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

November 9, 2023
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 November 9, 2023, ARS Pharmaceuticals, Inc. (the "Company") announced its financial results for the three and nine months ended September 30, 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 November 9, 2023
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: November 9, 2023

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

ARS Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Business Updates

Company is on track with ongoing repeat-dose study under allergen-induced allergic rhinitis conditions requested by U.S. FDA with topline data expected in Q1 2024

*Resubmission of New Drug Application (NDA) for **neffy** anticipated in H1 2024*

*Ended third quarter with $241.9 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 -- November 9, 2023 -- 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 third quarter of 2023.

“While we remain disappointed in the FDA’s decision to change the repeat-dose rhinitis study from a post-marketing requirement to a pre-approval requirement, we are moving quickly to complete the study and meet the urgent medical need for people with severe allergic reactions. We continue to expect resubmission of our New Drug Application for ***neffy*** in the first half of next year, with a U.S. launch anticipated in the second half of next year, if approved. We are incredibly appreciative of the outpouring of support we have received from patients and caregivers following the delay as they eagerly await the approval of ***neffy***,” said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma.

Mr. Lowenthal continued: “During our Type A meeting with the FDA in October, the agency reinforced that the completion of our repeat-dose rhinitis study for ***neffy*** will sufficiently address the agency’s outstanding questions. Further bolstering our confidence in the study’s prospects, we were pleased to announce the publication of positive results from the single and repeat dose clinical study of ***neffy*** in the *Journal of Allergy and Clinical Immunology*, which add to the growing body of clinical evidence for ***neffy*** and underscore its potential to be a safe and efficacious treatment option. ARS Pharma remains well capitalized to fund our operations for at least the next three years with anticipated cash and equivalents of approximately $195 million expected at the time of the anticipated ***neffy*** launch in the second half of 2024.”

U.S. Regulatory Status of neffy® (epinephrine nasal spray)

- In September, ARS Pharma announced that the FDA issued a Complete Response Letter (CRL) regarding its NDA for ***neffy***. In the CRL, the FDA requested completion of a pharmacokinetic/pharmacodynamic study assessing repeat doses of ***neffy*** compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis conditions to support approval.
    - No member of the May 2023 FDA Advisory Committee (PADAC), that concluded a favorable benefit-risk profile of ***neffy*** (16:6 for adults and 17:5 for children), requested a repeat dose study during allergen-induced allergic rhinitis, and ARS Pharma aligned with FDA in August 2023 that such a study could be completed as a post-marketing requirement.
    - ARS Pharma expects to report its findings from this study in the first quarter of 2024. With this study being previously planned as a post-marketing requirement, ARS Pharma was able to quickly ramp up following the CRL.
    - The company anticipates a resubmission of its NDA in the first half of 2024, positioning ARS Pharma for an anticipated FDA action date and potential launch in the second half of 2024.
- In October, ARS Pharma announced its participation in a Type A meeting with the FDA to understand the agency's view related to the CRL, and to confirm next steps to support an NDA resubmission seeking approval of ***neffy***.
    - At this Type A meeting, the FDA confirmed that the previously agreed upon design for the repeat-dose study to evaluate the similarity of twice dosing injection and twice dosing ***neffy*** under allergen-induced allergic rhinitis will generate the necessary data to answer its outstanding questions regarding ***neffy***.
    - The ***neffy*** NDA re-submission will be classified as Class 2, with an action expected within six months of submission.

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 the second quarter of 2024. Submissions to other regulatory authorities in additional countries are planned for 2024.
- In October, 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 (JACI)*. 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, ARS Pharma will present positive results during the 2023 American College of Allergy, Asthma and Immunology (ACAAI) meeting supporting that ***neffy*** is expected to be a safe and effective treatment option in sub-populations including upper respiratory tract infection, pediatrics ≥30 kg and patients with varying body mass index (BMI) or body weight.

- Following the ***neffy*** program delay, ARS Pharma implemented a plan to prioritize resources on clinical and regulatory activities while maintaining core commercial readiness status ahead of the anticipated FDA approval of ***neffy*** in H2 2024.

Third Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $241.9 million as of September 30, 2023, 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 $3.0 million for the quarter ended September 30, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $15.0 million for the quarter ended September 30, 2023.
- **Net Loss:** Net loss was $14.9 million for the quarter ended September 30, 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 3.3 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 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 complete the repeat-dose study under allergen-induced allergic rhinitis conditions and file its NDA re-submission to the FDA in the first half of 2024, with an anticipated launch of ***neffy***, if approved, in the second half of 2024; ARS Pharma’s expectation to report topline data from its repeat-dose study in the first quarter of 2024; 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; whether the repeat-dose study under

allergen-induced allergic rhinitis conditions will sufficiently address the FDA's outstanding questions; the potential for ***neffy*** to be a safe and efficacious treatment option; the classification of the ***neffy*** re-submission, anticipated timing for regulatory review decisions on ***neffy*** and the potential approval of ***neffy***; the timing of the EMA's decision of ARS Pharma's MAA and submissions to other foreign regulatory authorities; 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***; the ability to successfully complete the repeat-dose study under allergen-induced allergic rhinitis conditions within the anticipated timeframe, as a result of challenges inherent to enrolling, conducting and completing clinical trials; 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***; 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 June 30, 2023, filed with the Securities and Exchange Commission ("SEC") on August 10, 2023, and in ARS Pharma's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, being filed with the SEC today. This document 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)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 60,532	$ 210,518
Short-term investments	181,370	63,863
Prepaid expenses and other current assets	2,564	3,319
Total current assets	244,466	277,700
Right-of-use asset	300	445
Fixed assets, net	617	329
Other assets	3,173	2,961
Total assets	$ 248,556	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $208 and $16, respectively)	$ 10,945	$ 4,931
Lease liability, current	235	230
Contract liability, current	—	283
Total current liabilities	11,180	5,444
Lease liability, net of current portion	92	251
Contract liability, net of current portion	—	2,854
Total liabilities	11,272	8,549
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 95,796,254 and 93,943,316 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	9	9
Additional paid-in capital	361,571	349,408
Accumulated other comprehensive (loss) gain, net	(161)	407
Accumulated deficit	(124,135)	(76,938)
Total stockholders' equity	237,284	272,886
Total liabilities, convertible preferred stock and stockholders' equity	$ 248,556	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue under collaboration agreements	$ —	$ 189	$ 30	$ 1,316
Operating expenses:				
Research and development (including related party amounts of $307, $776, $1,382 and $1,888, respectively)	3,002	3,893	16,862	13,666
General and administrative (including related party amounts of $322, $73, $840 and $344, respectively)	14,976	2,926	40,462	7,723
Total operating expenses	17,978	6,819	57,324	21,389
Loss from operations	(17,978)	(6,630)	(57,294)	(20,073)
Other income (expense), net	3,112	47	10,097	(180)
Net loss	$ (14,866)	$ (6,583)	$ (47,197)	$ (20,253)
Change in unrealized gains and losses on available-for-sale securities	19	—	(568)	—
Comprehensive loss	$ (14,847)	$ (6,583)	$ (47,765)	$ (20,253)
Net loss per share, basic and diluted	$ (0.16)	$ (0.21)	$ (0.50)	$ (0.66)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	95,576,627	30,755,123	94,910,012	30,578,516