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

September 25, 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 7.01. Regulation FD Disclosure.

On September 25, 2023, ARS Pharmaceuticals, Inc. (the "Company") updated its corporate presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information under this Item 7.01 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 otherwise 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) Exhibits

Exhibit No.	Description
99.1	Company Presentation
104	Cover Page of 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.

Date: September 25, 2023

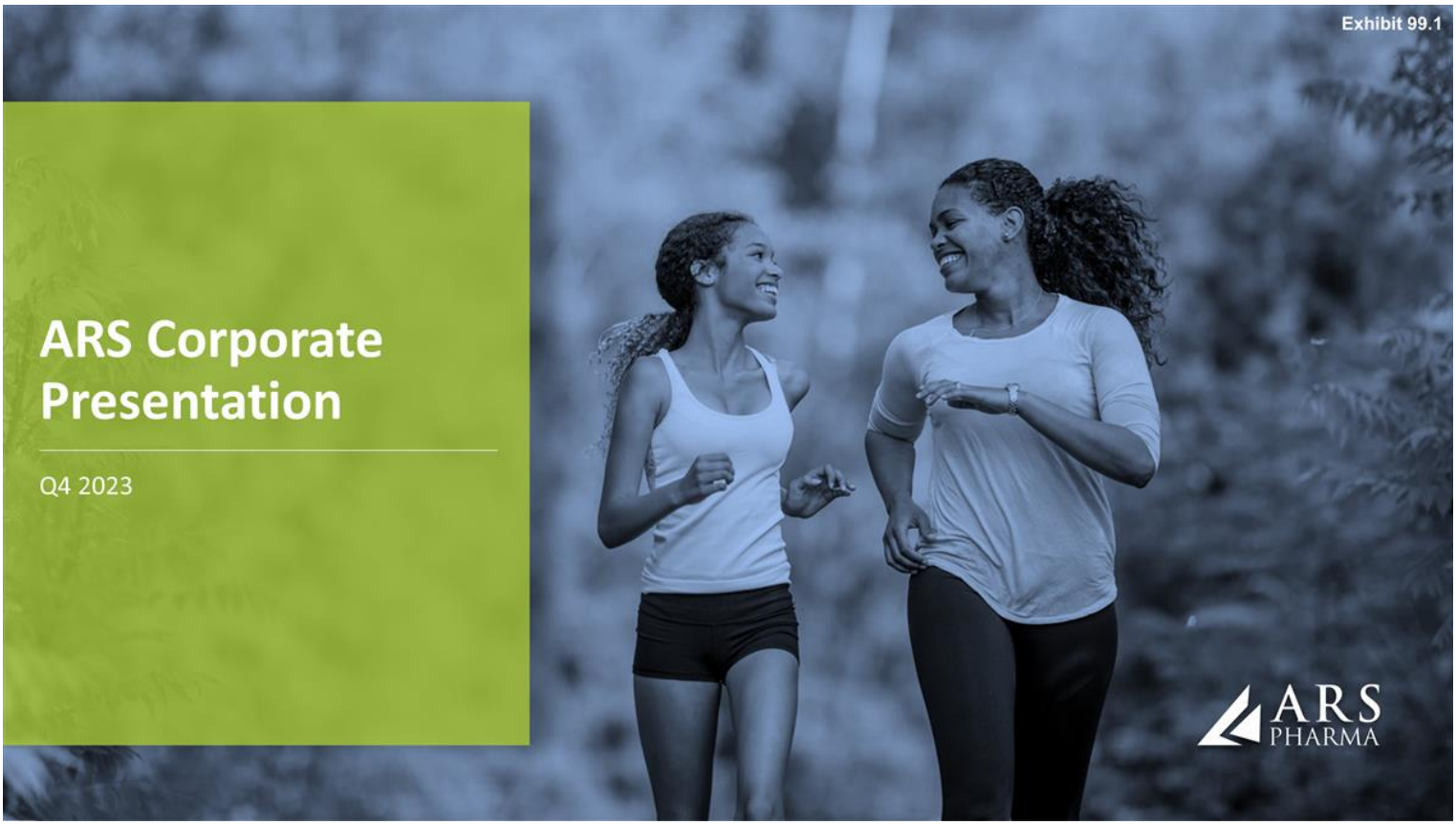
ARS Pharmaceuticals, Inc.

