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

May 14, 2025
Date of Report (Date of earliest event reported)

ARS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39756	81-1489190
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11682 El Camino Real, Suite 120 San Diego, California	92130
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 771-9307

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 obligations 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
Common Stock, $0.0001 par value per share	**SPRY**	**The Nasdaq Stock Market LLC**

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 May 14, 2025, ARS Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2025 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 of this Current Report on 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated May 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: May 14, 2025

By: /s/ Richard Lowenthal, M.S., MSEL
Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer
(Principal Executive Officer)

ARS Pharmaceuticals Reports First Quarter 2025 Financial Results and Highlights Progress in U.S. Commercial Launch of *neffy*® (epinephrine nasal spray)

*$7.8 million in total **neffy** U.S. net product revenue in first quarter of 2025*

***neffy** 1 mg available nationwide for children aged four and older and co-promotion agreement with ALK-Abelló Inc. increases **neffy** promotional reach to nearly 20,000 healthcare providers, including key pediatricians*

*More than 5,000 physicians have prescribed **neffy** to date, reinforcing the demand for a safe, effective, needle-free treatment for severe allergic reactions including anaphylaxis*

Conference call to be held today, May 14, 2025, at 5:30 a.m. PT / 8:30 a.m. ET

SAN DIEGO, May 14, 2025 – ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, today announced financial results for the first quarter of 2025 and provided an update on the continued U.S. commercial launch of ***neffy***® (epinephrine nasal spray), the first and only FDA approved and European Commission approved needle-free epinephrine treatment for Type I allergic reactions, including anaphylaxis.

First Quarter 2025 Financial Results

- **Revenue**: Total revenue for the first quarter of 2025 was $8.0 million, which was comprised of $7.8 million in net product revenue from ***neffy*** sales in the U.S. and $0.2 million in collaboration revenue from ALK-Abelló A/S (ALK).
- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter of 2025 were $3.0 million, which was primarily associated with continued clinical and development expenses for ***neffy***.
- **Selling, General and Administrative (SG&A) Expenses**: SG&A expenses for the first quarter of 2025 were $41.1 million, of which the significant majority were personnel-related and sales and marketing expenses associated with the commercialization of ***neffy***. The company is committed to make a substantial investment in the launch of ***neffy*** to ensure short and long-term patient and physician awareness and market share.
- **Net Loss:** Net loss for the first quarter of 2025 was $33.9 million, or $0.35 per share.
- **Cash Runway**: As of March 31, 2025, ARS Pharma had cash, cash equivalents, and short-term investments of $275.7 million, with 98,129,804 shares of common stock outstanding. The company reiterates its guidance that its financial position is expected to support its operating plans for at least the next three years.

***neffy* Commercial Launch Progress in the United States**

- **Availability of *neffy* 1 mg and 2 mg doses in U.S. pharmacies**: In early May, ***neffy*** 1mg dose became available nationwide for children aged four and older weighing 15 to 30 kilograms (33 to <66 lb.) alongside the 2 mg dose for adults and children who weigh 30 kg or more (≥ 66 lbs.). Food allergies remain a leading cause of anaphylaxis in children[1], affecting approximately six million pediatric patients, more than 40% of whom have experienced a severe allergic reaction[2].
- **U.S. co-promotion with ALK**: ARS Pharma recently expanded its collaboration with global allergy leader ALK through a co-promotion agreement to reach up to 9,000 pediatricians, bringing total direct promotional reach for ***neffy*** to nearly 20,000 healthcare providers in the U.S.
- **National direct-to-consumer (DTC) campaign launch**: Also on May 15th, ARS Pharma expects to launch a comprehensive DTC marketing campaign across connected, linear, and broadcast television, social media, influencer platforms, print, and digital advertising, to increase brand awareness and reach the mass audience of patients and caregivers. The DTC commercial is available for viewing at this link.

"We've built strong momentum for ***neffy's*** U.S. launch and are well positioned heading into the peak epinephrine prescribing season this summer," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "Children represent almost half of the prescriptions for epinephrine, underscoring the critical need for a needle-free, easy-to-use, easy-to-carry epinephrine option. We've had solid wins in market access, and the accelerated sales force expansion with our ALK partnership expands our reach to key pediatricians ahead of summer travel and the back-to-school season. Coupled with compelling clinical data and enhanced real-world adoption, we believe ***neffy*** is positioned to become the standard of care for those at risk of severe allergic reactions and a leading treatment option in the category."

