UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to

Commission File Number 001-39756

ARS Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**81-1489190** **(I.R.S. Employer Identification No.)**
11682 El Camino Real, Suite 300 **San Diego, California** **(Address of principal executive offices)**	**92130** **(Zip Code)**

Registrant's telephone number, including area code: (858) 771-9307

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, par value $0.0001 per share	**SPRY**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of March 4, 2026 there were 99,297,307 shares of registrant's common stock, $0.0001 par value per share, outstanding.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,094.9 million as of June 30, 2025 (the last trading day of the registrant's most recently completed second quarter) based on the closing price of $17.45 as reported on the Nasdaq Global Market on such date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than April 30, 2026, are incorporated by reference into Part III of this Annual Report on Form 10-K.

ARS Pharmaceuticals, Inc.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the rate and degree of market acceptance of *neffy* and any future product candidates;
- the likelihood of *neffy* attaining and maintaining favorable coverage;
- future economic conditions or performance, including *neffy* net product revenues and net product sales;
- research and development plans, including planned clinical trials, for our current or future intranasal epinephrine technology product candidates;
- the expected timing for reporting data;
- our expectations regarding the European Medicines Agency's ("EMA") review of our post-approval variation for *neffy* 1 mg;
- our plans to submit regulatory filings for *neffy* in additional geographies in collaboration with our partners and the timing thereof;
- the expected timing for regulatory review decisions for *neffy* and our intranasal epinephrine technology product candidates;
- the commercial potential of and commercialization strategy for *neffy* and our intranasal epinephrine technology product candidates;
- the size of the markets (including annual sales opportunities) for our current and future product candidates, as well as for *neffy* for its currently approved indications and geographic markets, the projected growth thereof, and our, and our collaboration and marketing partners', ability to capture and grow those markets;
- our expected competitive position;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the expected intellectual property protection for *neffy;*
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection for *neffy*, or any future product candidate;
- legislative and regulatory developments in the United States and foreign countries;
- estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to satisfy our obligations, comply with the covenants, and access, if needed, additional credit under our credit agreement; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors of this Annual Report. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

neffy and *EURneffy* are trademarks of ours that we use in this Annual Report. This Annual Report also includes trademarks, trade names, and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Annual Report appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to our trademark and trade names. The use or display of other companies' trade names or trademarks do not suggest or imply a relationship or affiliation with, or endorsement or sponsorship of us by, any other companies.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part I, Item 1A. Risk Factors in this Annual Report. Some of the material risks associated with our business include the following:

- We are highly dependent on the successful commercialization of *neffy*. To the extent *neffy* and *EURneffy* are not commercially successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock would likely decline.
- *neffy* and our current and future intranasal epinephrine technology product candidates 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, in which case we may not generate significant revenues or profits.
- If we are unable to achieve and maintain adequate levels of third-party payor coverage and reimbursement for *neffy* on reasonable pricing terms, its commercial success may be severely hindered.
- Competitive products may reduce or eliminate the commercial opportunity for *neffy* or our current and future intranasal epinephrine technology product candidates. If our competitors develop technologies or product candidates more rapidly than us, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize *neffy* and our current and future intranasal epinephrine technology product candidates may be adversely affected.
- If we are unable to successfully develop our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, or experience significant delays in doing so, the commercial potential of our current or future intranasal epinephrine technology product candidates or *neffy* will be more limited.
- If the U.S. Food and Drug Administration ("FDA") does not conclude that our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates or additional indications under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates or additional indications will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.
- Product liability lawsuits against us or any of our current and future licensing and collaboration partners could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates.
- If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.
- We rely completely on third parties to manufacture and warehouse both our domestic and international supply of *neffy* and our current and future intranasal epinephrine technology product candidates.
- We are dependent on international third-party licensees and assignees for the development and commercialization of *neffy* and our current and future intranasal epinephrine technology product candidates outside the United States. If these third parties are not successful in their development and commercialization efforts or if these third parties fail to meet their contractual, regulatory or other obligations, our business and results of operations could be adversely affected.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We expect that our timing of sales and results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.
- We have incurred significant losses since our inception.
- We may need additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.

- Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for *neffy*, our current and future intranasal epinephrine technology product candidates and other proprietary technologies.
- Our Credit Agreement contains conditions and restrictions that limit our flexibility in drawing on the additional funds thereunder and in operating our business. We may be required to repay our outstanding indebtedness under the Credit Agreement earlier than we expect and possibly at a time when we do not have sufficient capital to meet such obligations if an event of default occurs (including a material adverse change affecting our business), which could have a material adverse effect on our financial condition and results of operations.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

PART I

Item 1. Business.

As used in this Annual Report, unless the context indicates or otherwise requires, "ARS," "ARS Pharma," the "company," "we," "us," "our," and other similar terms refer to ARS Pharmaceuticals, Inc., a Delaware corporation and its consolidated subsidiaries.

neffy and *EURneffy* are trademarks of ours that we use in this Annual Report. This Annual Report also includes trademarks, trade names, and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Annual Report appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to our trademark and trade names. The use or display of other companies' trade names or trademarks do not suggest or imply a relationship or affiliation with, or endorsement or sponsorship of us by, any other companies.

Overview

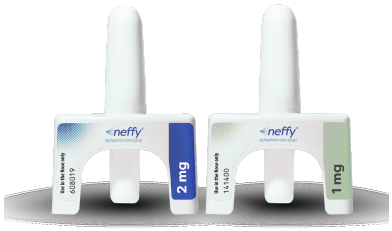
Company Summary

We are a biopharmaceutical company focused on the commercialization and development of *neffy* (currently identified in the European Union ("EU") and United Kingdom ("U.K.") by the trade name *EURneffy* and in China by the trade name 优敏速) for needle-free intranasal delivery of epinephrine for emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only FDA and European Commission ("EC")-approved needle-free epinephrine product, and also has approvals in the U.K., Japan, Australia, and China. It is the first new delivery method for epinephrine in more than 35 years. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail, which allows *neffy* to safely provide intranasal delivery of epinephrine at a low dose within the exposures of approved injectable products across a range of dosing conditions (including repeat dosing and allergen challenge).

We believe *neffy*'s "no needle, no injection" approach addresses a significant unmet need in the use of epinephrine. There are approximately 40 million people in the U.S. who experience Type I allergic reactions. Of this group, approximately 20 million people are reported to have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million of those were prescribed an epinephrine autoinjector. However, in recent years, only an estimated one-half of those consistently fill their prescribed autoinjector with them. We believe the market opportunity for *neffy* in the U.S. is significant. Those estimated 3.2 million patients who currently fill their active epinephrine autoinjector prescription would represent approximately $1.8 billion in annual U.S. net sales at *neffy*'s estimated gross-to-net yield based on epinephrine device unit volume in 2025.

In August 2024, the FDA approved *neffy* 2 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater, with *neffy* 1 mg subsequently approved in March 2025 for patients who are four years of age and older and weigh 15 kg to less than 30 kg. Our commercialization efforts for *neffy* currently include a direct sales force of 106 individuals targeting high-volume prescribers, an additional co-promotion U.S. sales force of approximately 70 individuals with our partner, ALK-Abelló, Inc. ("ALK U.S.", an affiliate of ALK-Abelló A/S ("ALK")), targeting pediatricians that launched in May 2025, as well as our *getneffy.com* virtual prescriber website formally launched in November 2025 to minimize physician and patient burden. Our sales force and virtual prescriber options are supported by branded direct-to-consumer marketing through streaming platforms, traditional broadcast and cable television, consumer-facing digital channels, non-personal promotion with healthcare providers, and disease awareness campaigns with advocacy groups.

Our U.S. commercial launch is building momentum, and our launch data shows meaningful physician and patient demand. As of February 2026, more than 22,500 physicians have prescribed *neffy* since launch. With increasing demand, we're securing broad insurance coverage, which we believe is a critical factor for accelerating adoption in the high patient volume epinephrine market. Currently, we have approximately 93% overall commercial coverage, inclusive of plans that may still require prior authorization, approximately 57% coverage with commercial insurance without prior authorization, and 8 of 50 Medicaid states covering *neffy* without prior authorization.