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

Exhibit 99.1

ARS Corporate Presentation

Q4 2023



Forward looking statements

This presentation contains forward-looking statements which include, but are not limited to, statements regarding: ARS's ability to complete the newly required trial and provide the additional information requested by the FDA in the CRL on the timing anticipated, or at all; the potential approval of ***neffy*** and the expected timing of the U.S. launch of ***neffy***; the potential market, demand and expansion opportunities for ***neffy***; ARS's expected competitive position; the design and potential benefits of ***neffy*** if approved, including the likelihood that doctors will prescribe ***neffy*** and that allergy patients and caregivers will choose to carry and dose ***neffy*** compared to needle-bearing options; the likelihood of ***neffy*** attaining favorable coverage; ARS's anticipated cash, cash equivalents and short-term investments on hand upon any future approval and launch of ***neffy***; 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. ARS's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the ability to obtain and maintain regulatory approval for ***neffy***; the ability to successful complete the newly requested trial on the timeframe anticipated, or at all, as a result of challenges inherent to enrolling, conducting and completing clinical trials; the results of the new clinical trial may not support 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'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 June 30, 2023, filed with the Securities and Exchange Commission ("SEC") on August 10, 2023. This and other documents ARS files with the SEC can also be accessed on ARS's website at ir.ars-pharma.com by clicking on the link "Financials & Filings."

The forward-looking statements included in this presentation 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 PHARMA

Potential to Transform the Treatment of Type I Allergic Reactions

- ***neffy®*: first potential "no needle, no injection" solution** for Type I allergic reactions to address an unmet market need
- **Registration program** demonstrates comparable PK and PD, without risk of needle-related safety concerns, fear and hesitation
- **Rapid and statistically significant response on PD surrogates for efficacy (SBP, HR)** observed even 1 minute after dosing with *neffy* vs. injection
- **Significant opportunity to disrupt** current epinephrine injectables market
- **FDA AdCom supports favorable benefit-risk assessment, but FDA requested one additional study (twice-dosing nasal challenge study)**
- **Anticipated NDA resubmission in H1 2024, with FDA action in H2 2024**
- **Potential multi-billion-dollar market** driven by HCP and consumer preference and adoption
- **NCE-like IP exclusivity** potential until at least 2038
- **$252 million in cash and securities** as of 6/30/2023 with an anticipated $195 million in cash and securities at anticipated FDA action in H2 2024

ARS PHARMA

Unmet need / current challenges

PROBLEM	NO TREATMENT AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
ONLY 10% - 20% of patients with active Rx use as indicated[7]	~50% of patients carry[1] (<20% carry two)	~25% - 60%[1, 3, 5, 6] do not administer	~40 - 60%[2] of patients delay	23 - 35%[4] fail to dose correctly

neffy SOLUTIONS

SMALL

- Fits in your pocket; can carry more than 1
- ~10% of cases require multiple doses of epinephrine[1]

NO NEEDLE NO INJECTION

- Rapid administration without a needle
- No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections
- Less hesitation to dose

EASIER AND MORE CONSISTENT DOSING

- 0% critical dosing errors in registration self-administration study
- Low 2 mg dose of *neffy* achieves comparable PK without overexposure risk

RELIABLE

- 99.999% delivery of effective dose in reliability testing; no inhalation required
- 24 month shelf-life at room temperature, with up to 3 months at high temperatures (122ºF)

1. Warren et al. Ann Allergy Asthma Immunol (2018), 2. Data on file from ARS market research, 3. Brooks et al. Ann Allergy Asthma Immunol (2017), 4. El Turki et al. Emerg Med J (2017), 5. Asthma and Allergy Foundation of America Patient Survey Report (2019), 6, Mehta et al. Expert Review of Clinical Immunology (2023), 7. Company estimates based on prior references (1) through (6) and IQVIA data

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neffy Designed for Needle-free, Easier Carriage

