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 9, 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 7.01 Regulation FD Disclosure.

Furnished as Exhibit 99.1 to this report is a Company presentation, which is being presented by the Company beginning at 8:00 a.m. Eastern Time on August 12, 2024.

The information in Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

FDA Approval of *neffy*® (epinephrine nasal spray)

On August 9, 2024, ARS Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") approved ***neffy*** (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in adults and children who weigh ≥30 kg.

The approval of ***neffy*** is based on data from five primary registration studies with a 2 mg intranasal dose of epinephrine. These primary clinical trials were supported by numerous pilot and supportive studies. ***neffy*** met all defined clinical endpoints and its pharmacokinetic and pharmacodynamic data were within the range of approved epinephrine injection products. These data included single- and twice-dosed studies in healthy adults, with self-administration and caregiver administration in Type I allergy patients, in pediatric patients ≥30 kg (66 lbs.) as well as in those with allergic rhinitis (congestion and runny nose). Adverse events in ***neffy*** clinical trials were generally mild in nature without any meaningful nasal irritation or pain, and no serious adverse events were reported in any clinical study.

neffy is expected to be available in the United States within eight weeks of FDA approval for patients who weigh greater than 30 kg (66 lbs.). The Company plans to file a supplemental NDA application with the FDA for ***neffy*** for children who weigh 15 to <30 kg by the end of the third quarter of 2024.

The European Committee for Medicinal Products for Human Use (the "CHMP") adopted a positive opinion on June 27, 2024, recommending the granting of a marketing authorization for ***neffy*** (tradename **EUR*neffy***, in the European Union). The European Medicines Agency ("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. Following the anticipated grant of marketing authorization by the European Commission expected in the third quarter of 2024, the Company anticipates that **EUR*neffy*** will be made available to patients in Europe in the fourth quarter of 2024 by a pharmaceutical company with an already established commercial footprint in Europe.

Forward-Looking Statements

This report contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, the timeline for ***neffy***'s commercial availability; the Company's plan to file a supplemental regulatory application for a ***neffy*** 1 mg product for children 15 kg to <30 kg; the timeline for potential regulatory approval and commercialization of **EUR*neffy*** in Europe; 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 "plans," "expected," "will," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company'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 maintain regulatory approval for ***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***; ***neffy*** may fail to achieve the degree of market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community necessary for commercial success; if we are unable to fully develop our sales, marketing and distribution capability, we may not be successful in commercializing ***neffy*** in the United States; the labeling for ***neffy*** in any future indication or patient population; the scope, progress and expansion of developing and commercializing ***neffy***; the potential for payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; the CHMP positive opinion should not be relied on as an indication that **EU*R*** ***neffy*** will ultimately be approved by the EMA; the EMA is not bound by the CHMP's opinion or any of its recommendations; the labelling for **EU*R*** ***neffy***, if approved; the scope, progress and expansion of developing and commercializing **EU*R*** ***neffy***, if approved, including the ability to enter into distribution and/or partnering arrangements and obtain favorable reimbursement; the Company's ability to protect its intellectual property position; and the impact of government laws, prescription drug price controls 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 the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 6, 2024.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Company Presentation, dated August 12, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