The EC has granted marketing authorization in the EU for *EURneffy* 2 mg (the trade name for *neffy* 2 mg in the EU and U.K.), for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater and on January 29, 2026, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA adopted a positive opinion, recommending marketing authorization in the EU for *EURneffy* 1 mg for children who are four years of age and older and weigh 15 kg to less than 30 kg. Through our collaboration with ALK, *EURneffy* 2 mg was launched in Europe, beginning with Germany in June 2025, followed by the U.K. in October 2025. We received approval of *neffy* 2 mg and 1 mg in Japan in September 2025, which is expected to launch in the first quarter of 2026 by our collaboration partner, Alfresa. We also received approval of *neffy* 2 mg and 1 mg doses in Australia in December 2025, with commercial launch by our collaboration partner, Seqirus, initiated in February 2026. In December 2025, we received approval in China of 优敏速 (the trade name for *neffy* 2 mg in China), with commercial launch by our collaboration partner, Pediatrix, expected to start in the first half of 2026. *neffy* 2 mg is under review by Health Canada, with a regulatory decision expected in the second quarter of 2026 and if approved, commercial launch by our collaboration partner, ALK, expected to start later in 2026. *neffy* has already been approved or is under regulatory review in countries representing approximately 98% of the current global epinephrine autoinjector sales. For more information regarding our partners and collaboration agreements, see "*Business—Our Collaboration and Licensing Agreements.*"

Real-world data supports that *neffy* delivers similar response rates as injections for the emergency treatment of Type I allergic reactions. In September 2025, we reported survey results of anaphylaxis treatment outcomes in the *neffy* experience program, which provides 1 mg and 2 mg doses of *neffy* to allergists for in-office use if patients experience an anaphylactic event during oral food challenges or allergen immunotherapy. These results showed that approximately 90% of patients experiencing anaphylaxis symptoms were effectively treated with a single dose of *neffy*, which is consistent with that historically reported for epinephrine injection. The results were presented as an oral presentation at the American College of Allergy, Asthma and Immunology ("ACAAI") meeting in early November 2025 and was also published in the Annals of Allergy, Asthma and Immunology, the official peer-reviewed journal of the ACAAI, in December 2025.

We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients at the American Academy of Allergy and Immunology medical conference in February 2024. In the second quarter of 2025, we initiated a Phase 2b randomized, placebo-controlled outpatient clinical trial involving chronic spontaneous urticaria patients on chronic treatment regimens, who still experience flares or exacerbations. Interim data from this clinical trial is anticipated in the second half of 2026, followed by the potential initiation of a single pivotal efficacy study in mid-2027. We estimate that there are approximately 1.5 million diagnosed chronic urticaria patients in the U.S., of whom approximately half are not well-controlled by antihistamines and continue to experience multiple acute flares a year, and therefore would be prescribed multiple epinephrine nasal spray devices if approved. The chronic urticaria indication represents an addressable market opportunity of more than $2.0 billion annually based on *neffy*'s current net pricing.

We currently own, co-own and exclusively license a robust global intellectual property portfolio including issued composition of matter and method patents relating to *neffy* and our intranasal epinephrine technology product candidates that are not expected to expire until 2038.

Epinephrine and Allergic Reactions Background

Type I allergic reactions are potentially life-threatening hypersensitivity reactions that can occur within minutes of exposure to an allergen and need to be treated immediately to relieve symptoms and prevent further progression. Initial symptoms significantly impact patient quality of life and include difficulty breathing, bronchospasms, hypotension, presyncope, itching, hives, swelling of eyes and lips, and abdominal pain and vomiting. If not treated immediately, more severe reactions known as anaphylaxis that involve constriction of the airways, swelling of the throat, rapid heart rate, severe hypotension and other respiratory and cardiac symptoms can develop and potentially present a medical and life-threatening emergency. Immediate administration of epinephrine is currently the only first-line treatment for Type I allergic reactions, including anaphylaxis. The only out-of-hospital delivery option today is an intra-muscular injectable product, typically offered as prefilled syringes or auto-injector devices, such as EpiPen, which is marketed by Viatris Inc., and generic versions of EpiPen, marketed by Teva Pharmaceuticals, Inc. These intra-muscular auto-injection devices have several limitations that include:

- they lack convenience of portability, with only 50% of patients who fill their prescriptions carrying the device;
- patients are reluctant to use the device, with approximately 25% to 60% of patients who carry the device refusing to administer;
- apprehension stemming from the use of a needle that leads to approximately 40% to 60% of patients delaying administration by up to 18 minutes even if they are carrying the device;
- a high rate of dosing errors, with meta-analyses reporting 23% of patients still failing to dose correctly even after training; and
- safety concerns including lacerations, caregiver self-injection and frequent potentially cardiotoxic blood vessel injections.