ARS PHARMA

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

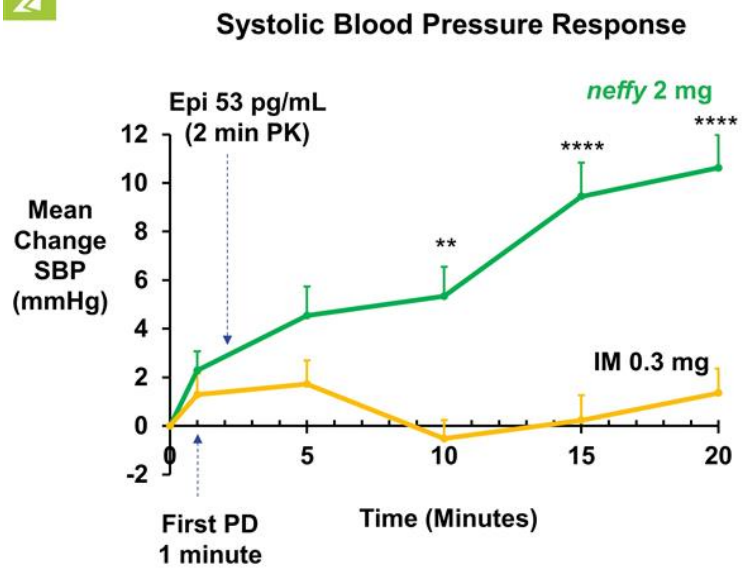
PD and PK Data

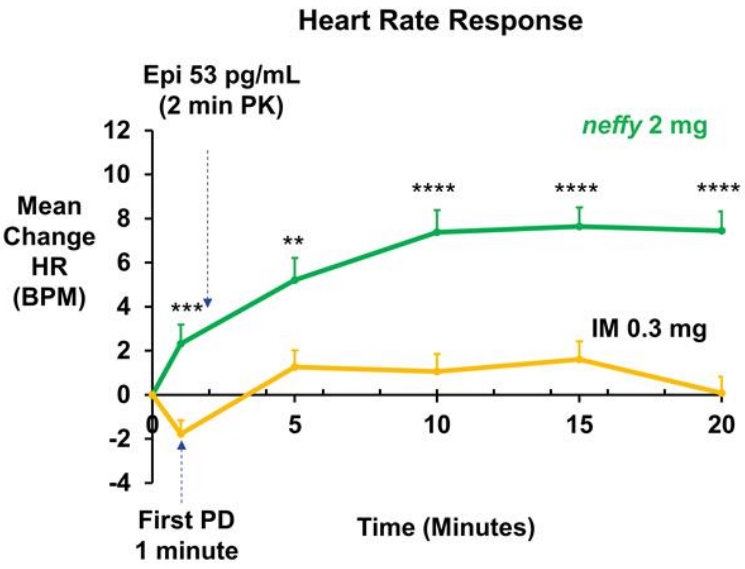
- 2 mg *neffy* met all clinical endpoints
- PD surrogates for efficacy comparable to approved products (SBP/HR ≥ approved injection products)
- Rapid and significant response on PD surrogates for efficacy observed even 1 minute after dosing
- PK bracketed by approved products (exposures ≥ IM/SC for efficacy,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

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%) 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*