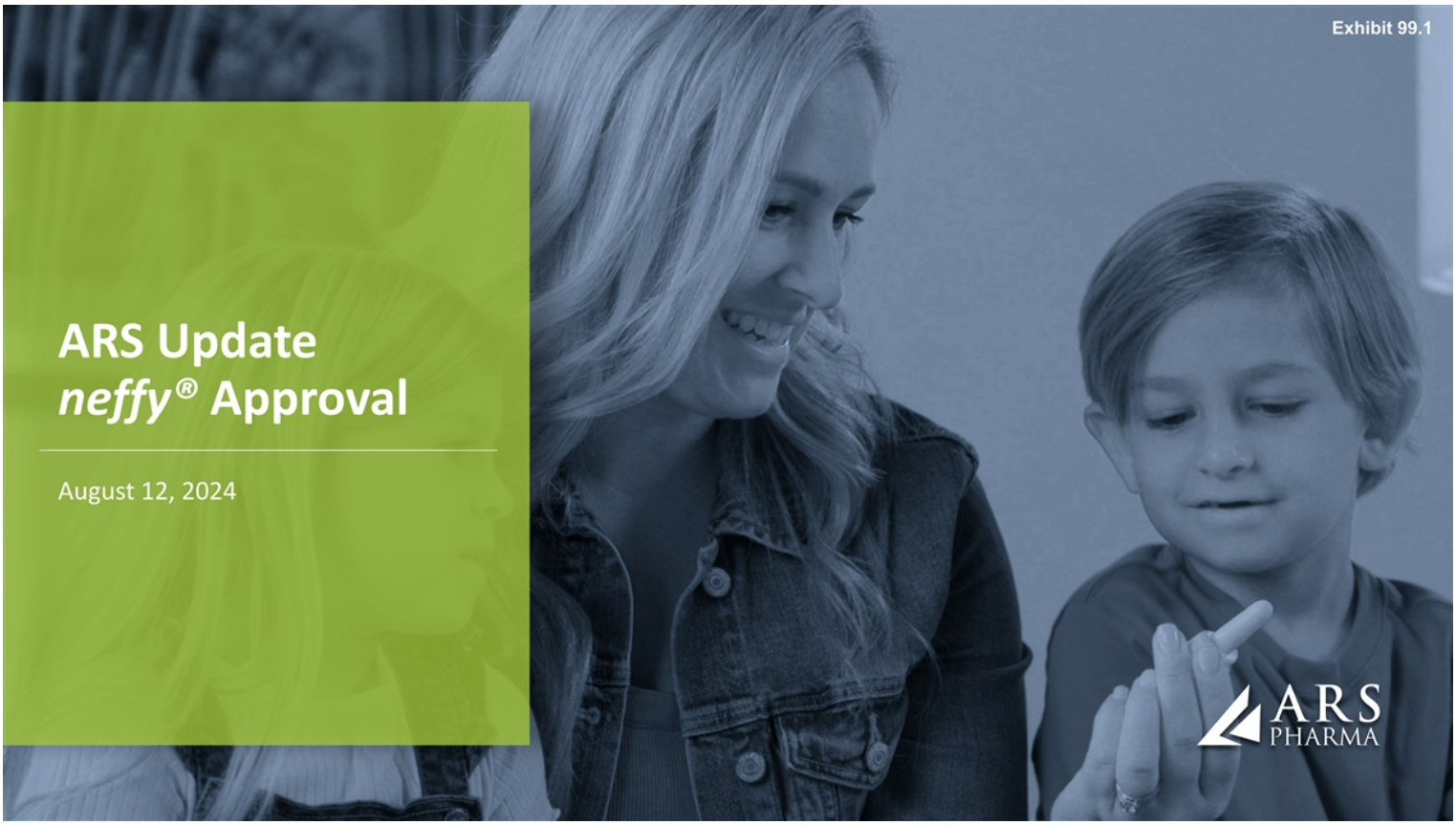
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: August 12, 2024

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

Exhibit 99.1



ARS Update
neffy® Approval

August 12, 2024

Forward-looking statements

Statements in this presentation that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, without limitation, statements regarding: the design and potential benefits of neffy, including the likelihood allergy patients and caregivers will choose to carry and dose neffy compared to needle-bearing options; ARS Pharma's expected competitive position; the potential market, demand and expansion opportunities for neffy; alignment with the FDA on post-marketing studies; plans to file a supplemental regulatory application for a neffy 1 mg dose for children 15 kg to <30 kg in Q3 2024; the timeline for potential regulatory approval and commercialization of neffy in Europe; the timing for potential foreign regulatory filings in, for example, China, Japan, Australia and Canada; the timing of data from the Phase 2b randomized placebo-controlled urticaria trial and initiation of a single pivotal study in urticaria; ARS Pharma's marketing and commercialization strategies, including potential partnerships in foreign jurisdictions; the expected composition and reach of ARS Pharma's commercial force; the potential for the neffy Experience Program; the availability and functionality of neffyconnect; the anticipated pricing and co-pay buydown; the likelihood of neffy attaining favorable coverage; the expected timing for when neffy will be commercially available; ARS Pharma's projected operating runway; the expected intellectual property protection for neffy; and any statements of assumptions underlying any of the foregoing. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. 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," "demonstrate," "expect," "indicate," "plan," "potential," "target," "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 maintain regulatory approval for neffy; results from clinical trials and non-clinical studies may not be indicative of results that may be observed in the future; potential safety and other complications from neffy; the labeling for neffy in any future indication or patient population; the scope, progress and expansion of developing and commercializing neffy; the potential for payors to delay, limit or deny coverage for 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; 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, 2024, filed with the Securities and Exchange Commission ("SEC") on August 6, 2024. 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 presentation 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.

