ARS Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

March 20, 2025

*$7.3 million in total **neffy**® (epinephrine nasal spray) U.S. net product revenue in 2024 since launch in late September 2024*

***neffy 1 mg** approved by U.S. FDA for children aged four and older and weighing 15 kilograms to < 30 kilograms (33 lbs. to < 66 lbs.), expanding the reach of **neffy** to approximately 2 million younger, school-aged children at risk of a severe allergic reaction*

$314.0 million in cash, cash equivalents, and short-term investments at year-end 2024, supporting an increased investment in commercialization in 2025 while maintaining an operating runway of at least three years

Company to host conference call today, March 20, 2025 at 5:30 a.m. PT / 8:30 a.m. ET

SAN DIEGO, March 20, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from allergic reactions that could lead to anaphylaxis, today announced its financial results for the fourth quarter and full year ended December 31, 2024, and provided highlights on the U.S. commercial launch of ***neffy***, the first and only needle-free epinephrine emergency treatment for Type I allergic reactions, including anaphylaxis, as well as recent business updates.

"Our strong execution throughout 2024 and into 2025 has positioned ARS Pharma for sustained growth and meaningful near-term value creation. The successful U.S. commercial launch of ***neffy***, FDA approval of ***neffy* 1 mg** for younger children, and our expansion into new global markets mark key milestones in our effort to build a transformative franchise in severe allergy treatment," said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "Our momentum is highlighted by the steady increase in physician adoption, positive patient feedback, and growing payer coverage, which form a strong foundation for long-term success. With a solid financial position and a disciplined operational strategy, we are well-equipped to further accelerate adoption and drive significant impact for both our stakeholders and the millions of people who depend on life-saving epinephrine treatment."

Fourth Quarter and Full Year 2024 Financial Results

- **ALK-Abelló (ALK) Accounting Treatment**: Under the terms of the companies' licensing agreement signed in November 2024, ARS Pharma received a non-refundable, upfront cash payment of $145 million from ALK. Of the total cash payment, $73.5 million was included in ARS Pharma's fourth quarter 2024 revenue. Of the remaining $71.5 million, $69.4 million was treated as a financing liability and $2.1 million was treated as a contract liability on the company's balance sheet due to Generally Accepted Accounting Principles (GAAP) accounting treatment. Under the terms of the licensing agreement, ARS Pharma holds the option to repurchase rights to certain regions partnered to ALK. Per GAAP, the portion of the $145 million cash payment that is attributable to the regions eligible for repurchase is treated as a financing liability instead of revenue. Notably, this accounting treatment did not impact the amount of non-refundable cash proceeds received and ARS Pharma has sole discretion in their use.
- **Revenue**: Total revenue for the fourth quarter of 2024 was $86.6 million, which included $6.7 million in net product revenue from ***neffy*** sales in the United States, $73.5 million in collaboration revenue from ALK, $6 million in collaboration revenue from the company's licensing partner in Japan (Alfresa Pharma), and $0.4 million in revenue from supply agreements. Full-year 2024 revenue totaled $89.1 million, reflecting $7.3 million in ***neffy*** sales, $81.5 million in collaboration revenue, and $0.4 million from supply agreements.
- **Research and Development (R&D) Expenses**: R&D expenses for the fourth quarter and full-year 2024 were $3.0 million and $19.6 million, respectively. These costs were primarily associated with product manufacturing to support the commercial launch of ***neffy*** in the U.S., along with other product development and personnel-related expenses.
- **Selling, General and Administrative (SG&A) Expenses**: SG&A expenses for the fourth quarter and full-year 2024 were $35.5 million and $71.7 million, respectively, primarily comprised of personnel-related and marketing expenses associated with the commercial launch of ***neffy***, as well as general operating expenses.
- **Net Income**: Net income for the fourth quarter of 2024 was $49.9 million, or $0.51 per share basic and $0.48 diluted. Net income for the full-year 2024 was $8.0 million, or $0.08 per share basic and diluted.

