ARS Pharmaceuticals Reports Third Quarter 2025 Financial Results and Highlights for neffy® (epinephrine nasal spray)

November 10, 2025

*$32.5 million in revenue, including $31.3 million in **neffy** U.S. net product revenue in third quarter of 2025*

Continued U.S. product growth driven by direct-to-consumer (DTC) investments and real-world evidence, expected to accelerate with seamless prescribing experience

Strong balance sheet of $288.2 million cash, cash equivalents and short-term investments anticipated to fund operations through cash-flow break-even

Conference call to be held today, November 10, 2025, at 5:30 a.m. PT / 8:30 a.m. ET

SAN DIEGO, Nov. 10, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, today announced financial results for the third quarter of 2025, and provided an update on the commercial launch of ***neffy***® (epinephrine nasal spray), the first and only FDA- and European Commission-approved needle-free epinephrine treatment for Type I allergic reactions, including anaphylaxis.

"We are executing our commercial strategy across multiple fronts, with each element reinforcing the others to drive momentum," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "Our direct-to-consumer campaigns are generating measurable increases in patient awareness; real-world evidence data are further strengthening prescriber confidence in ***neffy***'s effectiveness; and we are implementing advertising programs such as a free virtual prescriber option and zero dollar co-pay to further reduce barriers for patients, so that when healthcare providers want their patients to have ***neffy***, we are able to assist and address potential obstacles."

Third Quarter 2025 Financial Results

- **Revenue**: Total revenue for the third quarter of 2025 was $32.5 million, comprised of $31.3 million in net product revenue from ***neffy*** sales in the U.S., and $1.1 million in supply revenue from partners. The cash value of royalties received from ALK-Abelló A/S (ALK) related to the launch of **EUR*neffy***® in Germany at the end of June 2025 was $0.1 million, which was recorded to the financing liability on the company's balance sheet.
- **Research and Development (R&D) Expenses**: R&D expenses for the third quarter of 2025 were $2.8 million, which was primarily associated with the ongoing Phase 2b clinical trial in urticaria and the ongoing post-marketing registry study for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics and other development expenses for ***neffy***.
- **Selling, General and Administrative (SG&A) Expenses**: SG&A expenses for the third quarter of 2025 were $74.8 million, reflecting the company's substantial investment in the national DTC marketing campaign and continued sales and marketing expenses associated with the U.S. commercialization of ***neffy***. The company remains committed to continued investment in ***neffy*** promotion to further expand patient and physician awareness and to accelerate market share growth.
- **Net Loss**: Net loss for the third quarter of 2025 was $51.2 million, or $0.52 per share.
- **Cash Runway**: As of September 30, 2025, ARS Pharma had cash, cash equivalents, and short-term investments of $288.2 million, with 98,844,178 shares of common stock outstanding. This includes the $100 million draw down from the company's new $250 million senior security term loan facility with an affiliate of RA Capital Management, the company's largest shareholder, and an affiliate of OMERS Life Sciences as lenders. The $100 million draw is intended to fund investment in the commercial growth of ***neffy*** and support our marketing and medical affairs initiatives to generate and disseminate real-world evidence about ***neffy***'s effectiveness. The company believes that its quarter-end cash position will fund operations through expected cash-flow break-even.

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

- **DTC campaign growing awareness**: The DTC campaign has significantly increased consumer awareness of ***neffy*** since its launch late in the second quarter of 2025, growing from a baseline consumer awareness of approximately 20% pre-campaign to 56% as of September 2025.
- **Gross-to-net retention of at least 50%**: Unrestricted payor access is expected to be achieved while maintaining steady-state gross-to-net retention guidance of at least 50%, including co-pay support programs, where it is anticipated to remain long-term.

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

- **Increasing breadth and depth of healthcare provider (HCP) adoption**: Over 18,000 HCPs have prescribed ***neffy*** to date, representing an 86% increase from August 2025.

- **"Get *neffy* on Us" campaign launched**: The company initiated a new integrated commercial program to eliminate the time burden of an office visit and reduce cost barriers by giving patients with a current epinephrine auto-injector prescription or diagnosis the opportunity to switch to ***neffy*** via a free virtual provider at a $0 co-pay. Consumer surveys indicate that more than 70% of Type I allergy patients are open to using a virtual prescribing option.
- **Allergist real-world experience supports similar treatment outcomes as injection**: An updated analysis of real-world treatment outcomes with 680 patients was presented as an oral late-breaker at the American College of Asthma, Allergy and Immunology (ACAAI) in early November 2025. The data showed about 90% of patients experiencing anaphylaxis were effectively treated with a single dose of ***neffy***, and that this real-world effectiveness of ***neffy*** is indistinguishable from historically reported epinephrine injection. The ***neffy*** Experience Program provides 2 mg and 1 mg ***neffy*** to allergists for in-office use during an anaphylaxis event occurring during oral food challenges or allergen immunotherapy.
- **School access expansion**: More than 6,500 schools have opted into the ***neffy*****inSchools** program, each receiving two cartons (four single-use doses) of ***neffy*** 2 mg or 1 mg at no cost for emergency use through the School Health Corp. SHConnect platform.
- **U.S. registry study ongoing**: The ARS Pharma post-marketing, registry-based randomized, controlled study of ***neffy*** for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics in the U.S. is ongoing.