Robust response on PD surrogate markers for efficacy



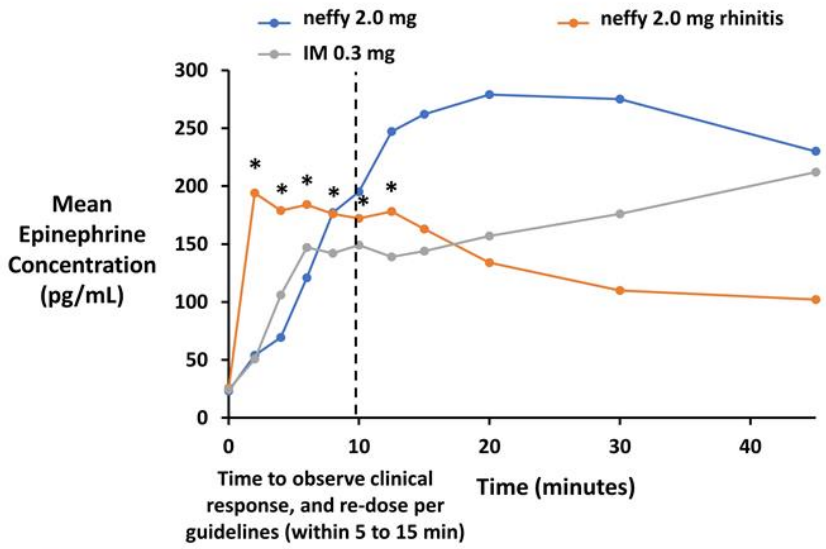


Significance level: ** p <0.01, *** p <0.001 **** p <0.0001

7 *Integrated analysis of ARS clinical studies (EPI-15 and EPI-16)*

neffy shows enhanced absorption during critical period of clinical response following nasal allergen-challenge (NAC)

Single-dose nasal challenge results in allergic rhinitis subjects

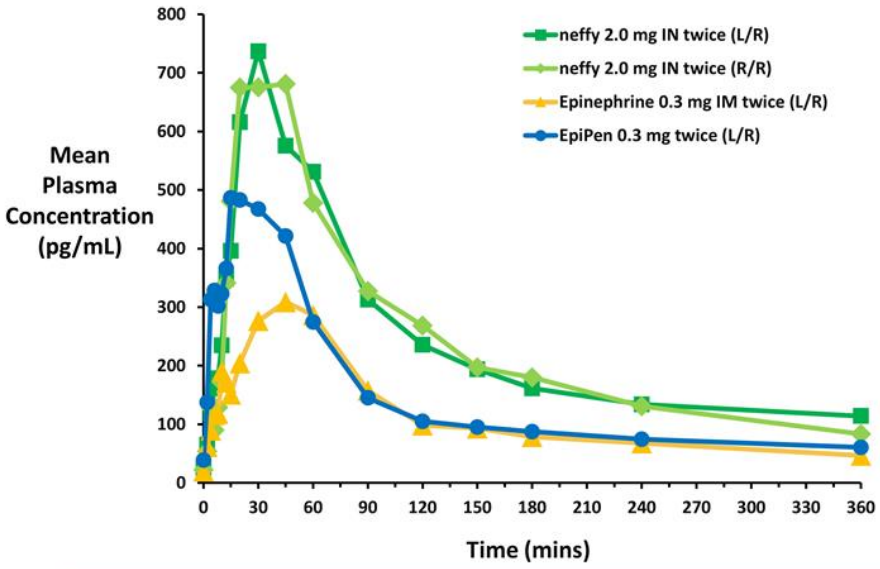


- Nasal congestion accelerates absorption of *neffy* in first 20 min
- Treatment guidelines recommend giving a second dose if no response is observed within 5 to 15 minutes of administration
- FDA Advisory Committee viewed NAC study data as "encouraging" and "favorable" due to the greater concentration levels during the time period when clinical response is observed with epinephrine
- FDA reported that the rate of nasal mucosal symptoms in anaphylaxis patients ranges from 2 to 11%

* Statistically significant differences between *neffy* with rhinitis compared to IM injection ($p < 0.05$)

FDA Complete Response Letter requests nasal allergen challenge (NAC) study with repeat doses of *neffy*