ARS PHARMA

neffy® *(epinephrine nasal spray)*

NOW APPROVED!

INDICATION

neffy is indicated for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in adults and children who weigh ≥30kg

ARS PHARMA

Type I Allergy Patients Face Significant Limitations with Current Treatment Options that *neffy* may help to address

PROBLEM:

ONLY 10% - 20% of patients with active Rx use as indicated[7]

SOLUTION:
neffy

NO TREATMENT READILY AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
Only 50% carry one[1] (<20% carry two)	**~25% - 60% do not administer** [1,3 5, 6]	**~40% - 60% of patients delay**[2]	**23% - 35% fail to dose correctly**[4]
SMALL	**NO NEEDLE NO INJECTION**	**EASIER AND MORE CONSISTENT DOSING**	**RELIABLE**
• Fits in your pocket; easy to carry the recommended 2 devices • ~10% of cases require repeat doses of epinephrine[1]	• Rapid administration without a needle • No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections • Less hesitation to dose	• Simple place and press administration (no hold time) • 100% of adults and children are able to dose ***neffy*** successfully without any training	• 99.999% delivery of effective dose in reliability testing; not obstructed by any anaphylaxis symptoms; no inhalation required • 30-month shelf-life at room temperature, with *neffy* stored at up to 3 months at high temperatures (122°F)

References: 1. Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018. **2.** Rooney E, et al. Poster Presentation at *ACAAI 2022* (Louisville, KY). **3.** Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017. 4. El Turki A, et al. *Emerg Med J.* 2017. **5.** Asthma and Allergy Foundation of American Patient Survey Report 2019. 6. Mehta GD, et al. *Expert Rev Clin Immunol.* 2023. **7.** ARS company estimates based on IQVIA data and references 1 through 6.

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U.S. prescribing information for neffy

Indication Statement:

- ***neffy*** is indicated for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh ≥ 30kg

Dosing and Administration:

- One spray of ***neffy*** administered in one nostril
- Administer second dose in same nostril starting 5 min after first dose in absence of clinical improvement or if symptoms worsen
- Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required
- Recommended patients are prescribed and have access to two ***neffy*** nasal sprays at all times
- Nasal use only

Available Dose Strengths:

- 2 mg nasal spray device

Contraindications:

- None

Boxed Warning:

- None

Warnings and Precautions:

- Potential altered absorption with underlying structural or anatomical nasal conditions
- Angina pectoris, ventricular arrhythmias, coexisting conditions

Adverse Reactions (incidence ≥2%):

- Nasal discomfort (9.7%), headache (6%), rhinorrhea (3%), nausea (3%), dizziness (3%), throat irritation (2%), vomiting (2%) with single doses

Alignment with FDA on post-marketing studies

- File completed EPI-10 study for pediatric patients 15 to 30 kg in body weight (1 mg dose)
- Registry to collect clinical data from allergy challenge clinics (PMC)
- Nominal cost and no material impact on operating runway anticipated

Rigorous registration program conducted in adults and children

- Goal was to develop a low-dose, small, easy to use, and well-tolerated epinephrine nasal spray
- > 1,200 administrations of neffy in > 700 subjects
  - 5 pilot and exploratory studies
  - 5 supportive studies with 1 mg dose (for 15 to 30 kg population)
  - 5 primary registration studies conducted in adults and children
- Demonstrated PK/PD parameters within the range of approved products to reference efficacy and safety
  - Bracketed pharmacokinetic (PK) exposures
  - Comparable pharmacodynamic (PD) response

Five Primary Studies	Patient Population
EPI 15: HCP administration (single and twice dosing)	Adult: healthy volunteers
EPI 16: nasal-allergen challenge (single dosing)	Adult: allergic rhinitis patients
EPI 17: self-administration	Adult: type I allergy patients
EPI 18: nasal-allergen challenge (repeat dosing)	Adult: allergic rhinitis patients
EPI 10: pediatric	Pediatric: type I allergy patients: ≥ 30kg body weight (NDA) Pediatric: type I allergy patients: 15 to < 30kg (sNDA planned)

Registrational studies demonstrate comparability on both PD surrogates for efficacy and PK with *neffy*

PD and PK Data

- 2 mg *neffy* met all clinical endpoints
- PD surrogates for efficacy comparable to approved products (SBP/HR ≥ approved injection products)
- Rapid and significant response on PD surrogates for efficacy observed even 1 minute after dosing
- PK bracketed by approved products (exposures ≥ IM/SC for efficacy, < EpiPen for safety)
- Repeat doses (including during rhinitis) within range of approved injection products

