ARS Pharmaceuticals Highlights Progress and Reports First Quarter 2023 Financial Results

May 15, 2023

*FDA Advisory Committee Votes in Support of Favorable Benefit-Risk Profile for **neffy**® for the Treatment of Allergic Reactions (Type I), Including Anaphylaxis*

*New Drug and Marketing Authorization Applications for **neffy** Under Review with FDA and EMA, Respectively; FDA PDUFA Target Action Date Anticipated mid-2023*

*$264.5 Million in Cash, Cash Equivalents and Short-term Investments to Support Operating Runway for the Next Three Years, Including the Planned Commercialization of **neffy** in the United States*

SAN DIEGO, May 15, 2023 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis, today highlighted recent progress and reported first quarter 2023 financial results.

"For the millions of people living with Type I allergic reactions including anaphylaxis, we believe that ***neffy*** (nasal epinephrine spray), a small, needle-free and easy-to-use nasal spray, could provide a much-needed alternative to the currently approved epinephrine injection devices. Despite their effectiveness, these devices are limited in usage because many patients and caregivers do not carry, avoid using or hesitate to use them," said Richard Lowenthal, president and chief executive officer of ARS Pharmaceuticals. "Throughout the first quarter, we've made important strides toward bringing ***neffy*** to patients. We are glad to have had the opportunity to discuss ***neffy*** with the FDA's Advisory Committee during our recent meeting and are incredibly pleased with the outcome and the committee's support of ***neffy*** for adults and children."

Eric Karas, chief commercial officer added, "As we look ahead, with both our NDA and MAA for ***neffy*** currently under review by the regulators in the U.S. and EU, we are laser focused on our commercial preparedness activities. Over the last several months, we've made significant progress in our Commercial Launch Readiness. We are preparing to launch a 125-person salesforce focusing on specialists and healthcare providers who prescribe epinephrine and will have an array of patient and provider services established to ensure affordability. Access to ***neffy*** is a key focus and priority for us, and we have started to work with drug benefit plans to educate and raise awareness about new routes of administration that will help ensure the prompt use of epinephrine for severe allergic reactions, including anaphylaxis."

***neffy*® Progress**

- **FDA Advisory Committee Supports *neffy* Potential for the Treatment of Allergic Reactions (Type I), Including Anaphylaxis, Under Review with FDA and EMA:** The U.S. Food and Drug Administration's (FDA) held a Division of Pulmonary-Allergy Drug Advisory Committee (PADAC) meeting on May 11, 2023, to review the New Drug Application (NDA) for ***neffy***. The committee voted 16:6 in favor for adults, and 17:5 in favor for children (<18 years of age and ≥30 kg), that available data support a favorable benefit-risk assessment for ***neffy*** in the treatment of severe allergic reaction (Type I), including anaphylaxis, for adults and children who weigh more than 30kg. The PADAC decision was based on a review of comprehensive data from clinical studies developed in agreement with the FDA, which support a positive risk-benefit profile for intranasal (IN) epinephrine safety and effectiveness, compared to epinephrine injection. We believe the studies demonstrated and the majority of the Committee's discussion supported that ***neffy*** shows:
    - Comparable or greater pharmacodynamic (PD) response (systolic blood pressure and heart rate) vs. intramuscular injection that is observed even at 1 minute after dosing of ***neffy***. Increases in systolic blood pressure and heart rate are the outcomes monitored by physicians to assess clinical response, and therefore ARS considered PD response to be a surrogate for efficacy. The majority conclusion of the Committee also suggests that PD was more important and informative given the high PK variability of injection products.
    - Comparable or greater pharmacokinetic (PK) data (epinephrine levels in the blood) vs. intramuscular injection at all time points based on integrated data across the three primary clinical studies. This includes a "real-world" self-administration study in allergic reaction (Type I) patients, where PK was statistically greater than intramuscular injection during the early timepoints when clinical response is observed. Importantly, exposures with ***neffy*** in all clinical studies were less than the upper limit represented by EpiPen to ensure safety.
    - Effective IN delivery of systemic epinephrine and PD response even with nasal congestion or runny nose (e.g., during allergic rhinitis or upper respiratory tract infection)
    - Comparable safety to injection that is generally mild in nature without any meaningful nasal irritation or pain, without needle-related risks
- **FDA PDUFA Target Action Date Anticipated Mid-2023:** The Company's new drug application (NDA) and marketing authorization application (MAA) for ***neffy*** for the emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children ≥30 kg (66 lbs), are under review by the FDA and the European Medicines Agency (EMA),

