UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

March 21, 2024
Date of Report (Date of earliest event reported)

ARS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39756	81-1489190
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11682 El Camino Real, Suite 120 San Diego, California	92130
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 771-9307

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SPRY**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 21, 2024, ARS Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2023 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 of this Current Report on 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated March 21, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: March 21, 2024

By: /s/ Richard Lowenthal, M.S., MSEL
Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer

Exhibit 99.1

ARS Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Full Year 2023 Financial Results

*Preparing to submit response to the FDA's CRL for **neffy**®(epinephrine nasal spray) in Type 1 allergic reactions in early Q2 2024, following successful completion of **neffy** repeat dose nasal allergen challenge study and nitrosamine assessments, with expected up to six-month review period*

*In Phase 2 urticaria clinical trial, **neffy** met primary endpoints and showed rapid symptom control; planning to initiate outpatient study later in 2024, potentially followed by initiation of a single pivotal efficacy study*

*Ended fourth quarter with $228.4 million in cash, cash equivalents and short-term investments with an expected operating runway of at least three years; well-capitalized to support anticipated H2 2024 launch of **neffy** in the U.S.*

SAN DIEGO -- March 21, 2024 -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect patients from severe allergic reactions that could lead to anaphylaxis, today reported business updates and financial results for the fourth quarter and full year 2023.

"We started the year by turning the page and quickly addressing the two deficiencies identified in the FDA's CRL for ***neffy*** late last year and are now working to finalize our response to the CRL, which we expect to submit in early Q2 2024. We want to deliver this needle-free, safe, effective, and easy to carry epinephrine solution to patients in need as quickly as possible. To do so, we remain well capitalized with anticipated cash and equivalents greater than $200 million at the time of the anticipated FDA approval of ***neffy***, expected in the second half of 2024," said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. Mr. Lowenthal further stated, "At the recent American Academy of Allergy, Asthma & Immunology (AAAAI) annual meeting in February 2024, six posters and oral presentations on ***neffy*** were presented, including efficacy data showing a 100% response rate with a single dose of ***neffy*** in the 15 enrolled pediatric subjects experiencing anaphylaxis symptoms following oral food challenge, further increasing our confidence in ***neffy's*** commercial ramp and potential. At AAAAI, we also presented positive topline data from our Phase 2 inpatient, randomized, controlled study of ***neffy*** in patients with refractory chronic spontaneous urticaria. ***neffy*** met all primary endpoints and showed rapid symptom control, supporting advancement to an outpatient study in chronic spontaneous urticaria patients who experience acute exacerbations of symptoms, which we plan to initiate later in 2024, followed by a potential pivotal study in 2025."

U.S. Regulatory Status of neffy (epinephrine nasal spray) for Type I Allergic Reactions

- In September 2023, ARS Pharma announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding its New Drug Application (NDA) for ***neffy***. In the CRL, the FDA requested completion of a pharmacokinetic (PK) / pharmacodynamic (PD) study assessing repeat doses of ***neffy*** compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis conditions to support approval.

- In February 2024, ARS Pharma announced the successful completion of the repeat dosing study of ***neffy*** in seasonal allergic rhinitis under nasal allergen challenge conditions. ARS Pharma also completed the nitrosamine testing requested in the CRL per the FDA's draft guidance issued in August 2023, with no measurable levels of nitrosamines detected.
- The favorable topline results from this repeat dose study, meant to represent a challenging nasal scenario that is potentially relevant to less than 0.5% of patients, showed repeat doses of ***neffy*** demonstrated a PK profile greater than or similar to repeat doses of intramuscular injection of epinephrine, and a PD profile greater than injection. In particular, repeat dosing in the same nostril was greater in exposure than dosing once in each nostril and greater than injection on both PK exposures and PD response at all time points, which may help inform labeling and instructions for use.
- Having addressed the deficiencies identified by the FDA, ARS Pharma is finalizing its response to the CRL, which it expects to submit in early Q2 2024. Following an expected up to six-month review period, ARS Pharma anticipates an FDA action date and potential launch in the second half of 2024.

