ARS Pharmaceuticals Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 13, 2024

*Commercial launch of **neffy**® (epinephrine nasal spray) underway in the United States*

*Supplemental NDA for **neffy**®1mg dose granted priority review by FDA; PDUFA target date set for March 6, 2025*

*Exclusive license agreement with ALK-Abelló to commercialize **neffy**® in Europe, Canada and certain other geographies; ARS Pharma to receive $145 million in upfront payment with total deal consideration of up to $465 million plus double-digit royalties*

Well-capitalized with $349.6 million in cash, cash equivalents and short-term investments on a pro forma basis, supporting an operating runway of at least three years

Company to host conference call and webcast today at 8:00 a.m. ET

SAN DIEGO, Nov. 13, 2024 (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 reported early progress on the U.S. commercial launch of ***neffy***® (epinephrine nasal spray) 2 mg for the treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh ≥30 kg (66 lbs.), as well as business highlights and financial results for the third quarter of 2024.

"The third quarter marked a transformative period for ARS Pharma, driven by the FDA approval of ***neffy*** in the U.S. and the European Commission approval of ***EURneffy***® in the European Union," stated Richard Lowenthal, President and CEO of ARS Pharmaceuticals. "With strong demand among healthcare providers and patients for ***neffy*** as the first and only needle-free epinephrine treatment, robust patient support systems in place, and favorable early payer discussions ongoing, we feel very good about the early momentum in our U.S. launch. We're also proud to have further expanded the reach of ***neffy*** outside the U.S. by partnering with ALK-Abelló, a global leader in allergy product commercialization. Operationally, we stand very well positioned with a balance sheet that is further strengthened by the $145 million upfront payment from ALK, positioning us to execute our U.S. commercial plans and business goals to enable patients around the world to have access to this vital epinephrine treatment."

U.S. commercial launch ongoing for neffy, the first and only needle-free epinephrine treatment for Type 1 allergic reactions, including anaphylaxis

On August 9, 2024, the FDA approved ***neffy***® **(**epinephrine nasal spray) 2 mg for the treatment of Type 1 allergic reactions, including anaphylaxis, in adults and children who weigh ≥30 kg (66 lbs.). ***neffy*** was first available for shipment on September 23, 2024, and in early October, the U.S. sales force started in the field and ***neffy*** became broadly available in retail pharmacies.

Launch to date:

- More than 5,700 healthcare providers had been reached by the neffy sales force
- More than 1,700 healthcare providers submitted a prescription for ***neffy***, using BlinkRx through ***neffyConnect***, a service that provides patients access and co-pay support, as well as free at-home delivery;
- Of the physicians who prescribed ***neffy***, 80% were in the highest decile category;
- More than 1,000 allergists enrolled in the ***neffy*** Experience Program, which enables physicians to administer ***neffy*** during their in-clinic allergy food challenges; and,
- Product presentations and contract discussions with several of the key payors are underway, with initial coverage decisions expected by yearend.

In September 2024, ARS Pharma submitted a supplemental New Drug Application (sNDA) for ***neffy*** 1 mg for the treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 15 to 30 kg (33-66 lbs.). In November 2024, the FDA granted the sNDA priority review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 6, 2025.

On-track with global strategy to make neffy® available worldwide

On August 22, 2024, the European Commission granted marketing authorization for **EUR*neffy***® (epinephrine nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh ≥30 kg. On November 8, 2024, ARS Pharma announced an exclusive licensing agreement with ALK-Abelló to commercialize ***neffy*** in Europe, Canada and certain other geographies outside the U.S. Under the terms of the agreement, ARS Pharma will receive an upfront payment of $145 million, and is eligible to receive up to an additional $320 million in sales, commercial and other milestones, as well as tiered double-digit royalties in the teens on net sales in the licensed territories.

The regulatory submission for approval in Australia has been filed by CSL Seqirus under its license agreement with ARS Pharma. In addition, regulatory submissions in both China and Japan are expected to be completed in November by the respective partners in those geographies. In December, ARS Pharma plans to file for regulatory submission in the United Kingdom and Canada on behalf of ALK-Abelló, and additional regulatory filings by ARS Pharma and ALK are anticipated in 2025 to further expand global patient reach with ***neffy***.

Clinical expansion of neffy® for urticaria to begin in 2025

ARS Pharma plans to initiate an outpatient Phase 2b study of its intranasal epinephrine technology in patients with chronic spontaneous urticaria, a prevalent skin disease, who have been treated previously with antihistamines and experience frequent acute flares. The Phase 2b trial is expected to begin in early 2025, followed by a potential single pivotal efficacy trial.

Third Quarter 2024 Financial Results

- **Revenue:** Total revenue was $2.1 million for the quarter ended September 30, 2024, comprised of $0.6 million in net product revenue for ***neffy*** sales, which reflects revenues from only one week following product launch in late September, and $1.5 million in collaboration revenue for the same period.
- **Research and Development (R&D) Expenses:** R&D expenses were $4.4 million for the quarter ended September 30, 2024, the majority of which is comprised of product manufacturing costs prior to the commercial launch of ***neffy***, other product development costs, and compensation costs.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $19.3 million for the quarter ended September 30, 2024, which is mainly comprised of personnel expenses and costs associated with starting the commercial launch of ***neffy***.
- **Net Loss:** Net loss was $19.1 million for the quarter ended September 30, 2024.
- **Cash Position:** Cash, cash equivalents and short-term investments were $204.6 million as of September 30, 2024. On a pro-forma basis, the Company's cash, cash equivalents and short-term investments balance was $349.6 million, adjusted for the $145 million upfront payment from ALK-Abelló in conjunction with the November 2024 licensing agreement. ARS Pharmaceuticals expects its capital to be sufficient to fund its current operating plan for at least three years.

