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

August 10, 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 August 10, 2023, ARS Pharmaceuticals, Inc. (the "Company") announced its financial results for the three and six months ended June 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 August 10, 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: August 10, 2023

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

ARS Reports Second Quarter 2023 Financial Results and Provides Business Updates

*ARS continues engagement with U.S. FDA on final labeling and post-marketing commitments for the **neffy**® new drug application; PDUFA target action date set for September 19, 2023*

*Ended second quarter with $252.2 million in cash, cash equivalents and short-term investments; well-capitalized to support anticipated launch of **neffy** in the U.S. and an expected operating runway of at least three years*

SAN DIEGO – August 10, 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 second quarter of 2023.

"Our primary focus is on making ***neffy***, an investigational new drug, available to people as quickly as possible and we believe that our interactions with FDA are nearly complete," said Richard Lowenthal, president and chief executive officer of ARS. "With a PDUFA date next month, we continue to advance our preparations to ensure we are well-positioned for a successful launch of ***neffy*** in the U.S., if approved. We are in the final stages of labeling and post-marketing commitment discussions with FDA and are putting the right structures in place to enable patient access to ***neffy*** quickly, within about eight weeks from the final label. We are excited to not only transition the company to a commercial organization, but to potentially bring to the allergy community the first medical treatment advancement in more than 35 years: an easy-to-carry, simple-to-administer, needle-free nasal spray to address the anxiety and hesitation associated with today's injectable devices."

Preparing for U.S. launch of neffy®

- In May, the U.S. Food and Drug Administration (FDA) convened an Advisory Committee meeting, which concluded a favorable benefit-risk profile of ***neffy***, with a 16:6 vote in favor for adults and 17:5 vote in favor for children (≥30 kg) for the treatment of patients with allergic reactions (Type 1), including anaphylaxis. The Advisory Committee vote, while not binding, will be considered by FDA when making its decision regarding the potential approval of ***neffy***.
- In June, FDA extended the Prescription Drug User Fee Act (PDUFA) target action date to September 19, 2023, for the New Drug Application (NDA) for ***neffy*** (Intranasal (IN) Epinephrine) for the treatment of allergic reactions (Type 1), including anaphylaxis, for adults and children ≥30 kg. If approved, ***neffy*** would be the first needle-free, non-injectable epinephrine treatment available.
- ARS's U.S. commercial preparedness activities are well underway, and its commercial leadership team and area sales managers are in place. The recruitment process for the expected 115 field-based representatives is progressing on track, pending FDA approval. The company is currently implementing marketing and market access strategies to increase awareness and readiness for the potential launch of ***neffy***.

Additional Business Updates and Anticipated Milestones

- ARS further broadened the scope of its intellectual property position for ***neffy*** with a recently issued U.S. patent on August 8, 2023, and an allowed second patent application by the U.S. Patent and Trademark Office. The issued patent and the allowed patent application are directed to the use of intranasal epinephrine formulations, including the use of bile acid absorption enhancers, for the treatment of allergic diseases, such as urticaria. Topline data from the company's ongoing Phase 2 randomized, placebo-controlled study of ***neffy*** in urticaria patients are expected by the fourth quarter of 2023.
- Marketing authorization application (MAA) for ***neffy*** is under review by the European Medicines Agency with a decision expected by year end 2023.

Second Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and short-term investments were $252.2 million as of June 30, 2023, which ARS believes are sufficient to fund its current operating plan for at least three years.
- **R&D Expenses:** Research and development (R&D) expenses were $7.3 million for the quarter ended June 30, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $13.3 million for the quarter ended June 30, 2023.
- **Net Loss:** Net loss was $17.4 million for the quarter ended June 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 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 belief that its interactions with FDA are nearly complete; the anticipated successful US launch of ***neffy***, if approved, and the timing thereof; ARS's expectation that it will be able to enable patient access to ***neffy*** within about eight weeks after approval; the expected number of field-based representatives and the expectation that ARS will complete its hiring goal upon approval of ***neffy***; the expected reporting of topline data from ARS's Phase 2 study of ***neffy*** in urticaria patients and the timing thereof; 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," "plans," "expects," "on track 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***; the Advisory Committee decision should not be relied on as an indication that ***neffy*** will ultimately be approved; the FDA is not bound by the Advisory Committee decision or any of its recommendations and there are a number of instances where the FDA has voted against the recommendations of advisory committees; the PDUFA target action date may be further delayed due to various factors outside ARS's control; even though ARS believes its interactions with the FDA are nearly complete, there is no guarantee that new issues will not be identified which could delay or prevent the approval of ***neffy***, and ARS's belief that its interactions with the FDA are nearly complete should not be relied on as an indication that the FDA will ultimately approve ***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; 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's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission ("SEC") on May 15, 2023, and in ARS's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, being filed with the SEC today. This document 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.

ARS Investor Contacts:
Justin Chakma
ARS Pharmaceuticals
justinc@ars-pharma.com

Monique Allaire
THRUST Strategic Communications
monique@thrustsc.com

ARS Media Contact:
Laura O'Neill
FINN Partners
laura.oneill@finnpartners.com

ARS Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and par value data)

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 119,017	$ 210,518
Short-term investments	133,191	63,863
Prepaid expenses and other current assets	2,826	3,319
Total current assets	255,034	277,700
Right-of-use asset	349	445
Fixed assets, net	594	329
Other assets	2,775	2,961
Total assets	$ 258,752	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $170 and $16, respectively)	$ 9,821	$ 4,931
Lease liability, current	233	230
Contract liability, current	—	283
Total current liabilities	10,054	5,444
Lease liability, net of current portion	146	251
Contract liability, net of current portion	—	2,854
Total liabilities	10,200	8,549
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 95,322,953 and 93,943,316 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	9	9
Additional paid-in capital	357,992	349,408
Accumulated other comprehensive (loss) gain, net	(180)	407
Accumulated deficit	(109,269)	(76,938)
Total stockholders' equity	248,552	272,886
Total liabilities, convertible preferred stock and stockholders' equity	$ 258,752	$ 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue under collaboration agreements	$ 10	$ 464	$ 30	$ 1,127
Operating expenses:				
Research and development (including related party amounts of $484, $572, $1,075 and $1,112, respectively)	7,308	4,350	13,860	9,773
General and administrative (including related party amounts of $181, $106, $518 and $271, respectively)	13,305	2,458	25,486	4,797
Total operating expenses	20,613	6,808	39,346	14,570
Loss from operations	(20,603)	(6,344)	(39,316)	(13,443)
Other income (expense), net	3,233	(76)	6,985	(227)
Net loss	$ (17,370)	$ (6,420)	$ (32,331)	$ (13,670)
Change in unrealized gains and losses on available-for-sale securities	(248)	—	(587)	—
Comprehensive loss	$ (17,618)	$ (6,420)	$ (32,918)	$ (13,670)
Net loss per share, basic and diluted	$ (0.18)	$ (0.21)	$ (0.34)	$ (0.45)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	94,911,268	30,606,773	94,571,180	30,488,749