Repeat-dosing (10 min apart) results in healthy subjects



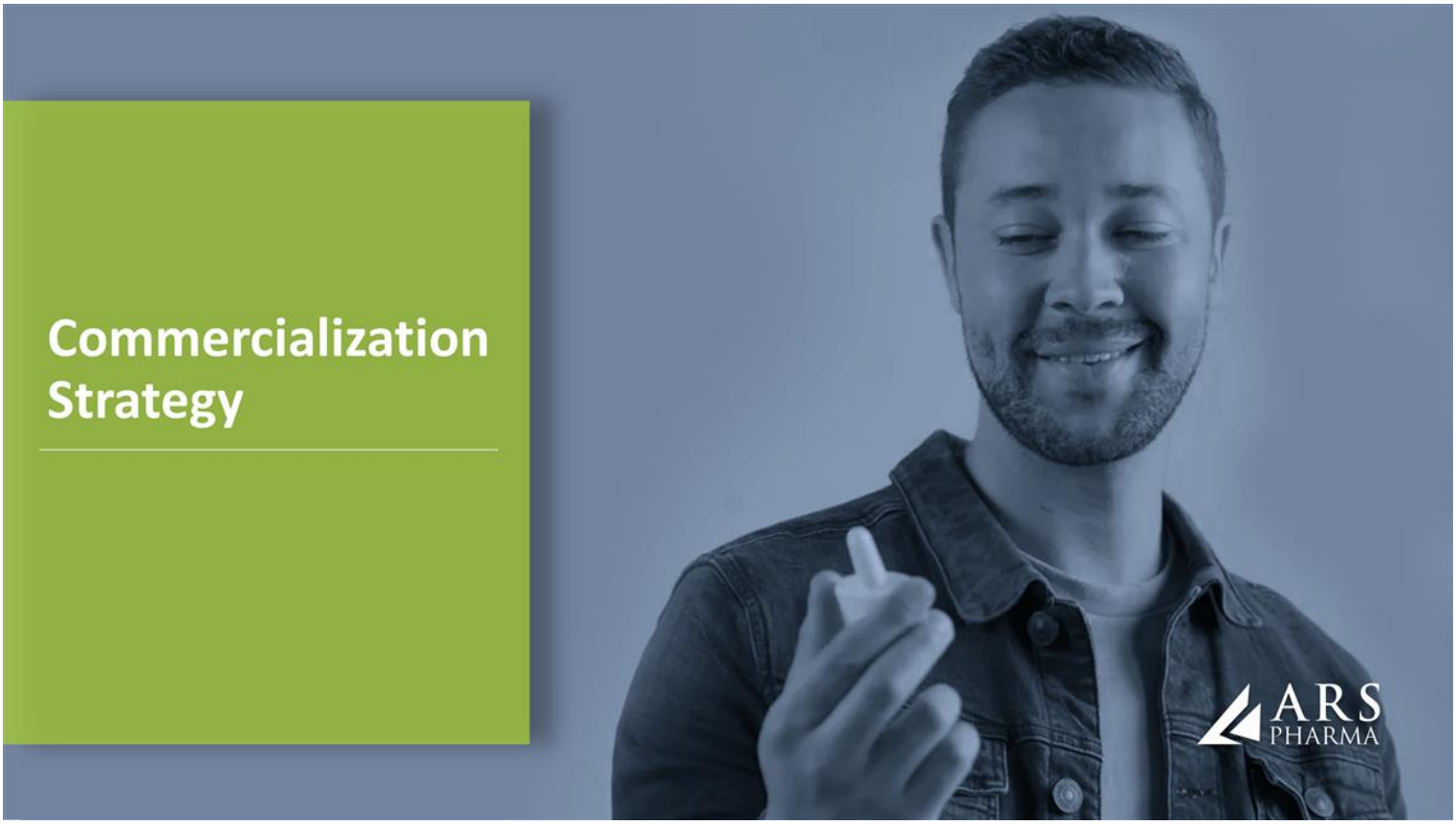
- *neffy* with repeat dosing is dose-proportional, whereas the approved injection products are not, and therefore overall exposure of *neffy* is higher
- FDA requested additional study to confirm that *neffy*'s repeat dose PK profile is at least comparable to repeat doses of injection under nasal allergen challenge conditions
- NDA resubmission expected in 1H 2024 with FDA action expected in 2H 2024

neffy market exclusivity potential until at least 2038

Extensive studies in the lab and clinic completed to develop a proprietary product with expected NCE-like exclusivity

- ✓ **Issued composition of matter patent (US10,576,156) on Intravail® + epinephrine** provides foundational exclusivity blocking any generic products. **Method of treatment patents (US11,173,209; US11,191,838)** block other alkyl glycosides.
- ✓ **Issued method of treatment patent (US10,682,414)** blocks any intranasal epinephrine product using a different technology using a low dose (<2.5 mg)
- ✓ **PCT patent granted in Europe (EP19751807), UK (GB2583051), Japan (JP6941224), Canada (3088909), Australia (AUS2019217643), Korea (10-2375232), China (2019800010042),** with same claims as the US

