Avalyn Reports Second Quarter 2026 Financial Results and Recent Business Highlights

Aug 12, 2026

Completed enrollment of MIST global Phase 2b trial of AP01 with 398 patients; topline data expected in the second half of 2027

Two abstracts accepted for presentation at the European Respiratory Society (ERS) Congress, including data modeling AP01 lung tissue distribution

Ended the second quarter of 2026 with $413.5 million in cash, cash equivalents and marketable securities; cash runway projected into 2029

BOSTON, Aug. 12, 2026 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2026, and recent business highlights.

“Completing global enrollment in MIST marks a significant milestone for Avalyn, and the degree of over-enrollment in this study is a testament to the high level of interest from investigators and patients,” said Lyn Baranowski, Chief Executive Officer of Avalyn Pharma. “This achievement also reflects the dedication and strong execution demonstrated by our teams, who have worked tirelessly to advance the program. Pulmonary fibrosis is a devastating disease with few effective medications, and too many patients remain untreated due to the tolerability challenges associated with currently available options. With AP01, AP02, and our emerging combination therapy product candidate AP03, we are building a differentiated platform designed to unlock the full value of established antifibrotic medications, support longer-term treatment, and improve patient outcomes. We are proud of the progress we have made and believe our approach has the potential to drive sustained pipeline expansion and position Avalyn as a leader in transforming the treatment of rare respiratory diseases.”

Recent Pipeline Progress

AP01 (inhaled pirfenidone)

- *MIST Phase 2b Trial Enrollment Complete.* MIST is a randomized, double-blind, placebo-controlled global trial evaluating two doses of AP01 dosed twice daily in patients with progressive pulmonary fibrosis (PPF). This 52-week trial is designed to assess safety and efficacy of AP01, with a primary endpoint of change in lung function measured by forced vital capacity (FVC). The study overenrolled beyond its target enrollment of 375, with a total of 398 patients randomized into three treatment cohorts. Topline data are anticipated in the second half of 2027.
- In September 2026, the Company plans to present two abstracts at the ERS Congress in Barcelona, Spain. The first poster will highlight data modeling effective AP01 distribution throughout the target tissue in both healthy and idiopathic pulmonary fibrosis (IPF) lungs. The second poster will describe the integration of patient perspectives into clinical trial design. Detailed poster session information will be provided in advance of the congress.

AP02 (inhaled nintedanib)

- *Enrollment On Track in AURA Phase 2 Trial.* AURA is a randomized, double-blind global trial evaluating two doses of AP02 dosed twice daily in patients with IPF. Enrollment was initiated in the first quarter of 2026. The 12-week study is designed to enroll 160 patients and will assess safety and efficacy as measured by FVC. Topline data are anticipated in late 2027.

AP03 (inhaled combination of nintedanib and pirfenidone)

- *Advancing Next-Generation Therapy.* A Phase 1 study of AP03, a fixed dose combination of inhaled pirfenidone and nintedanib, remains on track to initiate by the end of 2026.

Financial Results for Second Quarter 2026

Cash Position: Cash, cash equivalents, and marketable securities were $413.5 million as of June 30, 2026. The Company’s current cash, cash equivalents, and marketable securities, which includes net proceeds of approximately $316.6 million from its

initial public offering in May 2026, are projected to be sufficient to fund operations into 2029.

Research & Development (R&D) Expenses: R&D expenses were $24.7 million for the second quarter of 2026, as compared to $17.9 million for the second 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 $6.6 million for the second quarter of 2026, as compared to $3.9 million for the second 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 $28.9 million for the second quarter of 2026, as compared to $20.2 million for the second 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: topline data readout for MIST expected in the second half of 2027; the ongoing enrollment in the AURA Phase 2 trial of AP02 in patients with IPF and the expected timing of results in late 2027; the expected initiation of a Phase 1 trial of AP03 by the end of 2026, 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 advancement of its pulmonary fibrosis programs; 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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
OPERATING EXPENSES:				
Research and development	$ 24,729	$ 17,882	$ 47,618	$ 33,201
General and administrative	6,561	3,895	11,581	7,292
Total operating expenses	31,290	21,777	59,199	40,493
LOSS FROM OPERATIONS	(31,290)	(21,777)	(59,199)	(40,493)
OTHER INCOME (EXPENSE):				
Interest income	2,696	1,627	3,821	2,875
Interest expense	(272)	—	(370)	—
Other expense	(69)	(41)	(56)	(76)
Total other income	2,355	1,586	3,395	2,799
NET LOSS	$ (28,935)	$ (20,191)	$ (55,804)	$ (37,694)

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

	June 30, 2026	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 413,528	$ 138,359
Total assets	425,448	148,881
Total liabilities	27,102	15,316
Total stockholders' equity (deficit) and redeemable convertible preferred stock	$ 398,346	$ 133,565