

**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

February 14, 2023
Date of Report (Date of earliest event reported)

ARS Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39756
(Commission
File Number)

81-1489190
(IRS Employer
Identification No.)

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

92130
(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 February 14, 2023, ARS Pharmaceuticals, Inc. (the “Company”) announced in its corporate presentation that as of December 31, 2022, it had approximately \$275 million in cash and securities.

The information in this Item 2.02 of this Current Report on 8-K is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). 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 7.01. Regulation FD Disclosure.

On February 14, 2023, 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 Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. 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**

<u>Exhibit No.</u>	<u>Description</u>
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: February 14, 2023

ARS Pharmaceuticals, Inc.

By: /s/ Richard Lowenthal, M.S., MSEL

Name: Richard Lowenthal, M.S., MSEL

Title: President and Chief Executive Officer



THE FIRST NO-NEEDLE,
NO-INJECTION SOLUTION
for Type I Allergic Reactions



Q1 2023



Forward looking statements

This presentation contains forward-looking statements which include, but are not limited to, statements regarding the design and potential benefits of *neffy*; the anticipated Prescription Drug User Fee Act (PDUFA) date for *neffy*; the timing of regulatory approval for and the commercial launch of *neffy*, if approved; ARS Pharma's commercialization strategy; the potential market opportunity for *neffy*; the projected growth thereof and *neffy*'s ability to capture and grow that market; ARS Pharma's expected competitive position; ARS Pharma's potential to become the standard in treatment and transform the treatment of allergic reactions; the likelihood of *neffy* attaining favorable coverage; 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 Pharma'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*; 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; the ARS Pharma's ability to protect its intellectual property position; the impact of health epidemics or pandemics on ARS Pharma's business and the actions ARS Pharma may take in response thereto; 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—Risks Related to ARS Pharma" heading of the company's definitive proxy statement on DEFM14A filed with the Securities and Exchange Commission on October 6, 2022, available at www.sec.gov. These documents can be also accessed on ARS Pharma's web page at www.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 Pharma does not assume any obligation and does not intend to update these forward-looking statements, except as required by law.

Potential to Transform the Treatment of Type I Allergic Reactions



- **neffy: first “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
- **Significant opportunity to disrupt** current epinephrine injectables market
- **NDA accepted by FDA; mid-2023 PDUFA date anticipated**
- **Potential multi-billion-dollar market** driven by HCP and consumer preference and adoption
- **NCE-like IP exclusivity** potential until at least 2038
- **~\$275 million in cash and securities** as of 12/31/2022

Proven leadership team with track record developing and commercializing intranasal and consumer-driven medicines



Richard Lowenthal, M.S.
Chief Executive Officer, Co-Founder
 Led FDA approvals for multiple nasal spray products
 25+ years of experience



Sarina Tanimoto, M.D.
Chief Medical Officer, Co-Founder
 Led FDA approvals for multiple nasal spray products
 20+ years of experience



Eric Karas
Chief Commercial Officer
 Led Narcan® commercial ops at Emergent/Adapt, and Auxilium specialty
 25+ years of experience



Harris Kaplan
EVP, Commercial Strategy
 40+ years of commercial strategy across more than 125 product launches



Dan Relovsky
SVP, Marketing
 30+ years of marketing, sales and operational experience across specialty and consumer markets



Brian Dorsey
Chief Operating Officer
 25+ years of R&D experience as including multiple head of R&D roles including Pernix, Apricus and Somaxon



Kathy Scott
Chief Financial Officer
 30+ years of finance experience with multiple CFO roles including Neurana, Recros and Oncernal



Alex Fitzpatrick
Chief Legal Officer
 30+ years of legal experience with multiple GC roles including Evofem, Kyriba, Verenium, Blackbaud



Justin Chakma
Chief Business Officer
 10+ years of M&A, licensing, financing and strategy experience including Celgene, Receptos and Auspex



Robert Bell, Ph.D.
Chief Scientific Officer, Co-Founder
 30+ years of senior R&D leadership experience including Barr and Somerset

Top-tier board of directors



Pratik Shah, Ph.D.

Chairman of Board of Directors
Executive Chairman at Design,
Former Chairman of Synthorx
(acq. \$2.5B), Former CEO at
Auspex (acq. \$3.5B)



Richard Lowenthal, M.S.