We believe *neffy's* and our intranasal epinephrine technology product candidates' design, particularly the compact size and "no needle, no injection" delivery, eliminates needle-related apprehension and pain, improves portability and ease of use, is highly reliable, and will increase prescriptions for epinephrine, making it more likely that patients and caregivers will administer epinephrine sooner, achieve more rapid symptom relief, and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death.

Our Approach

neffy 2 mg is approved in the U.S, E.U., U.K., Japan, Australia, and China for the emergency treatment of Type I allergic reactions, including anaphylaxis, for adults and children who weigh 30 kg or greater; neffy 1 mg is approved in the U.S., Australia, and China for the emergency treatment of Type I allergic reactions, including anaphylaxis, for patients who are four years of age and older and weigh 15 kg to less than 30 kg.

neffy and our intranasal epinephrine technology product candidates are designed to address the shortcomings of intra-muscular injectable devices. Based on the factors set forth below, we believe that *neffy* and our intranasal epinephrine technology product candidates can transform the paradigm of epinephrine delivery by achieving more rapid symptom relief and preventing symptoms from becoming serious or life-threatening.

- ***Needle-free, easy-to-use, pocket-sized and highly reliable nasal spray.*** *neffy* and our intranasal epinephrine technology product candidates are easier to carry than approved intra-muscular injectables because they are pocket-sized, increasing the likelihood that the device is available for use in an emergency. The device is also highly reliable and easy to use. 100% of untrained adults and untrained children were able to successfully self-administer our intranasal epinephrine technology in our human factors validation study using the intended commercial instructions for use and quick reference guide.
- ***No risk of needle-related injuries.*** *neffy* and our intranasal epinephrine technology product candidates have no risk of needle-related injuries including injection into a blood vessel, lacerations, or caregiver self-injection because our sprayer device does not have a needle. Accidental injections to the hands or fingers of a caregiver or a child occur more than 3,500 times a year in the U.S. with epinephrine injection devices.
- ***Less hesitation to dose epinephrine.*** Early administration of epinephrine can reduce the severity, risk of hospitalization and mortality associated with severe Type I allergic reactions. In patient surveys, patients indicated a relief from fear of injection and an expectation to utilize *neffy* without delay in a manner more consistent with recommended guidelines because it's administered intranasally.
- ***Low potent dose of epinephrine.*** Higher exposures of epinephrine increase the risk of overexposure and potential adverse events including gastrointestinal ("GI") symptoms due to swallowing excess epinephrine that is not absorbed, if delivered orally. *neffy* and our intranasal epinephrine technology product candidates have high bioavailability matching the approved doses of injection at a low dose of 2 mg or 1 mg intranasally. Even in the unlikely situation where epinephrine would be 100% bioavailable after administration of *neffy* or our intranasal epinephrine technology product candidates, the resulting exposure is expected to be tolerable.
- ***Increased stability over other existing treatment options***. *neffy* 2 mg has a shelf-life of 30 months at room temperature, while *neffy* 1 mg has a shelf-life of 24 months at room temperature, as opposed to the reported shelf-life range of approved injection products from the date of product manufacture of 18 to 24 months. Furthermore, *neffy* has improved stability and shelf-life at high-temperature compared to existing products in the market (testing met specifications in conditions up to 3 months at 50°C or 122°F), which allows *neffy* to retain potency even if accidentally left in a high temperature environment.

Our Management Team, Financing History and Investors

We were created to innovate, develop and commercialize *neffy*, a novel, first-in-class treatment that addresses Type I allergy patients' desire and need for a no needle, no injection, easy-to-use, portable and reliable solution for delivering epinephrine. To achieve this goal, we have assembled a management team with extensive experience in the development and commercialization of drugs, such as approved nasal sprays NARCAN (naloxone nasal spray) and VALTOCO (diazepam nasal spray).

Our company was founded by Richard Lowenthal, M.S., MSEL, Robert Bell, Ph.D. and Sarina Tanimoto, M.D., MBA. Pratik Shah, Ph.D. was our first external investor.