Safety Data

- Adverse events generally mild in nature with no meaningful nasal irritation or pain up to 4 mg dose
- Most common adverse events (>5%) with single does of ***neffy*** were mild nasal discomfort (9.7%) and mild headache (6%), with no correlation of nasal discomfort to pain or irritation
  - Mean VAS pain scores between 5 to 8 out of 100
  - No irritation based on formal assessment
- No serious adverse events in any clinical study
- No risk of needle-related injuries or blood vessel injections with *neffy*

U.S. prescribing information for *neffy*: robust response on PD surrogate markers for efficacy

Figure 1: Median Pulse Rate (PR) and Systolic Blood Pressure (SBP) Change from Baseline Following One Dose of Epinephrine in Healthy Subjects [Study 1]

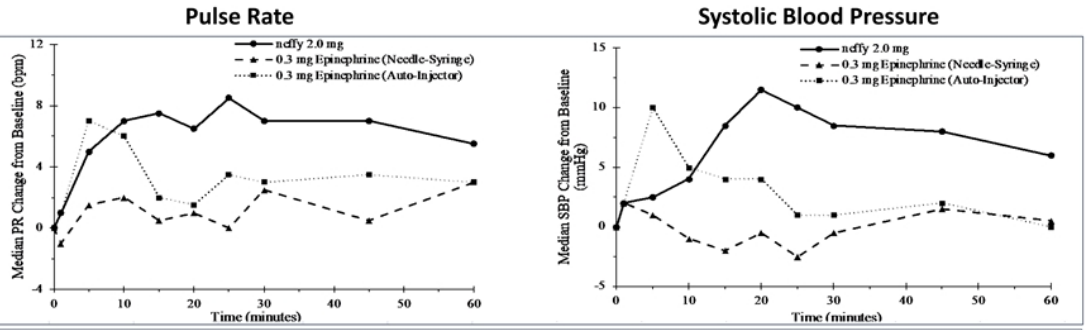
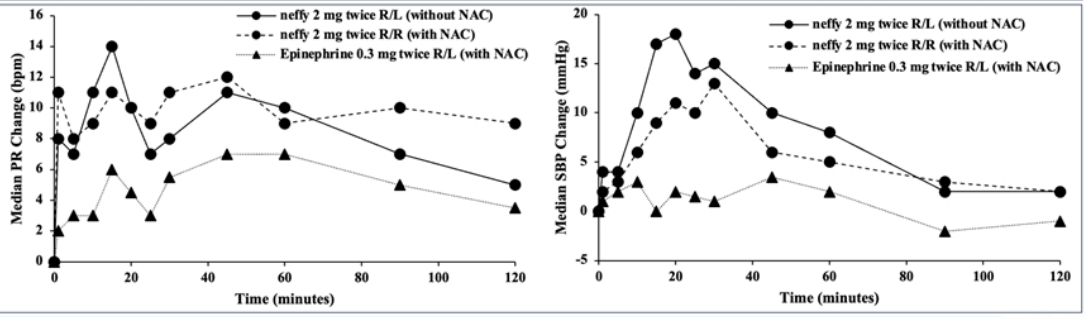


Figure 2: Median Change from Baseline for Systolic Blood Pressure (SBP) and Pulse Rate (PR) Following Two Doses of Epinephrine Administered 10 Minutes Apart in Right and Left Nares (R/L) or Right and Right Nares (R/R) in Subjects with Allergic Rhinitis with and without Nasal Allergen Challenge (NAC) [Study 4]



US launch is first step to making *neffy* available to more patients worldwide

sNDA for 1 mg dose (15 to 30kg children) expected to be filed with FDA in Q3 2024

Positive marketing authorization application (CHMP opinion) by EMA in June 2024

Product availability and Europe partnership announcement expected later in 2024

China NDA filing expected in 2024 (partnered with Pediatrix)

Australia MAA filing expected in 2024 (partnered with CSL Seqirus)

