by FVC, with topline data anticipated in late 2027.

AP03 (inhaled combination of nintedanib and pirfenidone)

- *Development Underway as Next-Generation Fixed-Dose Combination Therapy:* A Phase 1 trial of AP03, a therapeutic approach combining nebulized pirfenidone and nintedanib, is on track to initiate by the end of 2026.

Recent Corporate Highlights

- In May 2026, the Company completed an upsized IPO, with the sale of 19,166,667 shares of its common stock, which included the full exercise by the underwriters of their option to purchase an additional 2,500,000 shares of common stock, at $18.00 per share. The Company raised gross proceeds of approximately $345.0 million, before deducting underwriting discounts and commissions and other offering expenses.
- Avalyn further strengthened its team to support the next phase of growth with the appointments of Adam Golden as General Counsel and Head of Business Development, and Frank Salisbury as Senior Vice President, Commercial.

Upcoming Conference

- **Jefferies Global Healthcare Conference, New York City.** Management will present a company overview on Thursday, June 4, 2026, at 9:55-10:25 a.m. ET. Access to the webcast can be found here.

Financial Results for First Quarter 2026

- **Cash Position:** Cash, cash equivalents, and marketable securities were $123.1 million as of March 31, 2026. This amount excludes the net proceeds of approximately $316.1 million raised with the company's IPO in May 2026. The company's current cash, cash equivalents, and marketable securities, including the net proceeds from its IPO, are projected to be sufficient to fund its current operating plans into 2029.

- **Research & Development (R&D) Expenses:** R&D expenses were $22.9 million for the first quarter of 2026, as compared to $15.3 million for the first quarter of 2025. The increase in R&D expenses was primarily driven by the progression of the AP01 Phase 2b trial and on-going open label extension study, as well the AP02 Phase 2 trial.

- **General & Administrative (G&A) Expenses:** G&A expenses were $5.0 million for the first quarter of 2026, as compared to $3.4 million for the first quarter of 2025. The increase in G&A expenses was primarily driven by personnel-related expenses, including stock-based compensation.

- **Net loss:** Net loss was $26.9 million for the first quarter of 2026, as compared to $17.5 million for the first 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" 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: the anticipated enrollment of the MIST Phase 2b trial of AP01 in PPF in mid-2026 and the interpretation and potential implications of clinical data; the ongoing enrollment in the AURA Phase 2 trial of AP02 in patients with IPF and the expected timing of results by the end of 2027; 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 advancement of its pulmonary fibrosis programs; the planned initiation of a Phase 1 trial of AP03 by the end of 2026; and the potential for any of the Company's product candidates to establish or contribute to a new standard of care; 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, preclinical 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 March 31,	
	2026	2025
OPERATING EXPENSES:		
Research and development	$ 22,889	$ 15,319
General and administrative	5,020	3,397
Total operating expenses	27,909	18,716
LOSS FROM OPERATIONS	(27,909)	(18,716)
OTHER INCOME (EXPENSE):		
Interest income	1,125	1,248
Interest expense	(98)	—
Other expense	13	(35)
Total other income	1,040	1,213
NET LOSS	$ (26,869)	$ (17,503)

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

	March 31, 2026	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 123,127	$ 138,359
Total assets	135,663	148,881
Total liabilities	27,687	15,316
Total stockholders' deficit and redeemable convertible preferred stock	$ 107,976	$ 133,565