Business Outlook

- **Cash Position & Operating Runway**: As of December 31, 2024, ARS Pharma had cash, cash equivalents, and short-term investments of $314.0 million, with 97,954,172 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.
- **Anticipated 2025 ALK Milestones**: ARS Pharma projects to receive cash proceeds from milestone payments by ALK of approximately $5 million in both the second and fourth quarters of 2025. In accordance with GAAP, for cash payments under the terms of the ALK agreement, approximately half of the projected milestone payments would be recognized as revenue, and the remainder would be added to the financing liability on the company's balance sheet.

neffy U.S. Commercial Launch Highlights

ARS Pharma continues to execute the U.S. commercial launch of ***neffy***. Key achievements to date include:

- Direct sales force engagement with approximately 9,000 priority healthcare providers, with ***neffy*** prescriptions submitted by more than 4,000 healthcare providers via BlinkRx through ***neffyConnect***.
- Approximately 81% of prescribing physicians are among the highest decile allergists.
- Engagement with more than 1,000 physicians at the 2025 American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Scientific Meeting, with a significant company presence, including nine scientific presentations and a non-CME program.
- Enrollment of approximately 2,500 allergists in the ***neffy*** Experience Program, exceeding the company's initial program target enrollment of 1,000 allergists, with approximately 15,000 doses of ***neffy*** available to allergists for their use in treating anaphylaxis.
- Multiple favorable coverage decisions secured, including by Express Scripts, Cigna Healthcare, OptumRx, Navitus Health Systems, and TRICARE, with ongoing discussions and contract negotiations with other key payors, keeping the company on track for more than 60% access to commercial lives under contract by the end of the first quarter of 2025, and more than 80% by early third quarter of 2025.
- Addition of ***neffy*** to Medicaid coverage with no prior authorization in Texas, Alabama and Montana, with additional states expected to follow throughout 2025. Of note, commercial insurance, Medicaid and cash pay accounted for approximately 85-90% of all epinephrine prescriptions dispensed in 2024 in the United States.
- Broad direct to consumer (DTC) marketing campaign to be initiated in May 2025, prior to the peak epinephrine prescribing season over the summer, which will include connected and linear TV, print, social media and influencer campaigns, as well as broad and targeted advertising.
- Successful launch of ARS Pharma's ***neffy*****inSchools** program, offering eligible K-12 schools in the U.S. the opportunity to receive two cartons (four single-use doses) of ***neffy*** **2 mg** at no cost for emergency use through the School Health Corp. SHConnect platform. The program includes provisions for **1 mg** dose upon availability, and replacement doses when used or expired.

Global Regulatory Approvals and Activities for _neffy_ and EUR_neffy_

- **U.S. Pediatric Approval**: On March 5, 2025, the U.S. FDA approved ARS Pharma's sNDA for ***neffy*** **1 mg** as an emergency treatment for Type I allergic reactions, including anaphylaxis, in children aged four and older and weighing 15 kilograms to < 30 kilograms (33 to <66 lb.). ***neffy*** **1 mg** is expected to be available in pharmacies starting in May 2025.
- **U.S. Allergy Challenge Clinic Registry Study**: ARS Pharma plans to initiate a post-marketing registry-based study of ***neffy*** for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics in April 2025.
- **Canada & United Kingdom**: In collaboration with its licensing partner, ALK-Abelló A/S, ARS Pharma submitted applications for ***neffy*** **2 mg** in the U.K. and Canada in December 2024 and January 2025, respectively. Regulatory decisions are anticipated by mid-2025 in the U.K. (where it will be marketed as **EUR*neffy***®, if approved), and year-end 2025 in Canada.
- **China, Japan & Australia**: In December 2024, ARS Pharma's licensing partners for China, Japan and Australia submitted applications for ***neffy*** **2 mg** in their respective countries. A regulatory decision in Japan is expected in the second half of 2025, followed by decisions in China and Australia in the first half of 2026.
- **Global Commercial Launches**: In mid-2025, commercial launch is expected in Germany, as well as in the U.K., if approved.

Expansion of Intranasal Epinephrine into Urticaria

ARS Pharma plans 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, a prevalent skin disease affecting approximately 2 million people in the U.S. The trial is expected to enroll patients in the U.S. and Europe, with topline data anticipated in early 2026.

Conference Call and Webcast Information

ARS Pharma management will host a conference call and webcast at 8:30 a.m. ET today, March 20, 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

It is recommended that patients are prescribed and have immediate access to two ***neffy*** nasal sprays at all times. In the absence of clinical

improvement or if symptoms worsen after initial treatment, administer a second dose of ***neffy*** in the same nostril with a new nasal spray starting 5 minutes after the first dose.

neffy is for use in the nose only.

Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Absorption of ***neffy*** may be affected by underlying structural or anatomical nasal conditions.

Administer with caution to patients who have heart disease; epinephrine may aggravate angina pectoris or produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or taking cardiac glycosides, diuretics, or anti-arrhythmics.

The presence of a sulfite in ***neffy*** should not deter use.

neffy may alter nasal mucosa for up to 2 weeks after administration and increase systemic absorption of nasal products, including ***neffy***.

Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Epinephrine should be administered with caution in patients with these conditions, including elderly patients and pregnant women.

Most common adverse reactions are nasal discomfort, headache, rhinorrhea, dizziness, nausea, vomiting, throat irritation, nasal congestion, paresthesia, sneezing, upper respiratory tract congestion, epistaxis, rhinalgia, nasal dryness, dry throat, fatigue, and feeling jittery.

These are not all the possible side effects of ***neffy***. To report suspected adverse reactions, contact ARS Pharmaceuticals Operations, Inc. at 1-877-MY-NEFFY **(877-696-3339)** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing 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 Pharmaceuticals 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) (previously referred to as ARS-1), 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***; the expectation that ***neffy* 1 mg** will be available in the U.S. by the end of May 2025; 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, Japan and; ARS Pharma's belief that it remains on track to achieve its coverage goals of 60% and 80% by the end of the first quarter and third quarter of 2025, respectively; the expectation and timing for additional states to add ***neffy*** to their formularies; the expected timing of commercial launches in Germany and the U.K.; the expected timing of the milestones under the agreement with ALK; the needle-free profile of ***neffy*** increasing the likelihood that patients will both carry and administer adrenaline; 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," "expect," "if," "may," "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 Pharmaceuticals' ability to protect its intellectual property position; and the impact of government laws and regulations. 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 Pharmaceuticals’ Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission (“SEC”) on November 13, 2024, and in ARS Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2024, being filed with the SEC on March 20, 2025. These documents can also be accessed on ARS Pharmaceuticals’ 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 Pharmaceuticals 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share information)

	Year Ended December 31,	
	2024	2023
Revenue:		
Product revenue, net	$ 7,255	$ —
Revenue under collaboration agreements	81,529	30
Revenue under supply agreements	365	—
Total revenue	89,149	30
Operating expenses:		
Cost of goods sold (including related party amounts of $241 and $0, respectively)	977	—
Research and development (including related party amounts of $2,066 and $1,796, respectively)	19,580	20,266
Selling, general and administrative (including related party amounts of $465 and $940, respectively)	71,675	47,284
Total operating expenses	92,232	67,550
Loss from operations	(3,083)	(67,520)
Other income, net	11,369	13,155
Income (loss) before income taxes	8,286	(54,365)
Income tax provision	288	—
Net income (loss)	$ 7,998	$ (54,365)
Change in unrealized gains and losses on available-for-sale securities	171	(358)
Comprehensive income (loss)	$ 8,169	$ (54,723)
Net income (loss) per share:		
Basic	$ 0.08	$ (0.57)
Diluted	$ 0.08	$ (0.57)
Weighted-average shares outstanding used in computing net income (loss) per share:		
Basic	96,936,661	95,215,322
Diluted	102,390,828	95,215,322

ARS Pharmaceuticals, Inc.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 50,817	$ 70,971
Short-term investments	263,205	157,389
Accounts receivable, net	8,175	—
Inventories	5,212	—
Prepaid expenses and other current assets	6,886	3,366
Total current assets	334,295	231,726
Long-term inventories	5,307	—
Right-of-use asset	37	250
Fixed assets, net	1,029	574

Intangible assets, net	7,371	—
Other assets	3,114	638
Total assets	$ 351,153	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $656 and $178, respectively)	$ 22,841	$ 2,154
Contract liability, current	557	—
Lease liability, current	42	237
Total current liabilities	23,440	2,391
Financing liability	69,383	—
Contract liability	1,532	—
Lease liability, net of current portion	—	37
Total liabilities	94,355	2,428
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2024 and 2023; 97,954,172 and 96,414,963 shares issued and outstanding at December 31, 2024 and 2023, respectively	10	10
Additional paid-in capital	379,873	362,004
Accumulated other comprehensive gain, net	220	49
Accumulated deficit	(123,305)	(131,303)
Total stockholders' equity	256,798	230,760
Total liabilities and stockholders' equity	$ 351,153	$ 233,188