Chief Executive Officer, Co-Founder
Led FDA approvals for
multiple nasal spray products
25+ years of experience



Laura Shawver, Ph.D.

CEO at Capstan, former CEO at
Silverback, Synthorx (acq. \$2.5B)



Peter Kolchinsky, Ph.D.

Managing Partner and Founder
at RA Capital



Brent Saunders

Chairman at The Beauty Health Co.,
Former CEO of Allergan (acq. \$63B),
Actavis, Forest Labs, and Bausch +
Lomb (acq. \$8.7B)



Jonathan Leff

Partner at Deerfield Management
Chairman of Deerfield Institute



Peter Thompson, M.D.

Private Equity Partner at Orbimed



Rajeev Dadoo, Ph.D.

Managing Partner at SR One



Michael Kelly

Former President, US Operations at
Adapt (acq. \$735M), CEO at Covis
(acq. \$1.2B), founder at Azur



Philip Schneider

Former CFO at IDEC, former Board
member at Arena (acq. \$6.7B), Auspex
(acq. \$3.5B), GenProbe (acq. \$3.7B)



Saqib Islam, J.D.

CEO of Springworks, former CBO at
Moderna and EVP at Alexion

Type I allergic reactions: a life-threatening hypersensitivity reaction

Caused by exposure to a **specific allergen**, most commonly **food, venom, drugs**



~25 to 40 million people in US with systemic Type I allergic reaction to allergens (e.g., 2+ organ systems involved)



10+ million people with other Type I allergy indications (e.g. urticaria flares, asthma exacerbations)



Significant co-morbidities and symptomatic impact on patient quality of life



More than half a million¹ ER visits each year due to systemic Type I allergic reactions, costing an average of \$1600+ per visit²

Epinephrine is effective, but significant device limitations exist



Epinephrine recognized as the **only first-line therapy** by allergy society treatment guidelines¹, but...

Apprehension to dose due to needle

Lack of portability

Reluctance to use in public

Safety concerns: lacerations, caregiver self-injection, blood vessel hits

Lack of reliability

Not user friendly



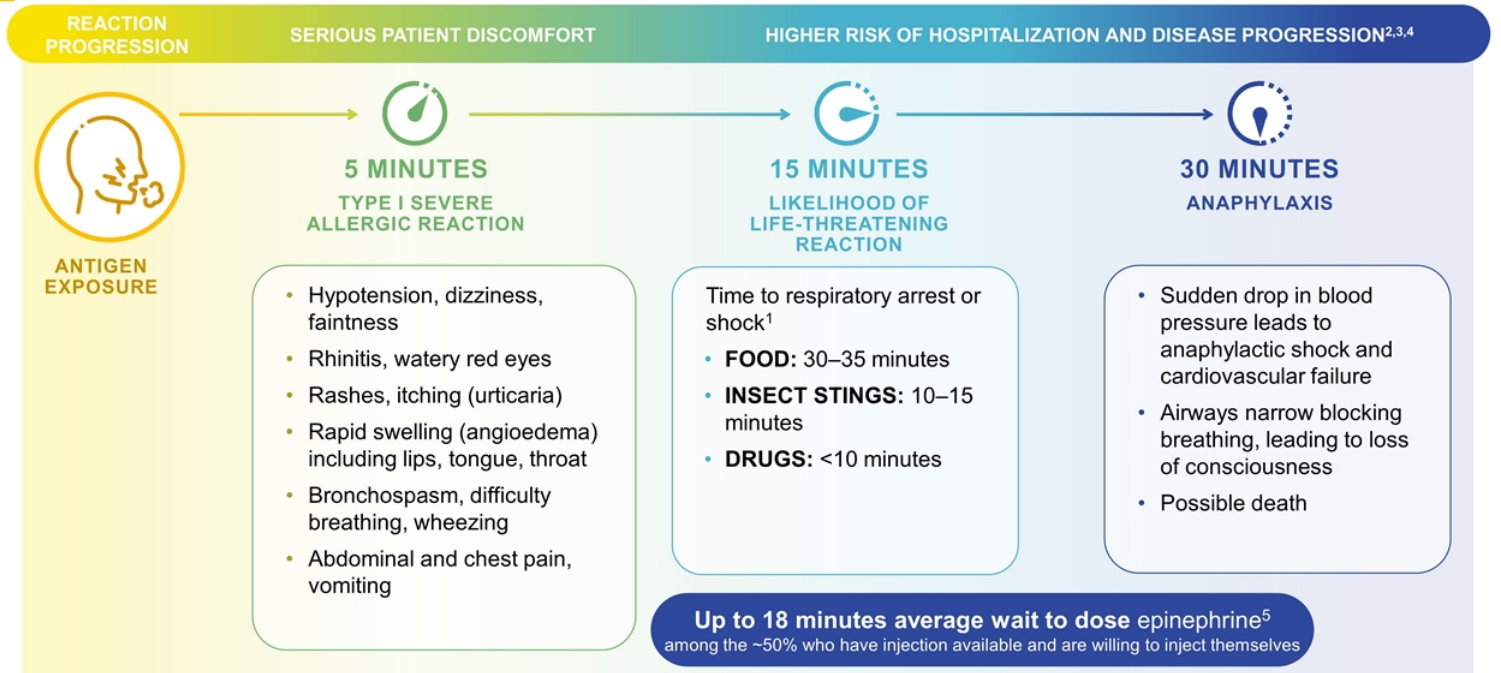
Epinephrine Auto-Injector Devices by Amneal and Impax: CDER Alert - FDA Alerts Patients and Health Care Professionals About Device Malfunction

