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

August 13, 2025

*$15.7 million in revenue, including $12.8 million in **neffy** U.S. net product revenue in second quarter of 2025*

*Growth for **neffy** in the U.S. driven by increased payor access with additional near-term growth anticipated from national direct-to-consumer (DTC) campaign and pediatric co-promote partnership*

93% commercial coverage achieved with streamlined prior authorization process with approval rates at the pharmacy benefit manager (PBM) comparable to overall epinephrine market

***EURneffy®** approved in the United Kingdom and launched in Germany, now representing a global footprint with this first and only needle-free epinephrine treatment*

Conference call to be held today, August 13, 2025, at 5:30 a.m. PT / 8:30 a.m. ET

SAN DIEGO, Aug. 13, 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 second quarter of 2025, and provided an update on the 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.

"The second quarter marks a pivotal inflection point for ***neffy***, highlighted by robust growth in prescriptions driven by expanding payor access and strong sales execution," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "As we move through the peak back-to-school prescribing season and with our most recent DTC investment and co-promote partnership, ***neffy*** is rapidly establishing itself as a preferred epinephrine option for patients, caregivers and schools. With continued commercial momentum in the U.S. and an expanded global presence marked by **EUR*neffy's*** approval in the U.K. and launch in Germany, we are advancing our vision to redefine the standard of care for allergic emergencies while creating lasting value for patients, providers and shareholders alike."

Second Quarter 2025 Financial Results

- **Revenue**: Total revenue for the second quarter of 2025 was $15.7 million, which was comprised of $12.8 million in net product revenue from ***neffy*** sales in the U.S., $2.6 million in milestone revenue from ALK-Abelló A/S (ALK) related to the launch of **EUR*neffy***® in Germany, and $0.3 million in supply revenue from partners. The cash milestone triggered from ALK to ARS Pharma was $5.0 million, with $2.6 million recognized as revenue and the remaining $2.4 million recorded to the financing liability on the company's balance sheet.
- **Research and Development (R&D) Expenses**: R&D expenses for the second quarter of 2025 were $4.0 million, which was primarily associated with the initiation of the Phase 2b clinical trial in urticaria, 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 second quarter of 2025 were $54.3 million, reflecting the company's substantial investment in the national direct-to-consumer marketing campaign and continued sales and marketing expenses associated with the U.S. commercialization of ***neffy***. The company is committed to investing in the ongoing promotion of ***neffy*** to further enhance patient and physician awareness and to continue accelerating market share.
- **Net Loss**: Net loss for the second quarter of 2025 was $44.9 million, or $0.46 per share.
- **Cash Runway**: As of June 30, 2025, ARS Pharma had cash, cash equivalents, and short-term investments of $240.1 million, with 98,697,658 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**

- **Prescription growth: *neffy* two-pack unit weekly volumes have continued to grow, increasing approximately 180% from the end of first quarter of 2025 to the end of second quarter of 2025. Notably, this volume growth pre-dated the company's rollout of its national DTC campaign.**
    - ARS Pharma's DTC campaign was rolled out in two stages, beginning in mid-May with connected TV (streaming) and followed by broadcast/linear TV in late June. The campaign has significantly increased consumer awareness since its late second quarter launch, driving added awareness of ***neffy*** from a baseline of approximately 20% pre-campaign to 49% in late July. Consistent with the observed time-to-effect during DTC launch campaigns for other pharmaceutical products, further ***neffy*** script momentum is expected in the second half of 2025 and beyond.

- **Commercial coverage goal exceeded**: 93% commercial coverage, including 57% without prior authorization, has been secured thus far with ***neffy's*** access and approval rates across the major PBMs consistent with the overall epinephrine market. Further, prior authorizations that are still required by a portion of payors under Zinc, a Group Purchasing Organization affiliated with CVS Caremark, one of the largest PBMs in the U.S., are being approved at more than an 80% success rate. Notably, the proportion of ***neffy*** dispensed prescriptions that is represented by payors under Zinc is currently in line with the overall epinephrine market despite the requirement for prior authorizations by a portion of payors under Zinc.
- **52% gross-to-net retention for Q2 2025**: Payor access has reached a critical milestone, with gross-to-net retention now at projected steady-state levels, where it should remain moving forward even with future coverage decisions by the remaining PBMs.

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

- **HCP adoption**: Over 9,700 HCPs have prescribed ***neffy*** to date, which represents a 73% increase from April 2025, of which about 70% continue to be among the highest decile prescribing HCPs.
- **Allergist real-world experience**: Approximately 2,800 allergists have enrolled in the ***neffy*** Experience Program, with approximately 20,000 doses across both 2 mg and 1 mg ***neffy*** on hand for in-office use during an anaphylaxis event occurring during oral food challenges or allergen immunotherapy.
- **School access expansion**: More than 3,200 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.

"A key factor driving our growth and momentum has been achieving a critical milestone in payor access, which has significantly reduced administrative barriers for providers," said Eric Karas, Chief Commercial Officer of ARS Pharma. "As the volume of ***neffy*** continues to increase, we anticipate that the economic factors for the remaining PBMs will continue to reduce prior authorization requirements. Additionally, the combination of our sales force execution and DTC advertising further positions us for market share growth. This, along with a more seamless physician prescribing experience and enhanced consumer awareness, creates a strong foundation for continued commercial expansion."