Additional highlights from the ***neffy*** U.S. commercial launch include:

- **Healthcare provider (HCP) engagement**: The ARS Pharma sales force has engaged over 10,000 priority HCPs, with more than 50% having prescribed ***neffy***.
    - Nearly 90% of prescribers are concentrated among the highest decile HCPs.
- **Allergist program adoption**: Approximately 2,500 allergists have enrolled in the ***neffy*Experience** Program, with approximately 13,000 doses placed for in-office use during an anaphylaxis event occurring during oral food challenges or allergen immunotherapy.
- **Payer access progress**: 57% commercial coverage has been secured thus far, with the addition of United Healthcare as of April 1, reducing barriers to prescribing and filling epinephrine as patients schedule appointments and visit physicians in the coming months. Discussions and contract negotiations are ongoing with other payers, keeping the company on track for more than 80% access to commercial lives by early third quarter of 2025.

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[1] https://www.mayoclinic.org/diseases-conditions/anaphylaxis/symptoms-causes/syc-20351468

[2] https://www.cdc.gov/school-health-conditions/food-allergies/?CDC_AAref_Val=https://www.cdc.gov/healthyschools/foodallergies/index.htm (1 in 13 children in the U.S. translates to ~ 6m children)

- **School access expansion**: More than 1,000 schools have opted into the ***neffy*inSchools** program, receiving two cartons (four single-use doses) of ***neffy*** 2 mg at no cost for emergency use through the School Health Corp. SHConnect platform. Starting in early May, ***neffy*** 1 mg dose also became available to eligible schools.

"Our efforts to scale the commercial footprint of ***neffy*** has been very encouraging," added Eric Karas, Chief Commercial Officer, ARS Pharma. "Demand for ***neffy*** continues to grow among both patients and physicians, with thousands of healthcare professionals prescribing ***neffy*** already, and thousands more participating in our ***neffy*Experience** program. Our national DTC campaign is set to launch on May 15th, and we expect to generate strong brand awareness driving patients and caregivers to request neffy from their healthcare provider over the coming months. In parallel, coverage wins with major pharmacy benefit managers ensures more patients and prescribers will be able to seamlessly access ***neffy*** this summer. These milestones, coupled with the positive feedback we continue to hear from those who have used ***neffy***, underscore its value and support our goal of establishing ***neffy*** as a category-defining brand in emergency allergy care."

Global Activities for *neffy* and EUR*neffy*

- **U.S. registry study**: ARS Pharma has initiated a post-marketing registry-based study of ***neffy*** for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics in the U.S.
- **Canada, United Kingdom and Germany:** Regulatory reviews are ongoing in the U.K. and Canada, with decisions anticipated for ***neffy*** 2 mg by mid-2025 in the U.K. (where it will be marketed as **EUR*neffy*®**, if approved), and year-end 2025 in Canada. In mid-2025, commercial launches are expected in Germany, as well as in the U.K., pending approval.
- **Japan, China, and Australia:** Regulatory decisions for ***neffy*** are expected in the second half of 2025 in Japan, year-end 2025 in Australia and in the first half of 2026 in China.

Clinical Expansion of Intranasal Epinephrine Program

- ARS Pharma is on-track to initiate a Phase 2b clinical trial in the second quarter of 2025 to evaluate its intranasal epinephrine technology as a treatment for acute flares in patients with chronic spontaneous urticaria, with topline data anticipated in early 2026.

Conference Call and Webcast Information

ARS Pharma management will host a conference call and webcast at 5:30 a.m. PT / 8:30 a.m. ET today, May 14, 2025. To access the webcast and slides, please visit the Events & Presentations page in the Investors & Media section of the Company's website. A replay of the webcast will be available for 30 days following the event. Dial-in information for conference participants may be obtained by registering for the event.

About *neffy*®

neffy is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children aged 4 years and older who weigh 33 lbs. or greater.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR ***neffy*** (epinephrine nasal spray)

INDICATION
neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients aged 4 years and older who weigh 33 lbs. or greater.

IMPORTANT SAFETY INFORMATION
neffy contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Always carry two ***neffy*** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of ***neffy*** if symptoms continue or come back. Each ***neffy*** contains a single dose of epinephrine. ***neffy*** is for use in the nose only.

Use ***neffy*** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of ***neffy***, a second dose is needed. If needed, administer a second dose using a new ***neffy*** in the same nostril starting 5 minutes after the first dose. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using ***neffy***.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. ***neffy*** and other medications may affect each other, causing side effects. ***neffy*** may affect the way other medicines work, and other medicines may affect how ***neffy*** works.

neffy **may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use** ***neffy*****.**

Common side effects of ***neffy*** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

Tell your healthcare provider if you have any side effects that bother you or that do not go away after using ***neffy***.