Mr. Lowenthal, our Co-Founder, President, Chief Executive Officer, and one of our directors, has more than 25 years of biotechnology and pharmaceutical development experience including leading the regulatory approvals of VALTOCO (diazepam nasal spray) and NARCAN (naloxone nasal spray). Dr. Bell, our Co-Founder and Chief Scientific Officer, has more than 25 years of product development experience including leading research and development at Barr Laboratories, Inc., Somerset Pharmaceuticals, Inc. and UDL Laboratories, Inc. Dr. Tanimoto, our Co-Founder and Chief Medical Officer, has more than 20 years of pharmaceutical experience in clinical drug development including supporting the approval of multiple nasal spray products such as VALTOCO and NARCAN. Dr. Shah, our Chairman, has more than 30 years of experience founding and leading biopharmaceutical companies and healthcare investment decisions including his role as Chairman and Chief Executive Officer of Design Therapeutics, Inc., former Chairman of Synthorx, Inc. (now part of Sanofi S.A.) and former Chief Executive Officer of Auspex Pharmaceuticals, Inc. (now part of Teva Pharmaceutical Industries Ltd.).

Our commercial team is led by Eric Karas, Chief Commercial Officer, who has more than 25 years of sales, marketing, market access and strategic planning experience across multiple specialty products, including leading commercial initiatives for NARCAN nasal spray at Emergent BioSolutions, Inc. and Adapt Pharma Operations Limited (now part of Emergent BioSolutions, Inc.).

The other key members of the ARS team bring extensive finance, business development and commercial operations experience and include Kathleen Scott, Chief Financial Officer; Justin Chakma, Chief Business Officer; Brian Dorsey, Chief Operating Officer; and Alex Fitzpatrick, Chief Legal Officer.

We have funded our operations to date primarily with proceeds from our equity financing from a syndicate of leading life sciences investors that include, among others, RA Capital, SR One and Deerfield, debt financing with affiliates of RA Capital and OMERS Administration Corporation, licensing and collaboration agreements, product sales, and the reverse merger with Silverback Therapeutics. We have entered into licensing and collaboration agreements for *neffy* with Alfresa Pharma Corporation ("Alfresa") for rights in Japan, Pediatrix Therapeutics, Inc. ("Pediatrix") — founded by F-Prime Capital, Eight Roads and Creacion Ventures — for rights in China, and Seqirus Pty Ltd. ("Seqirus") for rights in Australia and New Zealand. We have also entered into a licensing and collaboration agreement with ALK for territories outside the U.S. and the territories covered by the Alfresa, Pediatrix and Seqirus agreements; these territories include Canada, the U.K, E.U., and other countries.

Our Strategy

Our mission is to develop innovative, patient-friendly and easy-to-use treatments that empower people with allergies and their caregivers to treat at the first sign of symptoms. Our strategy is focused on commercializing and developing *neffy* as the first and only approved intranasal treatment for patients diagnosed with severe Type I allergic reactions and are at risk of anaphylaxis and for patients in other allergy indications. Key elements of our strategy include:

- ***Continue to educate healthcare providers about neffy.*** Our commercial infrastructure includes a national sales force of 106 individuals comprising sales reps, area sales managers, and nation sales directors, as well as 10 virtual sales reps and approximately 70 sales reps via our co-promotion partner, ALK U.S., which are collectively intended to reach, at a minimum, healthcare professionals that account for 50 to 55% of the current epinephrine prescriptions in the U.S. Our promotion targets high-prescribing allergists, pediatricians and primary care physicians through both traditional and non-traditional professional channels. As of February 2026, approximately 3,400 healthcare professionals have enrolled in our *neffy* experience program that allows healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenges, allergen immunotherapy, as well as on-going collection of real-world evidence that supports *neffy's* clinical equivalence to injection. We are also disseminating survey results from the *neffy* experience program that were published in a major peer-reviewed allergy journal, and showed that *neffy* demonstrated similar treatment response rates as those reported historically with injection in more than 680 treated patients. We anticipate that our promotional reach will eventually exceed greater than 80% of the current epinephrine prescriptions in the U.S. through a combination of continued sales force expansion and non-personal promotion that includes continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences.
- ***Continue to obtain payor coverage and grow sales of neffy.*** We have attained approximately 57% unrestricted commercial coverage (i.e. without prior authorization formwork) at a gross-to-net similar to other innovator products, and with 8 state Medicaid programs also covering *neffy* without prior authorization. We believe payors recognize the value and innovation of *neffy* for Type I allergic patients, including potential cost-savings to the healthcare system due to greater carriage and early use of epinephrine devices. With our payor contracting strategy, $0 co-pay for commercially eligible patients, a $199 cash price, and patient assistance programs, we anticipate that the out-of-pocket cost for acquiring *neffy* to patients may be less than, or equivalent to, generic epinephrine autoinjectors, thereby minimizing cost barriers to acquiring *neffy*.
- ***Continue to accelerate direct-to-consumer marketing efforts of neffy.*** We believe that the epinephrine market has been a historically promotionally sensitive product category, and that the favorable product attributes of *neffy* are attractive to consumers. Using direct-to-consumer omnichannel strategies to drive awareness and patients asking for *neffy*, we believe we can reach a majority of the approximately 3.2 million patients in the United States who filled a prescription for an epinephrine intra-muscular injectable device in 2023, as well as the 3.3 million patients who have received a prescription, but refused or discontinued treatment. These 6.5 million patients are primarily treated by the same high-prescribing allergists and pediatricians that our sales force is targeting. We believe that our direct-to-consumer marketing strategy will also activate a portion of the 13.5 million patients who are diagnosed and under the care of physicians (primarily non-allergists), but who have not been prescribed an epinephrine intramuscular injectable between 2020 and 2022. We also formally launched and began direct-to-consumer advertising of our *getneffy.com* virtual prescriber website in November 2025, which offers patients the option to obtain a *neffy* prescription the same day with a free visit via a virtual healthcare provider to eliminate the time-burden of an in-person visit. Our launch strategy is also supported by our *neffyconnect* program that provides support to physicians and patients, including our $25 co-pay savings card, $199 cash price and patient assistance programs; our *neffy*inSchools programs, where more than 9,000 schools to date have opted into receiving two cartons of *neffy* at no cost with accompanying school nurse education about *neffy*; partnerships with patient advocacy organizations including disease awareness campaigns; and multi-channel branded direct to consumer advertising including connected television, point of care, endemic and programmatic display, social media, and paid search that initiated in May 2025, as well as linear television advertising that started in June 2025.

- ***Commercialize neffy outside of the U.S. with our partners.*** The EC granted marketing authorization in the EU for *EURneffy* 2 mg (the trade name for *neffy* in the EU and U.K.), for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater. On January 29, 2026, the CHMP of the EMA adopted a positive opinion, recommending marketing authorization in the EU for *neffy* 1 mg for patients who are four years of age and older and weigh 15 kg to less than 30 kg. Through our collaboration with ALK, *EURneffy* 2 mg has successfully launched in Europe and the U.K. ALK anticipates peak sales for *neffy* of approximately $425 million USD in Canada, the EU and U.K. We also received approval of *neffy* 2 mg and 1 mg doses in Japan in September 2025, which is expected to launch in the first quarter of 2026. In addition, we received approval of *neffy* 2 mg and 1 mg doses in Australia in October 2025, which launched in February 2026. In December 2025, we received approval in China of 优敏速 (the trade name for *neffy* 2 mg in China), with commercial launch expected to start in the first half of 2026. We anticipate a regulatory decision for *neffy* 2 mg in Canada in the second quarter of 2026 and if approved, with commercial launch expected to start later in 2026.
- ***Conduct additional studies of neffy and our intranasal epinephrine technology product candidates to address additional Type I allergic reactions.*** For other conditions that can produce Type I reactions, there remains a significant unmet need. We are conducting clinical studies to support the expansion of labeling for *neffy* and our intranasal epinephrine technology product candidates to outpatient epinephrine use in other Type I allergy conditions such as urticaria for which epinephrine intra-muscular injectables are not approved. We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients at the American Academy of Allergy and Immunology medical conference in February 2024. In the second quarter of 2025, we initiated a Phase 2b randomized, placebo-controlled outpatient clinical trial involving chronic spontaneous urticaria patients, on chronic treatment regimens, who still experience flares or exacerbations. Interim data from this clinical trial is anticipated in the second half of 2026, followed by the potential initiation of a single pivotal efficacy study in mid-2027.