FDA alerts patients and health care professionals of EpiPen auto-injector errors related to device malfunctions and user administration

Bloomberg

7 fatalities and 35 hospitalizations reported due to failures

Early intervention with epinephrine is critical in a Type I allergic reaction



Limitations of injection lead to hesitation and decreased or ineffective usage *neffy* may address these limitations to transform the treatment paradigm

PROBLEM
*Only 10% - 20% of Rx filled or used as indicated*⁶



NO TREATMENT AVAILABLE
~50% of patients carry¹



REFUSAL OF TREATMENT
~25% - 50%^{1, 3, 5} do not administer



DELAY IN TREATMENT
~40 - 60%² of patients delay



FAILURE OF TREATMENT
23 - 35%⁴ fail to dose correctly

neffy SOLUTIONS



1

SMALL

- Fits in your pocket; can carry more than 1
- ~10% of cases require multiple doses of epinephrine¹



2

NO NEEDLE NO INJECTION

- Rapid administration without a needle
- No risk of needle-related injuries; lacerations² or cardiotoxic blood vessel injections
- Less hesitation to dose

3

EASIER AND MORE CONSISTENT DOSING

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

4

RELIABLE

- 99.999% delivery of effective dose in reliability testing; no inhalation required
- Same shelf-life as EpiPen, but also stable at high temperatures



Demonstrated PK and PD comparable to injection

Approved injection products have a range of PK profiles, but are all deemed efficacious (no known difference across products)

TREATMENT	Source	N	Mean Study C _{max} (pg/mL)	Median or Mean Study T _{max} (min)	Study T _{max} range (min)
Epinephrine 0.3 mg IM	Literature	200	209 – 489	30 to 60	3 – 120
	ARS	181	244 – 339	45	4 – 360
Symjepi 0.3 mg	ARS	88	337 – 438	22 to 30	4 – 240
Auvi-Q 0.3 mg*	Literature	67	486	20	5 – 60
EpiPen 0.3 mg	Literature	311	288 – 869	5 – 40	1 – 120
	ARS	196	333 – 753	6 – 24	2 – 240
Total Range			209 to 869	5 to 60	1 to 360

*Baseline corrected

- FDA stated *neffy* should be bracketed by PK of approved products
- 0.3 mg IM (needle & syringe) is the reference-listed drug (RLD) and considered to be the gold standard as autoinjectors are a variable mix of IV, SC or IM dosing depending on technique
- All approved products have indistinguishable clinical effect and time to observed clinical benefit: ~90% resolution on first dose within the first 5 to 15 minutes observed for both IM and autoinjectors in literature and practice
- All products approved based on only PK, despite significant PK differences – (i.e. not bioequivalent to each other)
- PD is supportive

neffy clinical program supports NDA filed and accepted by FDA

FDA confirmed three primary registration studies required for **neffy** approval

EPI-15: Single dose and twice dosing in healthy volunteers (n=42)

EPI-16: Nasal challenge in allergic rhinitis patients (n=36)

EPI-17: Self-administration in Type I allergy patients (n=42)

*IM needle & syringe is the gold standard and reference-listed drug
Primary outcomes for all trials: PK (bioavailability) and PD (SBP, HR)*

