ARS Pharmaceuticals Highlights neffy Regulatory Progress and Reports First Quarter 2024 Financial Results

May 9, 2024

__neffy__® (epinephrine nasal spray) New Drug Application (NDA) and CRL response under review by FDA with anticipated review completion by early October 2024

Response submitted for __neffy__ Marketing Authorization Application (MAA) to EMA's CHMP; CHMP opinion expected in the second quarter of 2024

Preparing to initiate outpatient study of __neffy__ for urticaria (hives) in second half of 2024

$223.6 million in cash and securities as of March 31, 2024, providing an expected operating runway of at least three years; well-capitalized to support anticipated U.S. launch of __neffy__ in the second half of 2024

SAN DIEGO, May 09, 2024 (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 reported business updates and financial results for the first quarter of 2024.

"With the completion of all requested ***neffy***® (epinephrine nasal spray) studies and submission of our response to FDA, we believe we are very close to delivering the first needle-free, safe, effective, and easy to carry epinephrine solution to the millions of people living with Type I allergies including anaphylaxis. Our primary focus is ensuring we are well-positioned for a successful launch of ***neffy*** in the U.S. upon approval, which is expected within the next six months. Importantly, we are well-capitalized with a multi-year operating runway that supports our ***neffy*** commercialization activities in the U.S.," said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. "Our goal is to ensure that patients around the world have access to ***neffy*** in a timely manner. We've completed our submission to the EMA's CHMP and expect an opinion on our MAA this quarter. We're also delighted to partner with Australian pharmaceutical leader CSL Seqirus to support the approval and commercialization of ***neffy*** in Australia and New Zealand. These positive updates reflect our team's strong execution and unwavering commitment to serving patients."

U.S. Regulatory Status of neffy for Type 1 Allergic Reactions

- In April, ARS Pharma submitted its response to the FDA's Complete Response Letter (CRL) issued regarding its NDA for ***neffy*** for the treatment of Type I allergic reactions including anaphylaxis. The response addressed all additional requests in FDA's CRL, which included the positive data from a repeat dose PK/PD study of ***neffy*** under nasal allergen challenge conditions, and updated testing that detected no measurable nitrosamine levels, conducted per FDA's draft guidance issued in August 2023. ARS Pharma anticipates an FDA review period of up to six months, and the PDUFA date is anticipated to be October 2, 2024, based on the submission receipt date of April 2, 2024. Assuming approval on or before the anticipated PDUFA date, ARS Pharma anticipates launching ***neffy*** in the U.S. in the second half of 2024.

Global Regulatory Status of neffy

- On April 30, ARS Pharma also submitted its Day 180 response to the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for its MAA for ***neffy***. Based on the timetable included in the Day 180 comments, ARS Pharma expects CHMP to issue its opinion on the ***neffy*** MAA later this quarter.
- ARS Pharma executed an exclusive license and distribution agreement for Australia and New Zealand with CSL Seqirus, a subsidiary of CSL Limited (ASX: CSL), which is the largest Australian pharmaceutical company. Under the terms of the agreement, CSL Seqirus plans to secure regulatory approval and reimbursement and commercialize ***neffy*** in Australia and New Zealand. ARS Pharma will receive an upfront payment as well as potential event-related milestone payments, with a combined value of up to $5 million. Following local regulatory approval of ***neffy***, ARS Pharma will be responsible for supplying finished product to CSL Seqirus at a transfer price paid to ARS Pharma.
- Submissions to other regulatory authorities in additional countries including China and Japan are planned for 2024.

Clinical Expansion of neffy for Urticaria

- ARS Pharma is on-track to initiate an outpatient study of ***neffy*** for patients with urticaria, who have been previously treated with antihistamines and experience frequent acute flares. The Phase 2b trial is expected to begin dosing patients in the second half of 2024, followed by the potential initiation of a single pivotal efficacy study in 2025.

Additional Business Highlights

- On March 7, 2024, ARS Pharma held its first ***neffy*** Investor Day. ARS Pharma management was joined by two leading allergists, Dr. Jonathan Spergel, M.D., Ph.D., and Dr. Thomas B. Casale, M.D., who provided an overview of the treatment landscape for severe Type I allergies and a review of the positive clinical data submitted in the ***neffy*** registration package.

A replay of the event can be accessed here.