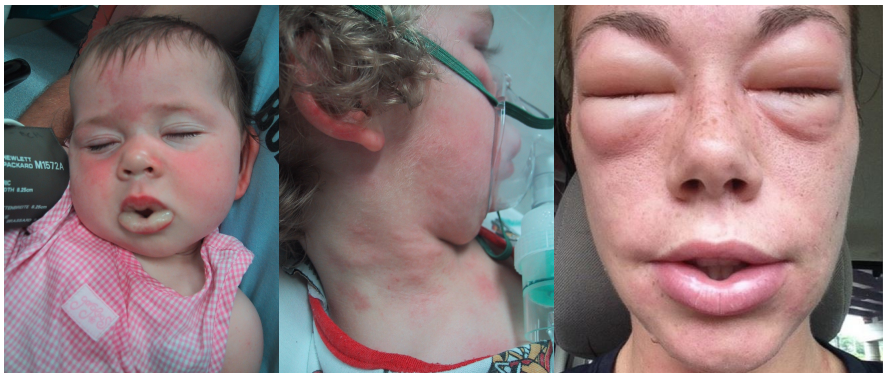
Overview of Type I Allergic Reactions and Current Challenges

Overview of Type I Allergic Reactions

The immune system plays an important role in monitoring and protecting the body against microbial threats. However, this system can lead to overstated immune and inflammatory responses that result in adverse outcomes known as hypersensitivity reactions. Type I allergic reactions are potentially life-threatening hypersensitivity reactions that can occur within minutes following exposure to an allergen and need to be treated immediately to relieve troublesome symptoms, mitigate severity and avoid a potentially fatal event. These severe reactions are caused by exposure to a specific allergen, typically stinging and biting insects, allergy injections, food, medicines, exercise or other unknown causes, and are mediated by immunoglobulin E IgE antibodies that bind to mast cells causing the release of histamines. The histamines induce smooth muscle contraction in the airways and a wheal and flare response in the skin producing swelling and inflammation. At the same time, widespread activation of mast cells leads to systemic effects of circulatory shock, hypotension or vascular collapse, and in the most severe cases respiratory arrest and death. The severity of a Type I allergic reaction is a function of the speed of onset and the number of organ systems affected by the reaction. As such, early intervention within minutes is critical in order to provide symptom relief and to prevent severe allergic reactions, known as anaphylaxis.

Table 1: Symptoms of Type I Allergic Reactions including Anaphylaxis

Body System	Common Symptoms of Type I Allergic Reactions
Respiratory	Chest tightness, wheezing, difficulty breathing ~50%+ frequency
	Upper airway or laryngeal Angioedema including swelling of throat ~20+% frequency
Cardiovascular	Hypotension, presyncope (feeling faint), loss of consciousness ~20% frequency
Dermatological	Urticaria (hives) and pruritus (itching) ~50%+ frequency
	Angioedema including swelling of lips, tongue and mouth ~ 50%+ frequency
Gastrointestinal	Abdominal pain and vomiting ~20% frequency



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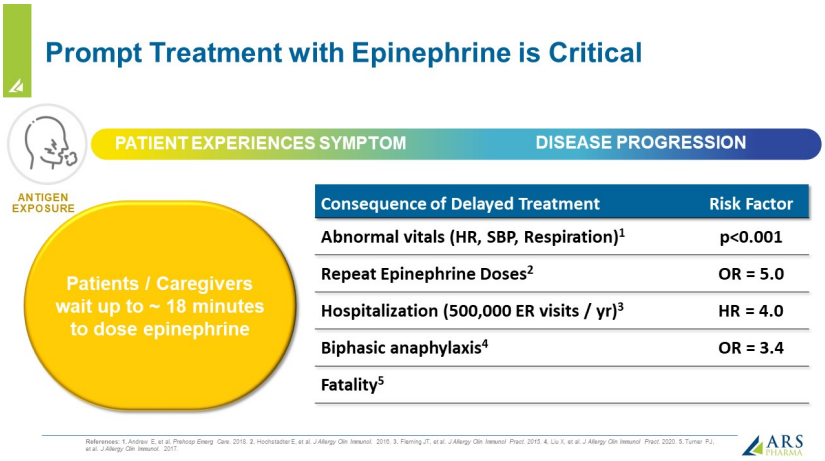
Role of Epinephrine in Treating Type I Allergic Reactions

Epinephrine, either in the form of *neffy* or injection products for out-of-hospital use, is recommended to be prescribed to all patients who have experienced a severe Type I allergic reaction and have either experienced anaphylaxis or are at risk of anaphylaxis. When properly used, these devices can allow for the early administration of epinephrine to stop or reduce the intensity of the systemic allergic reaction before refractory anaphylaxis develops.