Conference Call and Webcast Details

Management will host a conference call and webcast at 8:00 a.m. ET today, November 13, 2024. 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 here.

About *neffy*®

neffy is an intranasal epinephrine product for patients with Type I allergic reactions including food, medications, and insect bites that could lead to life-threatening anaphylaxis.

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

INDICATION

neffy 2 mg is indicated for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

IMPORTANT SAFETY INFORMATION

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.

Adverse reactions to ***neffy*** may include throat irritation, intranasal paresthesia, headache, nasal discomfort, feeling jittery, paresthesia, fatigue, tremor, rhinorrhea, nasal pruritus, sneezing, abdominal pain, gingival pain, hypoesthesia oral, nasal congestion, dizziness, nausea, and vomiting.

These are not all of 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.

For additional information on ***neffy***, please see Full Prescribing Information at www.***neffy***.com.

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 autoinjectors 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 autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency.

About Urticaria

Urticaria is a skin disorder that causes itchy hives and/or angioedema with an annualized incidence of 5 million in the U.S. About 40% of those cases become chronic urticaria, of which 50% are non-responsive to first-line antihistamine therapy. These non-responsive patients on stable therapy regimens can experience exacerbations or flares several times a year among acute cases, and even several times a week, including up to three or four emergency room visits per year. Angioedema is also a co-occurring symptom in about 33 to 67% of these patients. There are currently no approved community use treatments for acute flares experienced by urticaria patients on chronic regimens of antihistamines. ARS Pharmaceuticals is investigating ***neffy*** for episodic symptomatic relief of these acute flares or exacerbations to improve the quality of life of urticaria patients. If ***neffy*** is approved for this indication, patients would have the option to quickly resolve exacerbations or flares at home without escalating to chronic use of systemic biologics that may have more serious side effects and benefit-risk considerations or visiting the emergency room for further treatment.

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***® 2 mg (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 and pediatric patients who weigh 30 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 planned studies of ***neffy*** for urticaria and timing thereof; ARS Pharmaceuticals’ projected cash runway and belief that it is well capitalized and prepared to support the ongoing launch of ***neffy***; the belief that the commercial launch of ***neffy*** will progress through 2024 and into 2025; the expectation that payors will make coverage decisions as early as in [the fourth quarter of 2024]; ARS Pharmaceuticals’ plans regarding regulatory submissions in the United Kingdom, Canada, Japan and China; ARS Pharmaceuticals’ plans to enter into additional licensing and distribution agreements; the expected timing of the regulatory 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 ***neffy*** is approved in this 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,” “expects,” “if,” “may,” “potential,” “on track to,” “plans,” “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 labelling for ***neffy*** in any future indication or patient population, if approved; the scope, progress and expansion of developing and commercializing ***neffy***; the potential for payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharmaceuticals’ ability to protect its intellectual property position; the impact of government laws and regulations; and the PDUFA target action date may be delayed due to various factors outside ARS Pharmaceuticals’ control. 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 June 30, 2024, filed with the Securities and Exchange Commission (“SEC”) on August 6, 2024, and in ARS Pharmaceuticals’ Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, being filed with the SEC today. 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.

Investor Contacts:
Justin Chakma, ARS Pharmaceuticals
justinc@ars-pharma.com

Alex Straus, THRUST
alex@thrustsc.com

Media Contact:
Christy Curran, Sam Brown Inc.

christycurran@sambrown.com

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

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 39,657	$ 70,971
Short-term investments	164,967	157,389
Accounts receivable, net	773	—
Inventories	715	—
Prepaid expenses and other current assets	2,677	3,366
Total current assets	208,789	231,726
Right-of-use asset	92	250
Fixed assets, net	843	574
Intangible assets, net	7,500	—
Other assets	377	638
Total assets	$ 217,601	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $133 and $178, respectively)	$ 16,521	$ 2,154
Lease liability, current	102	237
Total current liabilities	16,623	2,391
Lease liability, net of current portion	—	37
Total liabilities	16,623	2,428
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 97,147,442 and 96,414,963 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	10	10
Additional paid-in capital	373,868	362,004
Accumulated other comprehensive gain, net	339	49
Accumulated deficit	(173,239)	(131,303)
Total stockholders' equity	200,978	230,760
Total liabilities and stockholders' equity	$ 217,601	$ 233,188

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,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	$ 568	$ —	$ 568	$ —
Revenue under collaboration agreements	1,500	—	2,000	30
Total revenue	2,068	—	2,568	30
Operating expenses:				
Cost of goods sold	112	—	112	—
Research and development (including related party amounts of $406, $307, $1,651 and $1,382, respectively)	4,423	3,002	16,553	16,862

Selling, general and administrative (including related party amounts of $129, $322, $337 and $840, respectively)	19,281	14,976	36,183	40,462
Total operating expenses	23,816	17,978	52,848	57,324
Loss from operations	(21,748)	(17,978)	(50,280)	(57,294)
Other income, net	2,620	3,112	8,344	10,097
Net loss	$ (19,128)	$ (14,866)	$ (41,936)	$ (47,197)
Change in unrealized gains and losses on available-for-sale securities	484	19	290	(568)
Comprehensive loss	$ (18,644)	$ (14,847)	$ (41,646)	$ (47,765)
Net loss per share, basic and diluted	$ (0.20)	$ (0.16)	$ (0.43)	$ (0.50)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	97,032,331	95,576,627	96,782,818	94,910,012