EPI-10 pediatric trial interim data included in NDA submission, FDA requested

neffy meets the endpoints discussed with FDA in completed clinical studies*

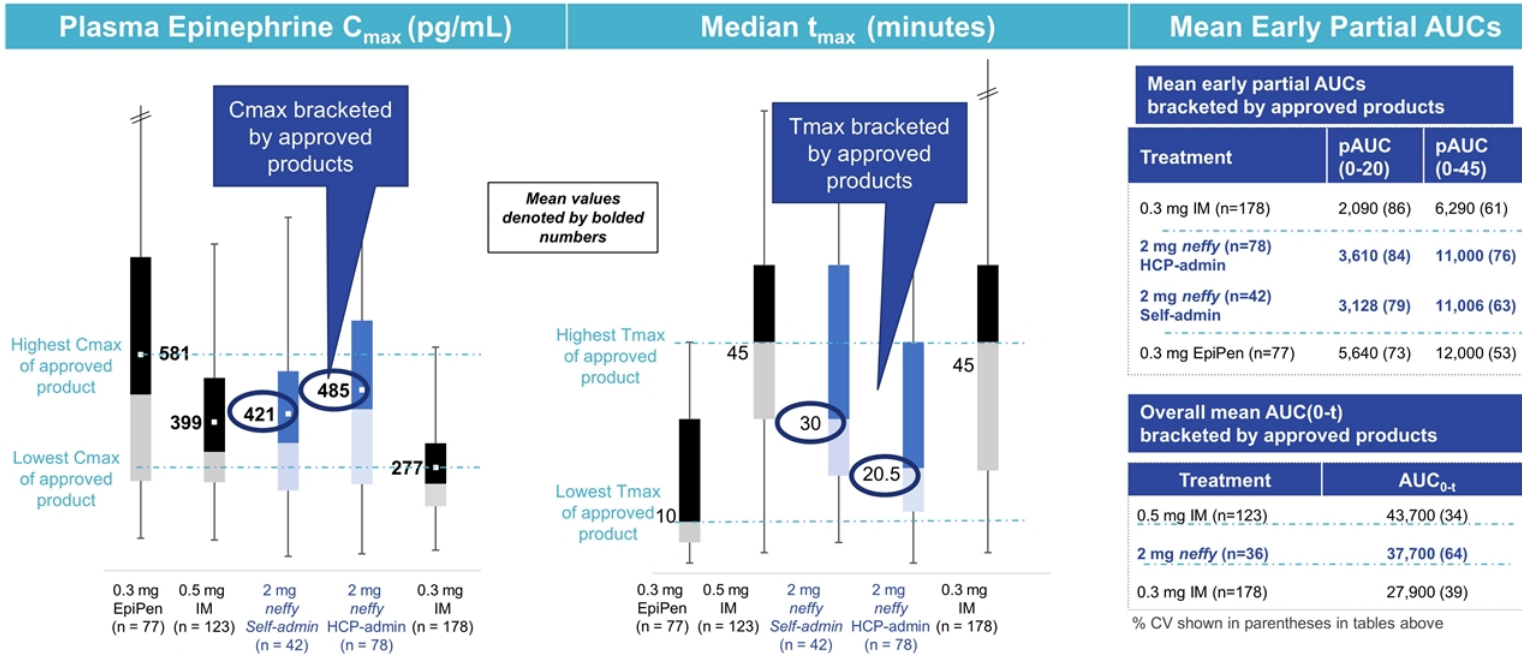
Criteria (C_{max} , t_{max} , early partial AUCs) is comparability to epinephrine injection products (bracketed by approved products)

NDA submission accepted by FDA in Q4 2022;