Global Expansion for *neffy* and EUR*neffy*

- ***neffy*** **approval in Japan**: In September 2025, the Pharmaceutical and Medical Devices Agency (PMDA) granted approval for ***neffy*** 2 mg and 1 mg in Japan for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh greater than 15 kg. Alfresa owns the rights to market ***neffy*** in Japan and expects ***neffy*** to be available in the fourth quarter of 2025. Under the terms of the agreement, following listing of ***neffy*** on the Japanese National Health Institute (NHI) Drug Price List, ARS Pharma is eligible to receive a final regulatory milestone payment of $2 million, and to sell ***neffy*** to Alfresa at a transfer price.
- **EUR*neffy*® launch in United Kingdom (U.K.)**: ALK successfully launched **EUR*neffy*®** 2 mg in the U.K. in October 2025. The United Kingdom is the largest market outside of the United States for adrenaline (epinephrine) auto-injector sales.
- **EUR*neffy*® 1 mg under review by EMA**: **EUR*neffy*®** 1 mg for children weighing 15 to < 30 kg is currently undergoing regulatory review by the European Medicines Agency (EMA), with approval anticipated in the first half of 2026.
- **Additional regulatory approvals anticipated**: Regulatory approvals for ***neffy*** in Canada (with ALK-Abelló) is expected in the first quarter of 2026, with launch expected to start in the first half 2026. Regulatory approval for ***neffy*** in China (in partnership with Pediatrix) is expected in the first half of 2026.

Clinical Expansion of Intranasal Epinephrine Program

- **Phase 2b trial in urticaria ongoing**: A Phase 2b trial (NCT06927999) to evaluate intranasal epinephrine technology as a treatment for acute flares is enrolling patients with chronic spontaneous urticaria in the U.S. and Europe, with topline data anticipated in mid-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, November 10, 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.

EUR*neffy*® is the trade name for ***neffy***® (epinephrine nasal spray) in Europe.

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 www.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 33 lbs. 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: evaluations, judgments, and expectations regarding ARS Pharma's marketing and commercialization strategies; the anticipated use of proceeds from the loan facility; ARS Pharma's guidance that its financial position is expected to support its operating plans through expected cash-flow break-even; expectations regarding the HCP prescribing experience; the projection that ARS Pharma will achieve unrestricted payor access while maintaining a steady-state gross-to-net retention of at least 50% for the long-term; the anticipated timing of regulatory decisions for neffy in Canada and China and the expected timing of commercial launches in Canada, China, and Japan; the anticipated timing of the EMA's regulatory decisions for **EUR*neffy*** 1 mg; the potential to achieve regulatory milestone payments and the timing of payment thereof; the anticipated timing for topline data from the urticaria trial and the potential for ARS Pharma's intranasal epinephrine technology to expand into the urticaria indication; 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," "potential," "plan," "will," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharma's 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 risk that ARS Pharma may not realize its expected return on investment from its DTC campaign; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed with the Securities and Exchange Commission ("SEC") on August 13, 2025 and in ARS Pharma's Quarterly Report on Form 10-Q for the quarter ended September 30, 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)

	September 30, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 59,557	$ 50,817
Short-term investments	228,652	263,205
Accounts receivable, net	36,451	8,175
Inventories	7,782	5,212
Prepaid expenses and other current assets	6,421	6,886
Total current assets	338,863	334,295
Long-term inventories	13,645	5,307
Right-of-use asset	1,439	37
Fixed assets, net	1,209	1,029
Intangible assets, net	14,729	7,371
Other assets	2,918	3,114
Total assets	$ 372,803	$ 351,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $4,269 and $656, respectively)	$ 49,768	$ 22,841
Contract liability, current	526	557
Lease liability, current	583	42
Total current liabilities	50,877	23,440
Term loans, net (including related party amounts of $4,811 and $0, respectively)	96,229	—
Financing liability	72,044	69,383
Contract liability, net of current portion	1,268	1,532
Lease liability, net of current portion	949	—
Other accrued liabilities	3,781	—
Total liabilities	225,148	94,355
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2025 and December 31, 2024; 98,844,178 and 97,954,172 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	10	10
Additional paid-in capital	400,931	379,873
Accumulated other comprehensive (loss) gain, net	(7)	220
Accumulated deficit	(253,279)	(123,305)
Total stockholders' equity	147,655	256,798
Total liabilities and stockholders' equity	$ 372,803	$ 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	$ 31,300	$ 568	$ 51,863	$ 568
Revenue under collaboration agreements	55	1,500	2,859	2,000
Revenue under supply agreements	1,146	—	1,469	—
Total revenue	32,501	2,068	56,191	2,568
Operating expenses:				
Cost of goods sold (including related party amounts of $2,046, $0, $3,400, and $0, respectively)	8,191	112	14,269	112
Research and development (including related party amounts of $559, $406, $1,804, and $1,651, respectively)	2,751	4,423	9,738	16,553
Selling, general and administrative (including related party amounts of $123, $129, $354, and $337, respectively)	74,751	19,281	170,167	36,183
Total operating expenses	85,693	23,816	194,174	52,848
Loss from operations	(53,192)	(21,748)	(137,983)	(50,280)
Other income (expense), net (including related party amounts of $(3), $0, $(3), and $0, respectively)	2,041	2,620	8,009	8,344
Net loss	$ (51,151)	$ (19,128)	$ (129,974)	$ (41,936)
Change in unrealized gains and losses on available-for-sale securities	39	484	(227)	290
Comprehensive loss	$ (51,112)	$ (18,644)	$ (130,201)	$ (41,646)
Net loss per share, basic and diluted	$ (0.52)	$ (0.20)	$ (1.32)	$ (0.43)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	98,807,600	97,032,331	98,412,739	96,782,818