Commercialization Strategy



Significant opportunity to address unmet needs in current US severe allergic reaction market (~$1B[1])

Consistent Market Growth
+5% y/y in the last ~15 years[1]

Promotional Responsiveness
~30% historic lift with meaningful promotion[1]
Currently no meaningful promotion

Prevalence data estimates 40M patients with type 1 allergic reactions[2]

16M diagnosed and under physician care[3]

~11M Type 1 diagnosed and under care; no treatment

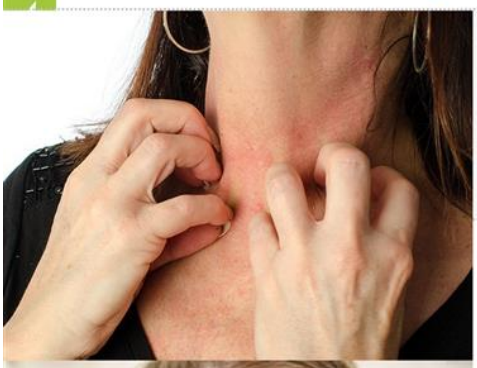
~3.3M patients fill Rx, but ~80-90% do not use as indicated[3]
(1) do not carry (~50%), (2) do not inject (25-60%), (3) wait to inject (40-60%) or (4) dose incorrectly (23-35%)

~2.5M haven't filled or refilled

1. Based on IQVIA data (~5 million two-packs sold per year) and weighted average generic/branded epinephrine auto-injector net pricing, 2. Gupta RS et al. Pediatrics (2011), Gupta RS et al. Pediatrics (2018), McGowan EC et al. JACI (2013), Jackson KD et al. NCHS (2013), Black LI et al. CDC (2019), Gupta RS et al. JAMA Open Network (2019), Verrill et al. Allergy Asthma Pro (2015), Bilo BM et al. Current Opin Allergy Clin Immunol (2008), 3. IQVIA Claims Data

ARS PHARMA

neffy has the ability to address the unmet need and is aligned with what healthcare providers, 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 AUTOINJECTOR[3]

1. ARS patient market research on file (2023), 2. Lowenthal et al. AAAAI 2023 (Poster #20), 3. Kaplan et al. ACAAI 2022 (Poster P008)

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Physicians supportive of adopting *neffy* into practice

n = 75 Physicians

8.5 out of 10 rating[1]

viewed as a major advance in therapy

10 = MAJOR ADVANCE / **1** = NOT AN ADVANCE AT ALL

100%

Would prescribe *neffy* if their patients asked for it

*No difference in uptake of **neffy** by physician specialty*[1]

1. *ARS physician market research on file (n = 75)*

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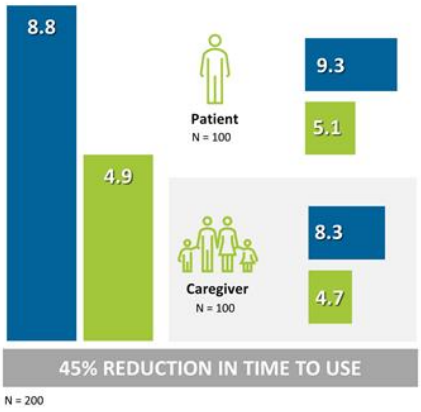
neffy: innovative treatment to overcome known challenges with injectables for SAR patients

Benefits of needle-free alternative to major unmet medical needs

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

Average Time (minutes) from Symptom Start to Device Use[1]



N = 200

% of Time Carrying at least One Epinephrine Device[2,3]

1. Kaplan et al. ACAAI 2022 (Poster P008). 2. Warren et al. Ann Allergy Asthma Immunol 2018. 3. ARS patient survey data on file

neffy strategic objectives

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***

neffy: the first needle-free way to administer epinephrine

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

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