Target PDUFA action date anticipated in mid-2023

neffy meets FDA-confirmed endpoints in 3 primary studies*

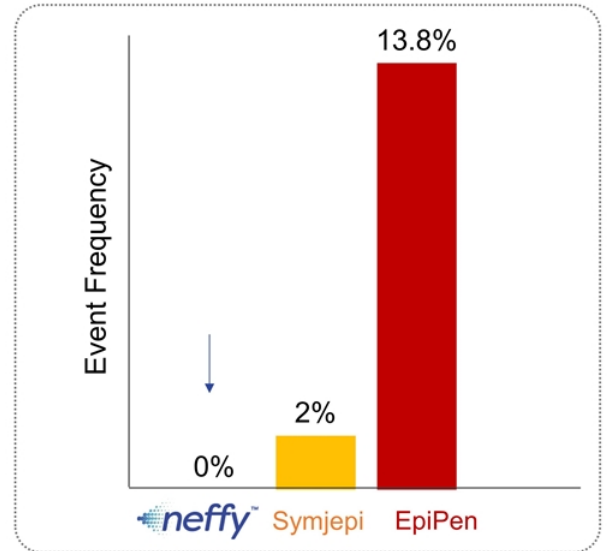
Integrated PK data summary for *neffy* and comparators



neffy well-tolerated across 600+ individuals dosed in clinical program

- Well-tolerated at all single-doses (0.5 mg to 2 mg) and repeat doses up to 4 mg within 10 minutes
- Mostly grade 1 events and comparable to injection products
- Low Pain Scores: recorded by VAS (100mm scale) with mean scores between 5 and 8 out of a score of 100 across studies
- No irritation based on formal scoring in all studies
- No serious treatment-related adverse events
- No risk of needle-related injuries or blood vessel injections

Risk of blood vessel injection during self-administration that could lead to adverse events



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

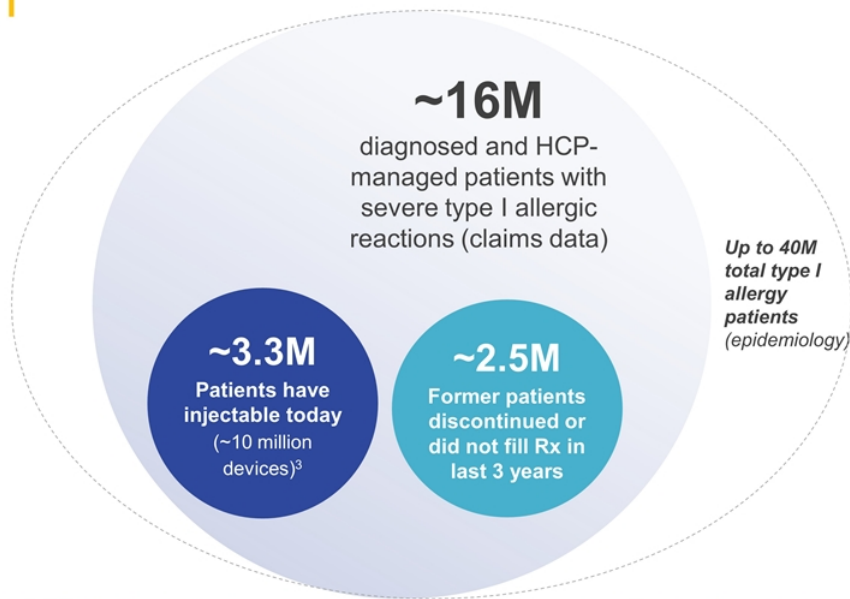
- ✓ Issued composition of matter patent (US10,576,156) on Intravail® + epinephrine provides foundational exclusivity blocking any generic products. Method of treatment patents (US11,173,209; US11,191,838) block other alkyl glycosides.
- ✓ Issued method of treatment patent (US10,682,414) blocks any intranasal 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



Commercial Opportunity and Strategy

Significant existing US market opportunity for *neffy* penetration

CURRENT ~\$1 BILLION¹ ANNUAL EPINEPHRINE MARKET IS THE IMMEDIATE OPPORTUNITY



MULTIPLE LEVERS OF CURRENT MARKET GROWTH

Consistent market growth
+5% y/y in the last ~15 years

Promotional responsiveness
+31% historic lift from Mylan
No meaningful promotion today

More devices per patient
Potential for twice as many *neffy* devices annually vs. injectables