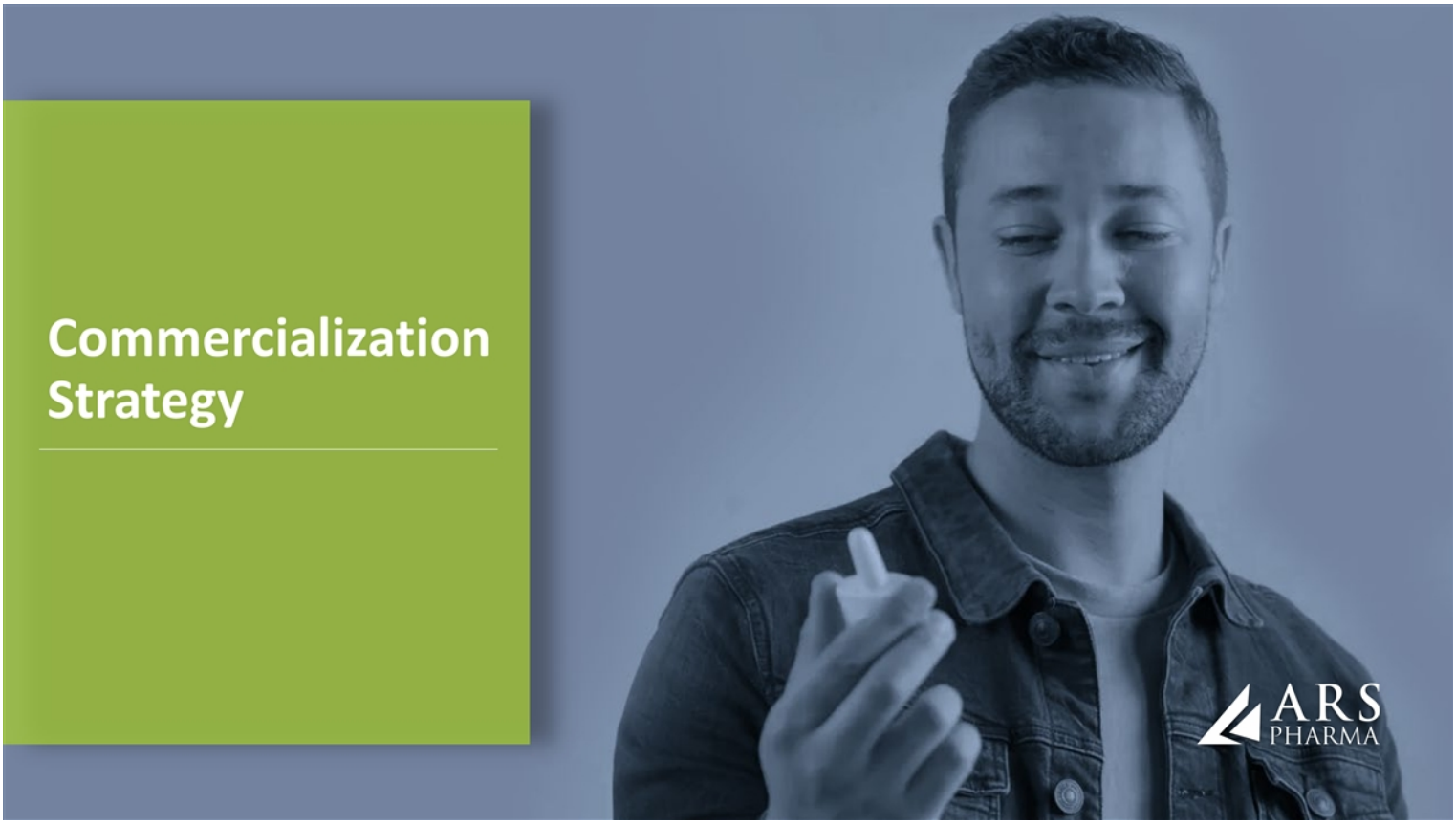
Japan NDA filing expected in 2024 (partnered with Alfresa)

Planning in progress for filing in other major ex-US regions including Canada

Expansion opportunities

- Data from Phase 2b randomized placebo-controlled trial in CSU patients on antihistamine therapy still experiencing acute exacerbations expected in 2025
- Potential single pivotal study in urticaria to initiate after Phase 2b study

Commercialization Strategy



Significant Opportunity to Address Unmet Needs in Current US Severe Allergic Reaction Market

Epidemiology prevalence data estimates ~40M patients with type 1 allergic reactions[2-9]

~20M diagnosed and under physician care over the last 3 years[10]

6.5M prescribed epinephrine[10]
Primarily managed by allergists & pediatricians

~3.2M fill ~5M 2-pack units of injectables annually, but ~80-90% do not use as indicated[11]
(1) do not carry (~50%), (2) do not inject (25-60%), (3) wait (40-60%) or (4) dose incorrectly (23-35%)

~3.3M don't fill regularly, haven't refilled or haven't filled – an additional ~5M 2-pack unit opportunity[10]
Due to limitations of autoinjectors including needle, size and portability