respectively. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date anticipated mid-2023. If approved, ***neffy*** would be the first non-injectable treatment available to patients with allergic reactions (Type I) including anaphylaxis.

First Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $264.5 million as of March 31, 2023, which ARS believes are sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development (R&D) expenses were $6.6 million for the quarter ended March 31, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $12.2 million for the quarter ended March 31, 2023.
- **Net Loss:** Net loss was $15.0 million for the quarter ended March 31, 2023.

About Type I Allergic Reactions including Anaphylaxis
Type I severe 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 25 to 40 million people in the United States who experience Type I severe allergic reactions. Of those, only 3.3 million currently have an 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 ARS Pharmaceuticals, Inc.
ARS is a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing ***neffy***® (also referred to as ARS-1), an intranasal epinephrine product in clinical development for patients and their caregivers with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. 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’s projected cash runway; the anticipated timing for regulatory review decisions on ***neffy*** and the potential approval of ***neffy***; the anticipated US launch of ***neffy***, if approved, and the timing thereof; ARS’s strategy of pursuing potential strategic transactions or partnerships for ***neffy*** in Europe, if approved; the estimated addressable patient population for ***neffy***; ARS’s plan to file a supplemental regulatory application for a ***neffy*** 1 mg product for children 15 kg to <30 kg immediately after the approval of ***neffy*** 2 mg in the United States and/or Europe; andother 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,” “plans,” “expects,” “will,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS’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, the ability to obtain and maintain regulatory approval for ***neffy***; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from ***neffy***; the labelling for ***neffy***, if approved; the scope, progress and expansion of developing and commercializing ***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’s 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—Risks Related to ARS Pharma” in the company’s definitive merger proxy statement filed with the Securities and Exchange Commission on October 6, 2022. This document can also be accessed on ARS’s web page at ir.ars-pharma.com by clicking on the link “Financials & Filings.”

The forward-looking statements included in this press release are made only as of the date hereof. ARS assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

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

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 87,862	$ 210,518

Short-term investments	176,687	63,863
Prepaid expenses and other current assets	2,801	3,319
Total current assets	267,350	277,700
Right-of-use asset	398	445
Fixed assets, net	584	329
Other assets	2,860	2,961
Total assets	$ 271,192	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $307 and $16, respectively)	$ 9,596	$ 4,931
Lease liability, current	232	230
Contract liability, current	10	283
Total current liabilities	9,838	5,444
Lease liability, net of current portion	199	251
Contract liability, net of current portion	—	2,854
Total liabilities	10,037	8,549
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 94,448,028 and 93,943,316 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	9	9
Additional paid-in capital	352,977	349,408
Accumulated other comprehensive gain	68	407
Accumulated deficit	(91,899)	(76,938)
Total stockholders' equity	261,155	272,886
Total liabilities, convertible preferred stock and stockholders' equity	$ 271,192	$ 281,435

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,	
	2023	**2022**
Revenue under collaboration agreements	$ 20	$ 663
Operating expenses:		
Research and development (including related party amounts of $591 and $540, respectively)	6,552	5,423
General and administrative (including related party amounts of $337 and $165, respectively)	12,181	2,339
Total operating expenses	18,733	7,762
Loss from operations	(18,713)	(7,099)
Other income (expense), net	3,752	(151)
Net loss	$ (14,961)	$ (7,250)
Change in unrealized gain on available-for-sale securities	(339)	—
Comprehensive loss	$ (15,300)	$ (7,250)
Net loss per share, basic and diluted	$ (0.16)	$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	94,227,313	30,369,413