Physicians supportive of adopting *neffy* into practice



n = 75
Physicians

8.5 out of 10 rating

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

neffy addresses the unmet need and is better aligned with what healthcare providers, patients and parents want



n = 150
Current Users

~80% OF PATIENTS EXPECTED TO SWITCH TO *neffy*

75% OF NON-FILLING PATIENTS STATED THEY WOULD ASK THEIR PHYSICIAN ABOUT *neffy* RX



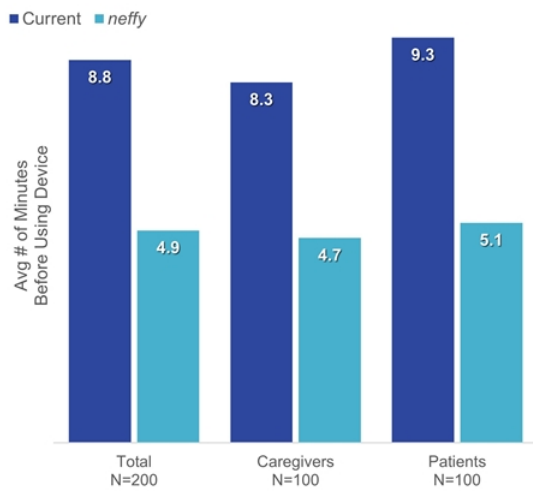
n = 100
Non-fillers

65% to 72% OF THE TIME, PEOPLE WHO USE AN OTC WOULD USE *neffy* FIRST

69% OF PEOPLE WOULD USE *neffy* SOONER THAN CURRENT AUTOINJECTOR

Caregivers are enthusiastic about *neffy* and its benefits

Time from Onset of Symptoms to Epinephrine Administration



Source: ARS Consumer Quant Research, 2022

”

This is fantastic.
Much easier than jabbing the thigh.

– Father

”

I want this. Is it available yet? Let me know when it is, I will literally call the doctor from my car.

– Mother

”

We are talking about someone's life and lifestyle here. **Great improvement.**

– Mother

”

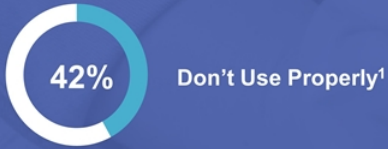
I don't have a co-pay, but I'd get this for my daughters **even if I have to pay \$50.**

– Mother

Guidelines recommend immediate treatment with epinephrine. Earlier administration is associated with improved clinical outcomes and decreased likelihood of hospitalizations.

By Addressing Needle Injector Deficiencies *neffy* can Become the Standard in Treatment

Propensity of Current SAR Patients Prescribed a Needle Injector



neffy Patient Research Shows...

45% ↑
Faster Treatment Time³

47% ↑
More Likely to Fill Rx³



(1) ARS Consumer Quant Research, 2022, (2) Warren et al. Ann Allergy Asthma Immunol (2018), (3) Data on file from ARS market research, (4) ARS human factors studies

Payer research supports positive reimbursement environment

Key findings from discussions with ~50 decision-makers within the major payers and PBMs:

- Category is generally not restricted, unlike biologics and orphan disease drugs with high WACs
- Payers view *neffy* as a valuable and differentiated treatment option
- High likelihood of attaining favorable coverage (Tier 2 or 3) for ~80% of lives



*"This is a **game-changer**; it really addresses the unmet needs we currently have in this space, specifically the safety and tolerability issues."*

– Payer

"Nasal delivery will overcome some negative perceived factors of an injection."

– Payer

*"If this is priced properly, this could be a '**state-of-the-art therapy**' for patients."*

– PBM

"There is no value in delaying access to a product like this and nothing to prior authorize (PA). We can't PA if the patient needs it."

– PBM

Commercial strategy and imperatives

From needle to neffy:

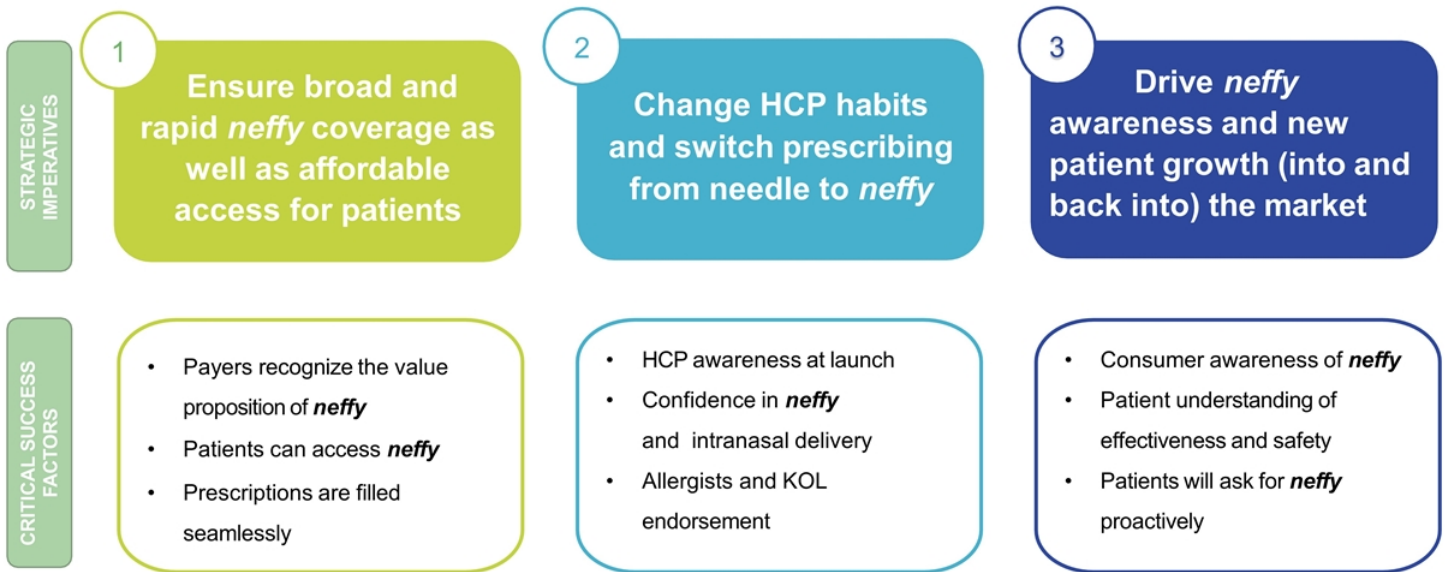
- Convert the existing market
- Bring back patients that are lapsed
- Bring in patients who should be carrying epinephrine now, but do not carry

1 Ensure broad and rapid *neffy* coverage as well as affordable access for patients

2 Change HCP habits and switch prescribing from needle to *neffy*

3 Drive *neffy* awareness and new patient growth (into and back into) the market

Strategic Imperatives and CSFs: From Needle to *neffy*



Integrated HCP Promotion to Drive Awareness and Reach with Current Epinephrine Prescribers Representing >40% of Prescriptions*