~13.5M Type I diagnosed but not prescribed Rx (past 3 years)[10]
Primarily managed by non-allergists and non-pediatricians
Diagnosing HCP not well-educated about treating anaphylaxis

Consistent Market Growth (Units)
+6.5% CAGR since 2010, +12.7% YoY in 2023[1]

Promotional Responsiveness
~50% increase over market growth trend with consumer promotion (2010 to 2015[1])

References: 1. Based on IQVIA prescription data (~5.2 million two-packs sold in 2023). **2.** Gupta RS, et al. *Pediatrics.* 2011. **3.** Gupta RS, et al. Pediatrics 2018. **4.** McGowan EC, et al. *J Clin Allergy Immunol.* 2013. **5.** Jackson KD, et al. *NCHS Data Brief.* 2013. **6.** Black LI, et al. CDC National Center for Health Statistics Data Brief. 2019. **7.** Gupta RS, et al. *JAMA Netw Open.* 2019. **8.** Verrill L, et al. *Allergy Asthma Pro.* 2015. **9.** Bilo BM, et al. *Current Opin Allergy Clin Immunol.* 2008. **10.** IQVIA Claims Data, 2023. **11.** Based on calculations from Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018., Rooney E, et al. Poster Presentation at *ACAAI 2022* (Louisville, KY). Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017., El Turki A, et al. *Emerg Med J.* 2017., Asthma and Allergy Foundation of American Patient Survey Report 2019, and Mehta GD, et al. *Expert Rev Clin Immunol.* 2023.

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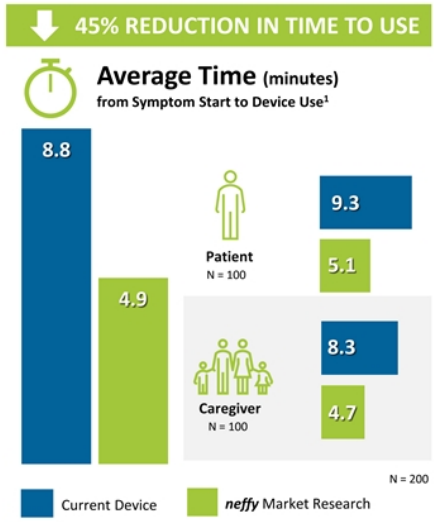
neffy: Innovative Treatment to Overcome Known Challenges with Needle-Injectors for SAR Patients

Benefits of needle-free alternative to address major unmet needs

- More allergy patients and caregivers are likely to carry ***neffy*** compared to current needle-bearing options[3]
- Patients are likely to dose ***neffy*** more rapidly with a needle-free device[1]



References: 1. Kaplan H, et al. Presentation at ACAAI 2022 (Louisville, Kentucky). **2.** Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018. **3.** ARS market research on file.

HCPs Indicate Substantial Opportunity to Convert and Grow Market

May 2024 ATU, Sample = 202 HCPs

87%

How Likely Would You Be to Prescribe *neffy* Upon Availability?*

****Would Prescribe to Definitely Prescribe***

66%

What % of the Time Would You Offer *neffy* to Your Patients that Currently Fill an Injectable Rx?

70%

Anticipated % of Patients that Don't Fill or Re-Fill Injectables with an active *neffy* Rx at One Year

References: 1. HCP Awareness, Trial, and Usage ("ATU") Market Research Study, May 2024

neffy Strategic Objectives for Commercialization

EDUCATE PRESCRIBERS
Drive adoption within specialty and high decile prescribers on the compelling value-proposition of ***neffy***

FACILITATE ACCESS
neffy access, affordability and support services

ACTIVATE PATIENTS
Create awareness and motivate patients and caregivers to seek ***neffy***

EDUCATE

Drive adoption within specialty and high decile prescribers

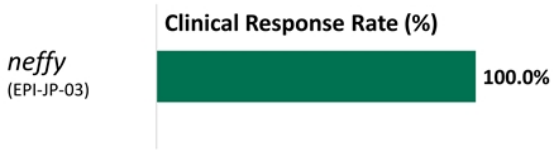
Healthcare Provider Launch Objectives

- Commercial force of 110 Sales and Virtual Representatives and Area Sales Managers
- Calling on 12,500 Allergy Specialists and High Decile Prescribers
  - Reaching 40-45% of Prescriptions from all HCPs
  - Reaching >80% of Prescriptions from Allergists and Pediatricians
- Education, awareness, and resources to drive adoption (***neffy*** Experience)