Clinical Status of neffy for Urticaria

- In late-February, ARS Pharma announced positive clinical data from a Phase 2 trial evaluating ***neffy*** in adults with chronic spontaneous urticaria.
- There are currently no approved community use treatments for acute flares experienced by urticaria patients on chronic regimens of antihistamines or biologics. ***neffy*** may provide episodic symptomatic relief of these acute flares or exacerbations to improve the quality of life of urticaria patients. Patients would have the option to quickly resolve exacerbations or flares at home without escalating to chronic use of systemic biologics or immunosuppressants that may have more serious side effects and benefit-risk considerations, or having to visit the emergency room for further treatment.
- The Phase 2, randomized, placebo-controlled, cross-over study in 18 adults with chronic spontaneous urticaria who were treated at the clinical site, met its primary endpoints with both 1 mg and 2 mg ***neffy*** demonstrating statistically significant and clinically meaningful improvement in pruritus, hives, body surface area and erythema from baseline as early as 5 minutes after dosing. These data were presented in an oral session at the 2024 AAAAI annual meeting.
- ARS Pharma plans to initiate an outpatient urticaria study in patients treated with antihistamines who experience frequent acute flares later in 2024, potentially followed by initiation of a single pivotal efficacy study.

Additional Business Updates and Anticipated Milestones

- Marketing authorization application (MAA) for ***neffy*** is under review by the European Medicines Agency (EMA) with a decision now expected in mid-2024. Submissions to other regulatory authorities in additional countries are planned for 2024.
- On March 7, 2024, ARS Pharma held a virtual ***neffy*** Investor Day. The ARS Pharma management team was joined by two leading allergists, Dr. Jonathan Spergel, M.D., Ph.D. and Dr. Thomas B. Casale, M.D. A replay of the event can be accessed here.

- In March 2024, a new U.S. patent was issued (US 11,918,655) by the U.S. Patent and Trademark Office that covers methods of treating Type I allergic reactions, including anaphylaxis, with intranasal epinephrine formulations having a wider dose range of 0.1 to 4.0 mg epinephrine with or without absorption enhancing agents. This newly issued patent recognizes the novelty of ***neffy*** and its ability to safely deliver low potent doses of epinephrine with comparable PK and PD to marketed epinephrine injectables.
- In February 2024, ARS Pharma presented six posters and oral presentations at the 2024 AAAAI Annual Meeting, including efficacy data for ***neffy*** from two distinct clinical studies in oral food challenge induced anaphylaxis and chronic spontaneous urticaria patients. The chronic urticaria data are discussed above, and the oral food challenge induced anaphylaxis efficacy data demonstrated that 100% of the 15 enrolled pediatric patients responded to a single dose of ***neffy*** with a 16-minute median time to complete resolution of symptoms. The Company expects this data will support post-marketing promotion of ***neffy***, if approved.
- In November 2023, ARS Pharma presented positive results during the 2023 American College of Allergy, Asthma and Immunology meeting supporting that ***neffy*** is expected to be a safe and effective treatment option for severe allergic reactions in sub-populations including patients with upper respiratory tract infections, pediatric patients weighing greater than or equal to 30 kg and patients with varying body mass index or body weight.
- In October 2023, ARS Pharma announced that results from the single and repeat dose clinical study of ***neffy*** were published in the *Journal of Allergy and Clinical Immunology*. The clinical study evaluated single and repeat doses of ***neffy*** compared to single and repeat doses of approved injection products in healthy subjects. In November 2023, the results from the self-administration clinical study of ***neffy*** were also published in the *Journal of Allergy and Clinical Immunology: In Practice*.