Specialty
Salesforce



Virtual
Salesforce



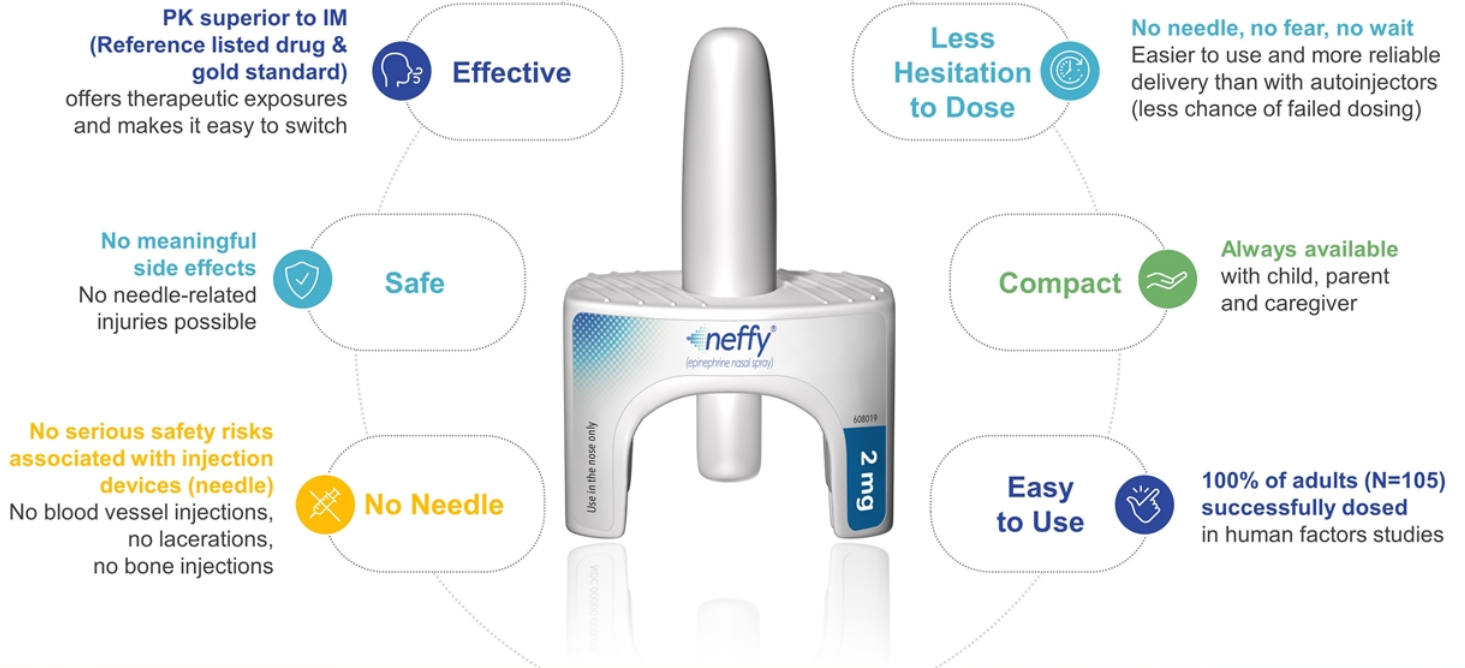
Non-Personal Promotion

FTEs	~125 FTEs	Top 50,000 Decile 5 to 10
HCP Reach	~ 15,000 HCPs	

HCP promotion will be supported by DTC promotion to drive expansion within the addressable SAR market

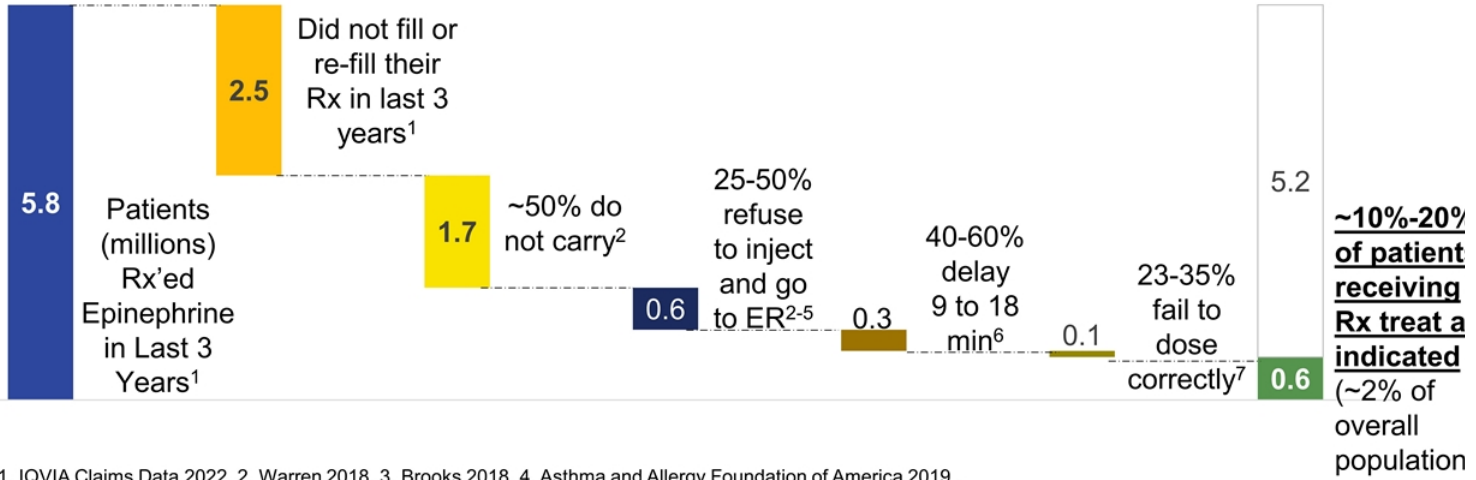
* Reaching >80% of Prescriptions from Allergists, ENTs, and Pediatricians

neffy is positioned potentially to transform the treatment of serious allergic reactions



Many patients/caregivers do not administer treatment or delay use during reaction

Approx. 40,000,000 people with serious Type I Allergic Reactions
 ~5,800,000 people received Rx from a Physician in Last 3 Years



1. IQVIA Claims Data 2022, 2. Warren 2018, 3. Brooks 2018, 4. Asthma and Allergy Foundation of America 2019, 5. Casale 2022, 6. ARS data presented at AAAAI 2023, 7. El Turki 2017