ARS Pharmaceuticals Highlights Progress and Reports Fourth Quarter and Full Year 2022 Financial Results

March 23, 2023

*New Drug Application and Marketing Authorization Application for **neffy**® Currently Under Review with the FDA and EMA; FDA PDUFA Target Action Date Anticipated in Mid-2023*

Strong Financial Position with $274.4 Million in Cash, Cash Equivalents and Short-term Investments to Support Operating Runway for the Next Three Years

SAN DIEGO, March 23, 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 fourth quarter and full year 2022 financial results.

"This is an incredibly exciting time for ARS, with potential regulatory approvals for ***neffy***® around the corner and a resulting transition to a commercial-stage company. Our goal with ***neffy*** is to provide patients with the ability to deliver epinephrine with comparable pharmacokinetics to an intramuscular injection, but in an easy to use and rapidly administered needle-free nasal spray. We believe we are well on our way to achieving this goal," said Richard Lowenthal, president and chief executive officer of ARS Pharmaceuticals. "Both our NDA and MAA for ***neffy*** are currently under review by the regulators in the U.S. and E.U. and we are on-track with our commercial preparedness activities for a potential U.S. launch later this year, if approved. We also recently reacquired European rights to ***neffy*** which enhance our optionality to evaluate potential partnerships or strategic transactions. The team has done a remarkable job executing the development of ***neffy***, and we look forward to engaging with the regulatory agencies in an effort to impact the lives of millions of people with serious allergic reactions."

neffy Progress

- ***neffy* NDA and MAA for the Treatment of Allergic Reactions (Type 1), Including Anaphylaxis, Under Review with FDA and EMA:** 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), were accepted for review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date that is anticipated in mid-2023. If approved, ***neffy*** would be the first non-injectable treatment available to patients with allergic reactions (Type I), including anaphylaxis.

  The regulatory submissions to the FDA and EMA were based on data from four primary registrational studies showing that 2.0 mg intranasal dose of ***neffy*** met all clinical endpoints recommended by regulators and that its pharmacokinetics were within the range of approved epinephrine injection products. These data, which were presented at the 2022 American College of Allergy Asthma and Immunology Annual Scientific Meeting (ACAAI) and the 2023 American Academy of Allergy, Asthma and Immunology (AAAAI) meeting, included studies in adults, with self-administration and caregiver administration, as well as in children with Type I allergies ≥30 kg (66 lbs). In addition, ***neffy*** has been well-tolerated to date with more than 600 individuals receiving at least one dose, and many with repeat administration. Adverse events in the clinical trials were generally mild in nature without any meaningful nasal irritation or pain.

- **Presented Data Supporting Use of *neffy* During the 2023 AAAAI Meeting:** ARS presented positive data supporting ***neffy*** during the 2023 American Academy of Allergy, Asthma and Immunology (AAAAI) meeting. Presentations highlighted clinical trial data demonstrating that ***neffy*** delivered consistent epinephrine levels to attain a pharmacokinetic (PK) and pharmacodynamic (PD) profile within the range of approved intramuscular (IM) injection products with a dose proportional exposure between once and twice dosing.

  ARS also presented findings from surveys of 300 patients identifying that the needle is the principal reason why patients do not fill their epinephrine prescription today, and why they delay epinephrine use and use OTC products first despite treatment guidelines recommending immediate use of epinephrine.

Fourth Quarter and Full Year 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $274.4 million as of December 31, 2022. ARS believes its existing cash, cash equivalents and short-term investments will be sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development (R&D) expenses were $4.7 million for the quarter ended December 31, 2022, and $18.4 million for the year ended December 31, 2022.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.7 million for the quarter ended December 31,

2022, and $18.5 million for the year ended December 31, 2022. G&A expenses for the fourth quarter increased over the prior three quarters mainly due to costs related to the merger with Silverback Therapeutics, Inc. and beginning preparations for the potential commercialization of ***neffy***.

- **Net Loss:** Net loss was $14.4 million for the quarter ended December 31, 2022, and $34.7 million for the year ended December 31, 2022.

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***; ARS's commercial readiness for the potential US launch of ***neffy***, if approved, and the timing thereof; ARS's strategy of pursuing potential partnerships or strategic transactions for ***neffy*** in Europe; the estimated addressable patient population for ***neffy***; 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," "plan," "expect," "goal," "look forward to," "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; the impact of government laws and regulations; ARS's ability to execute its plans and strategies; and uncertainties related to ARS's capital requirements. 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 ("SEC") on October 6, 2022, and under the caption "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2022, being filed with the SEC later today. These documents 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.
Consolidated Balance Sheets
(In thousands, except par value and share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 210,518	$ 60,063
Short-term investments	63,863	—
Prepaid expenses and other current assets	3,319	667
Total current assets	277,700	60,730
Right-of-use asset	445	621
Fixed assets, net	329	72
Other assets	2,961	23
Total assets	$ 281,435	$ 61,446
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $16 in 2022 and $159 in 2021)	$ 4,931	$ 3,107

Lease liability, current	230	144
Contract liability, current	283	1,457
Note payable, current	—	3,479
Total current liabilities	5,444	8,187
Lease liability, net of current portion	251	480
Contract liability, net of current portion	2,854	2,996
Note payable, net of current portion	—	4,930
Preferred stock warrant liability	—	83
Total liabilities	8,549	16,676
Commitments and contingencies		
Convertible preferred stock and stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Series A convertible preferred stock, $0.01 par value; no shares and 4,764,000 shares authorized at December 31, 2022 and 2021, respectively; no shares and 4,764,000 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	365
Series B convertible preferred stock, $0.01 par value; no shares and 606,060 shares authorized at December 31, 2022 and 2021, respectively; no shares and 606,060 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	1,000
Series C convertible preferred stock, $0.01 par value; no shares and 7,749,999 shares authorized at December 31, 2022 and 2021, respectively; no shares and 7,692,309 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	19,868
Series D convertible preferred stock, $0.01 par value; no shares and 9,337,066 shares authorized at December 31, 2022 and 2021, respectively; no shares and 9,337,066 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	54,806
Stockholders' equity (deficit)		
Common stock, $0.0001 par value; 200,000,000 and 56,000,000 shares authorized at December 31, 2022 and 2021, respectively; 93,943,316 and 30,369,413 shares issued and outstanding at December 31, 2022 and 2021, respectively	9	3
Additional paid-in capital	349,408	10,984
Accumulated other comprehensive gain	407	—
Accumulated deficit	(76,938)	(42,256)
Total stockholders' equity (deficit)	272,886	(31,269)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 281,435	$ 61,446

ARS Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share information)

	Years Ended December 31,	
	2022	**2021**
Revenue under collaboration agreements	$ 1,316	$ 5,506
Operating expenses:		
Research and development (including related party amounts of $2,144 in 2022 and $1,072 in 2021)	18,376	20,273
General and administrative (including related party amounts of $603 in 2022 and $476 in 2021)	18,456	4,687
Total operating expenses	36,832	24,960
Loss from operations	(35,516)	(19,454)
Other income (expense):		
Other income (expense), net	974	(789)
Change in fair value of financial instruments	(140)	—
Total other income (expense):	834	(789)
Net loss	$ (34,682)	$ (20,243)
Unrealized gain on available-for-sale securities	407	—
Comprehensive loss attributable to common stockholders	$ (34,275)	$ (20,243)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (0.70)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	39,956,043	28,872,242