EDUCATE

neffy shows robust and rapid clinical resolution of oral food challenge anaphylaxis symptoms (preview of *neffy* Experience in US)

Efficacy Study of *neffy* in Oral Food Challenge Induced Anaphylaxis (EPI-JP-03, n = 15 pediatric subjects)[1]



100% of patients responded to a single dose of *neffy* in the first 15 minutes, and did not require a second dose of epinephrine per treatment guidelines

100% of patients experienced complete resolution of the anaphylaxis symptoms with single dose of *neffy*[2]

16 min median time to complete resolution of anaphylaxis following single dose of *neffy*

neffy Experience Program (rescue therapy at allergy challenge clinics)

- Enable real-world experience with ***neffy***
- Target allergist offices that conduct in-office food challenge testing
- HCPs will have the ability to gain first-hand knowledge of ***neffy's*** effectiveness
- Patients undergoing allergy challenge will also be exposed to ***neffy***

References: 1. Ebisawa M, et al. Presentation at AAAAI 2024 (Washington DC). **2.** 100% of EPI-JP-03 patients dosed with *neffy* did not require a second dose in the first 15 minutes per guidelines because a response was not being observed, and 100% of patients achieved complete resolution of symptoms. 1 of the 15 subjects (6.7%) challenged with egg experienced a biphasic reaction 2h 45 min after being dosed with a single dose of *neffy* and achieving complete resolution of symptoms. This is consistent with the 12.8% frequency of biphasic reactions reported in children with food-induced anaphylaxis.(Gupta RS, et al. *J Allergy Clin Immunol Pract*. 2021).

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FACILITATE

Committed to ensuring *neffy* access for all patients

neffyconnect

Virtual pharmacy (BLINKRx) available to Healthcare Providers via EMR systems which centralizes all services for *neffy* fulfillment

- Patient education and training resources
- Inclusive insurance support and co-pay buydown (down to $25)
- Benefit investigation, prior authorization, and appeals support
- Home delivery or retail pick up
- Triage to Patient Assistance Program (PAP)

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FACILITATE

neffy profile supports strong value-proposition, and offers potential savings to patients and payers

INNOVATION

ARS is proud to bring an innovative treatment option to the marketplace that provides freedom and peace of mind by enabling patients to dose at first sign of allergic symptoms

SUPPORT

ARS is committed to the SAR community of patients, caregivers, advocates, and physicians – **co-pay buy-down to $25 for commercial patients**, and **patient assistant program**

ACCESS & AFFORDABILITY

ARS believes that affordability should never prevent access: ***neffy***connect was developed to deliver on that commitment
Cash price for two doses of *neffy* is $199

RAPID & BROAD UNRESTRICTED FORMULARY COVERAGE

anticipated given high degree of interest in ***neffy***, positive receptivity in early conversations, strong value proposition vs. competition, and programs to support formulary exceptions

	neffy	Branded IM Injection	Generic IM Injection
Patient Co-Pay – most insured	**$25**	**$35**[1]	Avg **$40**
Cash Price - uninsured	**$199**	**$150-$289**[1]	**$111-$272**
Product expiration (up to)	30 months	18 months	18 months
Average Patient Cost Per Month (Co-Pay or Cash Price/Shelf Life)	**$0.83 / $6.63**	**$1.94 / $12.19**	**$2.22 / $10.63 (average)**

References: 1. Cash price is available only through Aspen (Specialty Pharmacy) and Walgreens, **2.** List price (WAC) of two doses of *neffy* is $710

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ACTIVATE

Create awareness & motivate to seek *neffy*

Consumer Launch Objectives

- Drive awareness & motivate patients to request ***neffy*** by name
- Enable patients and caregivers to feel fully empowered to act during a potential crisis moment
- Activate patients and caregivers to share their ***neffy*** story to encourage peer uptake

neffy: The only needle-free way to administer epinephrine

- Rapid, reliable delivery
- Small and easy to carry
- Place and Press administration
- Well-tolerated in extensive trials

Expected availability in 8 weeks

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Closing Thoughts
*Post-Marketing Requirements/Post-Marketing Commitments
ARS
PHARMA

ARS in 2024 and beyond

neffy® in type I allergies

- Q3 2024: 2 mg availability with commercial field force deployed in parallel
- Q3 2024: Anticipated sNDA for 1 mg dose to be filed with FDA
- Mid-2025: Targeted at least 80% unrestricted access in US

Global opportunity and pipeline

- Q3 2024: Anticipated approval in Europe
- 2024: Filings by partners in Australia, China and Japan; filings in Canada and others
- 2025: Phase 2b trial results expected for treating acute urticaria exacerbations in CSU patients on antihistamine therapy

Solid company fundamentals

- Strong balance sheet of $218.7M[1]
- Expected operating runway of at least 3 years to support US commercialization
- Robust composition of matter and method of treatment IP protection through at least 2038

1. Cash, cash equivalents and investments as of June 30, 2024

We appreciate your unwavering support and commitment to *neffy*!