Global Expansion for *neffy* and EUR*neffy*

- **EUR*neffy*® approved in United Kingdom (U.K.)**: In July 2025, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) granted approval for **EUR*neffy*** 2 mg for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh greater than 30 kg – another major milestone as the first needle-free treatment in the largest market outside the U.S. for epinephrine auto-injector sales. Under the companies' license agreement, ALK owns the rights to market **EUR*neffy*** in the U.K. and expects 2 mg product availability beginning late in the second half of 2025.
- **EUR*neffy*® launched in Germany**: ALK successfully launched **EUR*neffy*®** 2 mg in Germany in June 2025, triggering a $5.0 million milestone payment under the two companies' licensing agreement. This represents the first commercial launch outside the U.S., and we believe it is indicative of the global demand for our intranasal epinephrine product.
- **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), Japan (in partnership with Alfresa), and Australia (in partnership with CSL), are expected by the end of 2025, with commercial rollouts planned in the first half of 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 initiated**: In June 2025, ARS Pharma initiated a Phase 2b clinical trial *(NCT06927999)* to evaluate its intranasal epinephrine technology as a treatment for acute flares in patients with chronic spontaneous urticaria. The trial is enrolling patients in the U.S. and Europe, with topline data anticipated in the first half of 2026. This program expansion represents a significant opportunity to extend the utility of the company's intranasal epinephrine technology to a new indication affecting approximately two million people in the U.S. alone.

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, August 13, 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: ARS Pharma's guidance that its financial position is expected to support its operating plans for at least the next three years; the expectation for further ***neffy*** script momentum in the second half of 2025 and beyond; the projection that gross-to-net retention is now at steady-state levels at approximately 50% and that this will provide greater predictability for revenue modeling; the expectation that PBMs will continue to reduce prior authorization requirements; the belief that ARS Pharma is positioned for market share growth and continued commercial expansion; the belief that the commercial launch in Germany is indicative of global demand for ARS Pharma's

intranasal epinephrine product; 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 the estimated patient population for this indication; the anticipated timing of regulatory decisions for ***neffy*** and the expected timing of commercial launches in Canada, China, Japan and Australia; the anticipated timing of the EMA's regulatory decisions for ***neffy***; the expected timing of commercial launch in the U.K.; 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 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 March 31, 2025, filed with the Securities and Exchange Commission ("SEC") on May 14, 2025 and in ARS Pharma's Quarterly Report on Form 10-Q for the quarter ended June 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)

	June 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 51,540	$ 50,817
Short-term investments	188,590	263,205
Accounts receivable, net	25,126	8,175
Inventories	8,738	5,212
Prepaid expenses and other current assets	7,442	6,886
Total current assets	281,436	334,295
Long-term inventories	13,374	5,307
Right-of-use asset	1,564	37
Fixed assets, net	1,075	1,029
Intangible assets, net	12,972	7,371
Other assets	3,051	3,114
Total assets	$ 313,472	$ 351,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $1,091 and $656, respectively)	$ 44,264	$ 22,841
Contract liability, current	746	557
Lease liability, current	589	42
Total current liabilities	45,599	23,440
Financing liability	71,959	69,383
Contract liability, net of current portion	1,103	1,532
Total liabilities	121,151	94,355
Commitments and contingencies		
Stockholders' equity		

Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at June 30, 2025 and December 31, 2024; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at June 30, 2025 and December 31, 2024; 98,697,658 and 97,954,172 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	10	10
Additional paid-in capital	394,485	379,873
Accumulated other comprehensive (loss) gain, net	(46)	220
Accumulated deficit	(202,128)	(123,305)
Total stockholders' equity	192,321	256,798
Total liabilities and stockholders' equity	$ 313,472	$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	$ 12,800	$ —	$ 20,563	$ —
Revenue under collaboration agreements	2,594	500	2,804	500
Revenue under supply agreements	323	—	323	—
Total revenue	15,717	500	23,690	500
Operating expenses:				
Cost of goods sold (including related party amounts of $866, $0, $1,354, and $0, respectively)	4,984	—	6,078	—
Research and development (including related party amounts of $582, $518, $1,245, and $1,245, respectively)	4,035	6,896	6,987	12,130
Selling, general and administrative (including related party amounts of $107, $114, $231, and $208, respectively)	54,312	8,944	95,416	16,902
Total operating expenses	63,331	15,840	108,481	29,032
Loss from operations	(47,614)	(15,340)	(84,791)	(28,532)
Other income, net	2,731	2,824	5,968	5,724
Net loss	$ (44,883)	$ (12,516)	$ (78,823)	$ (22,808)
Change in unrealized gains and losses on available-for-sale securities	(118)	(21)	(266)	(194)
Comprehensive loss	$ (45,001)	$ (12,537)	$ (79,089)	$ (23,002)
Net loss per share, basic and diluted	$ (0.46)	$ (0.13)	$ (0.80)	$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	98,361,771	96,827,687	98,212,035	96,656,690