Fourth Quarter and Full Year 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $228.4 million as of December 31, 2023, which ARS Pharma believes is sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development expenses were $3.4 million and $20.3 million for the quarter and year ended December 31, 2023, respectively. Total research and development expenses in 2023 increased from $18.4 million in 2022 primarily due to higher payroll costs and stock-based compensation, partially offset by a decrease in license milestone expenses.
- **G&A Expenses:** General and administrative expenses were $6.8 million and $47.3 million for the quarter and year ended December 31, 2023, respectively. Total general and administrative expenses in 2023 increased from $18.5 million in 2022 primarily due to an increase in pre-commercial launch activities, payroll costs, consulting and stock-based compensation expenses.
- **Net Loss:** Net loss was $7.2 million and $54.4 million for the quarter and year ended December 31, 2023, respectively.

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 US, 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, among chronic urticaria cases. 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. ***neffy*** may provide episodic symptomatic relief of these acute flares or exacerbations to improve the quality of life of urticaria patients. 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 ARS Pharma’s: plan to submit its response to the FDA’s CRL early in the second quarter of 2024, with an anticipated FDA action date and launch of ***neffy***, if approved, in the second half of 2024; plans to initiate an outpatient urticaria study later in 2024, potentially followed by initiation of a single pivotal efficacy study; projected operating runway; belief that it is well capitalized to support the launch of ***neffy*** in the U.S., if approved; expected competitive position; belief that patients using ***neffy***, as opposed to autoinjectors, will be more likely to fill their prescriptions, carry their devices, and ultimately use their devices; the timing of the EMA’s decision and submissions to other foreign regulatory authorities; expectation that recent chronic urticaria data and oral food challenge induced anaphylaxis efficacy data will support post-marketing promotion of ***neffy***; belief that ***neffy*** may provide episodic symptomatic relief and improve the quality of life of urticaria patients; 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,” “plans,” “potential,” “will” 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***; 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 successful and sufficient to support approval; the PDUFA target action date may be further delayed due to various factors outside ARS Pharma’s control; 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 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 September 30, 2023, filed with the Securities and Exchange Commission (SEC) on November 9, 2023, and in ARS Pharma’s Annual Report on Form 10-K for the year ended December 31, 2023, being filed with the SEC later today. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma’s website at ir.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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 70,971	$ 210,518
Short-term investments	157,389	63,863
Prepaid expenses and other current assets	3,366	3,319
Total current assets	231,726	277,700
Right-of-use asset	250	445
Fixed assets, net	574	329
Other assets	638	2,961
Total assets	$ 233,188	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $178 and $16, respectively)	$ 2,154	$ 4,931
Lease liability, current	237	230
Contract liability, current	—	283
Total current liabilities	2,391	5,444
Lease liability, net of current portion	37	251
Contract liability, net of current portion	—	2,854
Total liabilities	2,428	8,549
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2023 and 2022; 96,414,963 and 93,943,316 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	10	9
Additional paid-in capital	362,004	349,408
Accumulated other comprehensive gain, net	49	407
Accumulated deficit	(131,303)	(76,938)
Total stockholders' equity	230,760	272,886
Total liabilities, convertible preferred stock and stockholders' equity	$ 233,188	$ 281,435

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share information)

	Year Ended December 31,	
	2023	2022
Revenue under collaboration agreements	$ 30	$ 1,316
Operating expenses:		
Research and development (including related party amounts of $1,796 and $2,144, respectively)	20,266	18,376
General and administrative (including related party amounts of $940 and $603, respectively)	47,284	18,456
Total operating expenses	67,550	36,832
Loss from operations	(67,520)	(35,516)
Other income, net	13,155	974
Change in fair value of financial instruments	—	(140)
Net loss	$ (54,365)	$ (34,682)
Change in unrealized gains and losses on available-for-sale securities	(358)	407
Comprehensive loss	$ (54,723)	$ (34,275)
Net loss per share, basic and diluted	$ (0.57)	$ (0.87)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	95,215,322	39,956,043