Patients

Parents and Caregivers

Advocates

ARS Employees

THANK YOU!

Advisors and Directors

ARS Stakeholders and Investors

Healthcare Professional and Study Investigators

ARS PHARMA

neffy® *(epinephrine nasal spray)*

NOW APPROVED!

INDICATION

neffy is indicated for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in adults and children who weigh ≥30kg

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Appendix

neffy Designed for Ease of Use and Easy Carry and to Minimize Risk of Side Effects

Relative Size of *neffy* two pack
Compared to iPhone 15 and EpiPen

*Case holds **two** neffy 2mg devices*

- Proprietary Intravail technology allows consistent intranasal absorption
- High bioavailability at low 2 mg dose minimizes risk of side effects
- No meaningful pain or irritation
- Issued composition of matter and method of treatment patent exclusivity until at least 2038

ARS PHARMA

Differentiated FDA label for *neffy* compared to injection may reduce hesitancy to dose and lead to broader adoption

Label differentiation	Injection[1]	*neffy*[2]
1. Emergency medical assistance after dosing not automatic, consistent with new AAAAI treatment guidelines	"In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care."	"Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode, and in the event further treatment is required."
2. Removes all injection-related warnings and precautions, which may reduce anxiety and hesitation to dose	• Accidental IV injection may result in cerebral hemorrhage • Accidental injection into digits, hands or feet may result in loss of blood flow to the affected area, and immediate visit to emergency room • Needle-related injury due to lacerations, bent needle and embedded needles • Serious injection site infections including necrotizing fasciitis and myonecrosis	No injection-related warnings or precautions
3. Wider temperature stability, which may facilitate carriage and continuous readiness	Excursions permitted from 59°F to 86°F	Excursions permitted from 5°F to 122°F

References: 1. EpiPen FDA Label – Prescribing Information (2/2023), 2. *neffy* FDA Label – Prescribing Information (8/2024)

neffy can address the unmet need and is aligned with what patients and parents want[1]

n = 392
Current Users

88% OF PATIENTS LIKELY TO VERY LIKELY TO ASK THEIR PHYSICIAN ABOUT *neffy Rx*[1]

89% OF NON-FILLING PATIENTS STATED THEY WOULD ASK THEIR PHYSICIAN ABOUT *neffy* RX[1]

n = 88
Non-fillers

72%
OF THE TIME,
PEOPLE WHO USE AN OTC WOULD USE *neffy* FIRST[2]

81%
OF PEOPLE
WOULD USE *neffy* SOONER THAN CURRENT NEEDLE INJECTORS[3]

References: 1. ARS patient market research on file. 2. Lowenthal R, et al. Presentation at AAAAI 2023 (San Antonio, Texas). 3. Kaplan H, et al. Presentation at ACAAI 2022 (Louisville, Kentucky).

ARS PHARMA

neffy profile including 30-month shelf-life may increase market opportunity within current active Rx patient segment

	neffy	needle-injectors
Shelf-life (up to)	30 months	~18 months
Time between refills	18 months (patient market research)[1]	15 months (IQVIA longitudinal data)[2]
Preference share	~15 absolute % point increase in patient preference share vs. 18-month shelf-life[1]	
Cartons* per refill cycle	Greater than 2 cartons/cycle[1]	1.2 to 1.4 cartons/cycle[2]
Likelihood to use device	72% would use *neffy* instead of OTC antihistamine prior to autoinjector[3] 45% reduction in time to use vs. autoinjector[4]	

*One carton contains two devices

Anticipate strong volume growth among today's active Rx patient segment, in addition to lapsed/non-filler and untreated patient segments

References: 1. ARS patient market research on file, **2.** IQVIA longitudinal patient data, **3.** Lowenthal R, et al. Presentation at AAAAI 2023 (San Antonio, Texas), 4. Kaplan H, et al. Presentation at ACAAI 2022 (Louisville, Kentucky).