These are not all of the possible side effects of ***neffy***. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at **1-800-FDA-1088** or ww.fda.gov/medwatch.

Please see the full Prescribing Information and Patient Information for *neffy*.

About Type I Allergic Reactions Including Anaphylaxis
Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine auto-injectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for severe Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their active epinephrine auto-injector prescription, and of those, only half consistently carry their prescribed auto-injector. Even if patients or caregivers carry an auto-injector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.
ARS Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® (trade name **EUR*neffy***® in the EU), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult patients and pediatric patients 4 years of age and older who weigh 15 kg or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. For more information, visit www.ars-pharma.com.

Forward Looking Statements
Statements in this press release that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: the belief that ARS Pharma is well positioned for sustained growth and meaningful value creation; ARS Pharma's projected cash runway and belief that it is well capitalized and prepared to support the ongoing launch of ***neffy***; expected benefits from the co-promotion agreement with ALK; the extent to which ARS Pharma's efforts to reach key prescribing pediatricians will be accelerated through the co-promotion agreement prior to the back-to-school season or thereafter; the ability of our national DTC campaign to drive patients and caregivers to request ***neffy*** from their healthcare provider; the planned studies of ***neffy***, including for the treatment of urticaria, and the timing thereof; the anticipated timing of regulatory decisions for ***neffy*** in the U.K., Canada, China, Germany, Japan and Australia; ARS Pharma's belief that it remains on track to achieve its coverage goal of 80% by the end of the third quarter of 2025; the expected timing of commercial launches in Germany and the U.K.; the needle-free profile of ***neffy*** increasing the likelihood that patients will both carry and administer epinephrine; the potential market and demand for ***neffy***; the potential benefits to urticaria patients if our intranasal epinephrine technology is approved for this indication; financial projections; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipate," "believe," "can," "could," "expect," "if," "may," "on track to/for," "potential," "plan," "will," "would," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharmaceuticals' current expectations and involve assumptions that may never materialize or may prove to be incorrect.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: potential safety and other complications from ***neffy***; the ability to maintain regulatory approval for ***neffy*** in its currently approved indications; the scope, progress and expansion of developing and commercializing ***neffy***; the scope, progress and expansion of developing our intranasal epinephrine technology; clinical trial results; the potential for governments and payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market for ***neffy*** and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharma's' ability to protect its intellectual property position; and the impact of government laws, regulations and policies. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in ARS Pharma's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission ("SEC") on March 20, 2025, and in ARS Pharma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, to be filed with the SEC today. These documents can also be accessed on ARS Pharma's website at www.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

The forward-looking statements included in this press release are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on LinkedIn and X.

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ARS Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and par value data)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 39,864	$ 50,817
Short-term investments	235,863	263,205
Accounts receivable, net	9,303	8,175
Inventories	7,270	5,212
Prepaid expenses and other current assets	11,560	6,886
Total current assets	303,860	334,295
Long-term inventories	11,939	5,307
Right-of-use asset	72	37
Fixed assets, net	1,075	1,029
Intangible assets, net	7,241	7,371
Other assets	3,131	3,114
Total assets	$ 327,318	$ 351,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $710 and $656, respectively)	$ 27,009	$ 22,841
Contract liability, current	540	557
Lease liability	73	42
Total current liabilities	27,622	23,440
Financing liability	69,383	69,383
Contract liability, net of current portion	1,339	1,532
Total liabilities	98,344	94,355
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at March 31, 2025 and December 31, 2024; 98,129,804 and 97,954,172 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	10	10
Additional paid-in capital	386,137	379,873
Accumulated other comprehensive gain, net	72	220
Accumulated deficit	(157,245)	(123,305)
Total stockholders' equity	228,974	256,798
Total liabilities and stockholders' equity	$ 327,318	$ 351,153

ARS Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenue:		
Product revenue, net	$ 7,763	$ —
Revenue under collaboration agreements	210	—
Total revenue	7,973	—
Operating expenses:		
Cost of goods sold (including related party amounts of $488 and $0, respectively)	1,094	—
Research and development (including related party amounts of $666 and $726, respectively)	2,952	5,234
Selling, general and administrative (including related party amounts of $124 and $93, respectively)	41,104	7,958
Total operating expenses	45,150	13,192
Loss from operations	(37,177)	(13,192)
Other income, net	3,237	2,900
Net loss	$ (33,940)	$ (10,292)
Change in unrealized gains and losses on available-for-sale securities	(148)	(173)
Comprehensive loss	$ (34,088)	$ (10,465)
Net loss per share, basic and diluted	$ (0.35)	$ (0.11)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	98,060,636	96,486,480