ARS Pharmaceuticals Provides Business Highlights and Reports Second Quarter 2024 Financial Results

August 6, 2024

__neffy__® (epinephrine nasal spray) New Drug Application (NDA) under review by FDA; discussions are ongoing to finalize labeling with FDA; PDUFA date in early October 2024

__EURneffy__® (adrenaline nasal spray) recommended for approval by EMA's CHMP; formal marketing authorization anticipated in the third quarter of 2024

Outpatient study of __neffy__ for urticaria (hives) on track to initiate in the fourth quarter of 2024

$218.7 million in cash, cash equivalents and short-term investments as of June 30, 2024, providing an expected operating runway of at least three years; well-capitalized to support anticipated U.S. launch of __neffy__, if approved

SAN DIEGO, Aug. 06, 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 highlights and financial results for the second quarter of 2024.

"Thanks to the diligent work by the entire ARS team, we believe we are in the final steps with FDA, with draft physician labeling in hand and commercial readiness efforts well underway to support the successful launch of ***neffy*** upon FDA approval," stated Richard Lowenthal, Co-founder, President, and CEO of ARS Pharma. "We are also greatly encouraged by the EMA's CHMP positive opinion adopted for **EUR*neffy*** and are in advanced discussions to select a pharmaceutical partner with a strong commercial infrastructure who will launch **EUR*neffy*** in Europe. Importantly, our robust balance sheet provides us with a multi-year operating runway that supports our planned ***neffy*** commercialization activities in the U.S. We are well positioned to bring this treatment to the millions of patients living with Type I allergies, including anaphylaxis, and their dedicated caregivers, who we believe are in dire need of a needle-free, safe, effective, and easy-to-carry epinephrine treatment solution."

Second Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $218.7 million as of June 30, 2024, which ARS Pharma believes is sufficient to fund its current operating plan for at least three years.
- **Research and Development (R&D) Expenses:** R&D expenses were $6.9 million for the quarter ended June 30, 2024, compared to $7.3 million for the quarter ended June 30, 2023. R&D expenses decreased from 2023 to 2024 primarily due to a decrease in device development costs.
- **General and Administrative (G&A) Expenses:** G&A expenses were $8.9 million for the quarter ended June 30, 2024, compared to $13.3 million for the quarter ended June 30, 2023. G&A expenses decreased from 2023 to 2024 primarily due to a decrease in pre-commercial launch investment related to ***neffy***, which we expect to increase as we approach anticipated FDA approval.
- **Net Loss:** Net loss was $12.5 million for the quarter ended June 30, 2024, compared to a net loss of $17.4 million for the quarter ended June 30, 2023.

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

- ARS Pharma has received draft physician labeling for ***neffy*** (epinephrine nasal spray) for the treatment of Type I allergic reactions including anaphylaxis from the U.S. Food and Drug Administration (FDA) and discussions are ongoing with FDA to finalize patient labeling. ARS Pharma's response to FDA's Complete Response Letter (CRL) issued regarding its NDA for ***neffy*** has been considered a complete response by FDA with a PDUFA target action of October 2, 2024. Upon FDA approval, ARS Pharma anticipates launching ***neffy*** in the U.S. in the fourth quarter of 2024.

Global Regulatory Status of neffy

- On June 27, 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the granting of a marketing authorization for ***neffy*** (tradename **EUR*neffy*** in the European Union) for the emergency treatment of allergic reactions (anaphylaxis). The EMA decision is normally issued 67 days from the adoption of the CHMP opinion, and, if favorable, is followed by a grant of marketing authorization by the European Commission (EC), which is expected to occur in the third quarter of 2024. Following grant of marketing authorization by the EC, ARS Pharma anticipates that **EUR*neffy*** will be made available to patients in Europe in the fourth quarter of 2024 by a pharmaceutical partner with an established commercial footprint in Europe.

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 fourth quarter of 2024, followed by the potential initiation of a single pivotal efficacy study in 2025.

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 this group, over the last three years, approximately 20 million people have been diagnosed and experienced 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 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 European marketing authorization application; ARS Pharma’s projected cash runway and belief that it is well capitalized and prepared to support the successful launch of ***neffy*** in the U.S., if approved; the belief that ***neffy*** will be approved for the treatment of Type I allergic reactions and the timing thereof; the timing for the potential U.S. launch of ***neffy***, if approved; the needle-free profile of ***neffy*** increasing the likelihood that patients will both carry and administer adrenaline; the belief that ***neffy*** will be made available to patients in Europe in the fourth quarter of 2024; the belief that ARS Pharma will be able to enter into a partnership with a pharmaceutical partner with an established footprint in Europe for the commercialization of ***neffy*** in Europe; the planned studies of ***neffy*** for urticaria and 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,” “believes,” “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 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; although FDA has considered ARS Pharma’s response to the CRL as a complete response, there is no guarantee that new issues will not be identified which could delay or prevent the approval of ***neffy***; the PDUFA target action date may be further delayed due to various factors outside ARS Pharma’s control; the positive opinion from CHMP does not guarantee the EC will approve the related marketing authorization; the risks associated with conducting clinical and outpatient studies; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on May 9, 2024, and in ARS Pharma’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, being filed with the SEC today. These documents can also be accessed on ARS Pharma’s web page 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 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)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 36,626	$ 70,971
Short-term investments	182,118	157,389
Prepaid expenses and other current assets	1,994	3,366
Total current assets	220,738	231,726
Right-of-use asset	146	250
Fixed assets, net	636	574
Other assets	446	638
Total assets	$ 221,966	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $122 and $178, respectively)	$ 6,565	$ 2,154
Lease liability, current	160	237
Total current liabilities	6,725	2,391
Lease liability, net of current portion	—	37
Total liabilities	6,725	2,428
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 96,939,797 and 96,414,963 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	10	10
Additional paid-in capital	369,487	362,004
Accumulated other comprehensive (loss) gain, net	(145)	49
Accumulated deficit	(154,111)	(131,303)
Total stockholders' equity	215,241	230,760
Total liabilities and stockholders' equity	$ 221,966	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue under collaboration agreements	$ 500	$ 10	$ 500	$ 30
Operating expenses:				
Research and development (including related party amounts of $518, $484, $1,245 and $1,075, respectively)	6,896	7,308	12,130	13,860
General and administrative (including related party amounts of $114, $181, $208 and $518, respectively)	8,944	13,305	16,902	25,486
Total operating expenses	15,840	20,613	29,032	39,346
Loss from operations	(15,340)	(20,603)	(28,532)	(39,316)
Other income, net	2,824	3,233	5,724	6,985
Net loss	$ (12,516)	$ (17,370)	$ (22,808)	$ (32,331)
Change in unrealized gains and losses on available-for-sale securities	(21)	(248)	(194)	(587)
Comprehensive loss	$ (12,537)	$ (17,618)	$ (23,002)	$ (32,918)
Net loss per share, basic and diluted	$ (0.13)	$ (0.18)	$ (0.24)	$ (0.34)

Weighted-average shares outstanding used in computing net loss per share, basic and diluted	96,827,687	94,911,268	96,656,690	94,571,180

Source: ARS Pharmaceuticals, Inc.