- In March 2024, results from the upper respiratory tract infection clinical study of ***neffy*** were published in the *Journal of Allergy and Clinical Immunology: In Practice.* The results demonstrated that the pharmacokinetic and pharmacodynamics of ***neffy*** were not affected by upper respiratory tract infection symptoms.

First Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $223.6 million as of March 31, 2024, which ARS Pharma believes is sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development (R&D) expenses were $5.2 million for the quarter ended March 31, 2024, compared to $6.6 million for the quarter ended March 31, 2023. R&D expenses decreased from 2023 to 2024 primarily due to a decrease in device development costs, partially offset by an increase in clinical trial costs.
- **G&A Expenses:** General and administrative (G&A) expenses were $8.0 million for the quarter ended March 31, 2024, compared to $12.2 million for the quarter ended March 31, 2023. G&A expenses decreased from 2023 to 2024 primarily due to a pause in pre-commercial launch activities related to ***neffy***.
- **Net Loss:** Net loss was $10.3 million for the quarter ended March 31, 2024, compared to $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 40 million people in the United States who experience Type I severe allergic reactions. Of those, only 3.2 million 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 Urticaria
Urticaria is a skin disorder that causes itchy hives and/or angioedema with an annualized incidence of 5 million in the United States, with about 40% becoming chronic urticaria; 50% of chronic urticaria cases 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 Pharma 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 Pharma 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, the anticipated timing for regulatory review decisions on the ***neffy*** NDA and MAA; our belief that ***neffy*** will be approved for the treatment of Type I allergic reactions; the timing for the potential U.S. launch of ***neffy***, if approved; the planned outpatient study of ***neffy*** for urticaria and the timing thereof; the potential initiation of a single pivotal efficacy study for ***neffy*** in urticaria and the timing thereof; ARS Pharma’s projected cash runway; ARS Pharma’s belief that it is well capitalized to support the launch of ***neffy*** in the U.S., if approved; planned submissions of ***neffy*** to other foreign regulatory authorities for approval and the timing thereof; 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,” “plans,” “believes,” “expects,” “on track to,” “will,” “potential” 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, the ability to obtain and maintain regulatory approval for ***neffy*** in any indication; even though the FDA has stated that completion of the repeat-dose study under allergen-induced allergic rhinitis conditions for ***neffy*** will sufficiently address the agency’s outstanding questions, there is no guarantee that new issues will not be identified which could delay or prevent the approval of ***neffy***; whether the FDA will view the results from ARS Pharma’s repeat dose study under allergen induced allergic rhinitis conditions for ***neffy*** as sufficient to support approval for Type I allergic reactions; the PDUFA target action date may be further delayed due to various factors outside ARS Pharma’s control; potential safety and other complications from ***neffy***; the labelling for ***neffy*** in any indication, 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 Pharma’s ability to protect its intellectual property position; uncertainties related to capital requirements; 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 Pharma’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (“SEC”) on March 21, 2024, and in ARS Pharma’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, being filed with the SEC today. These documents can also be accessed on ARS

Pharma'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 Pharma 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, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 56,006	$ 70,971
Short-term investments	167,626	157,389
Prepaid expenses and other current assets	2,609	3,366
Total current assets	226,241	231,726
Right-of-use asset	198	250
Fixed assets, net	616	574
Other assets	528	638
Total assets	$ 227,583	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $280 and $178, respectively)	$ 3,498	$ 2,154
Lease liability, current	217	237
Total current liabilities	3,715	2,391
Lease liability, net of current portion	—	37
Total liabilities	3,715	2,428
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 96,574,049 and 96,414,963 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	10	10
Additional paid-in capital	365,577	362,004
Accumulated other comprehensive (loss) gain, net	(124)	49
Accumulated deficit	(141,595)	(131,303)
Total stockholders' equity	223,868	230,760
Total liabilities and stockholders' equity	$ 227,583	$ 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 March 31,	
	2024	2023
Revenue under collaboration agreements	$ —	$ 20
Operating expenses:		
Research and development (including related party amounts of $726 and $591, respectively)	5,234	6,552
General and administrative (including related party amounts of $93 and $337, respectively)	7,958	12,181
Total operating expenses	13,192	18,733

Loss from operations	(13,192)	(18,713)
Other income, net	2,900	3,752
Net loss	$ (10,292)	$ (14,961)
Change in unrealized gains and losses on available-for-sale securities	(173)	(339)
Comprehensive loss	$ (10,465)	$ (15,300)
Net loss per share, basic and diluted	$ (0.11)	$ (0.16)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	96,486,480	94,227,313