EpiPen epinephrine autoinjector was first approved by the FDA for the emergency treatment of Type I hypersensitivity reactions, including anaphylaxis, in December 1987. Other FDA-approved epinephrine intra-muscular injection products include Twinject approved in May 2003, Adrenaclick approved in November 2009, and Auvi-Q approved in August 2012. In June 2017, the FDA approved Symjepi epinephrine injection, which is a pre-filled syringe for the same indication. These injection devices were approved by the FDA without pharmacokinetic ("PK") data based on an assumption that injections and devices were all effectively the same as the reference listed drug of intra-muscular injection with a needle and syringe. Intra-muscular injection with a needle and syringe is considered the gold standard and is almost exclusively used in non-community use clinical settings. Although there are no known differences in efficacy or time to observed effect in clinical practice between these devices, current data indicates that different devices deliver an intra-muscular dose of epinephrine with a range of PKs. A single dose with either an intra-muscular injection with needle and syringe or an auto-injector device results in resolution of allergic reaction for approximately 90% of cases within 5 to 15 minutes.



Treatment guidelines recommend that epinephrine be administered immediately at the first sign of a severe allergic reaction. Epinephrine is the only medication that can reverse severe allergic reactions and reduce hospitalization and death. Early administration of epinephrine is associated with better outcomes and decreased likelihood of hospitalizations. The sooner epinephrine is administered following allergen exposure, the less severe the systemic allergic reaction may become, and the less likely it will develop into an anaphylaxis event. As shown in the graphic above, delayed treatment is a statistically significant risk factor for multiple negative clinical outcomes for patients. A short delay of even a few minutes in the recognition and treatment of anaphylaxis can lead to more serious symptoms, including potential hypoxia or death. Additionally, accompanying symptoms of even non-life-threatening allergic reactions can adversely impact health-related quality of life and can lead to loss of productivity, negatively impact social life, as well as lead to depression and anxiety and feelings of fear, frustration, worry and lack of control. A second dose of epinephrine is required for adequate treatment in about 10% of cases, irrespective of whether epinephrine was dosed using an auto-injector such as EpiPen or needle and syringe, or the only approved nasal spray, *neffy*.

While antihistamines such as diphenhydramine, also known as Benadryl (marketed by Johnson & Johnson), can sometimes relieve the dermatological symptoms and pruritus associated with severe Type I allergic reactions, treatment guidelines state that antihistamines should never be administered instead of epinephrine because they do not reverse the cardiovascular symptoms such as hypotension and shock, or respiratory distress. Instead, antihistamines can potentially mask symptoms and allow the disease to continue to progress silently.

In the United States, dosing recommendations for epinephrine use by intra-muscular injection are from 0.1 mg to 0.5 mg depending on the patient's weight with repeat dosing administered as needed to control a severe allergic reaction. 0.1 mg, 0.15 mg and 0.3 mg are the approved doses for the epinephrine auto-injectors. Approximately 77% of epinephrine auto-injectors prescribed in the U.S. in 2023 for outpatient use were the 0.3 mg dose level for persons greater than 30 kg in weight, approximately 22% contain doses of 0.15 mg for persons between 15 kg to 30 kg and 1% contained 0.1 mg doses for persons less than 15 kg. A low dose of epinephrine is important for safety as overexposure to epinephrine can lead to adverse events.

Limitations of Existing Injectable Epinephrine Products

Epinephrine intra-muscular injectables have been proven to be highly effective if they are administered timely and effectively, but the limitations of these products include painful application, inconvenient size and a complicated mechanism of administration. These limitations discourage patients and caregivers from carrying these devices and administering epinephrine in a timely manner. Both patient adoption and use of intra-muscular injection devices have been limited among eligible patients with severe Type I allergic reactions at risk of anaphylaxis.

In studies published in peer-reviewed journals, only 23% to 48% of patients self-administered with an auto-injector during a severe Type I allergic reaction, likely due to less than half of patients actually carrying their prescribed injection device, and only half administering even if the device was available. Across our market research studies, approximately 40% to 60% of patients reported using an antihistamine first, which is not known to be effective, and if carrying an intra-muscular injectable, waited an average of 8 to 18 minutes to administer the device. The principal device-related reasons for delay were presence of a needle, concern about serious cardiac side effects, and potential pain. Patients, and particularly parents who administer to their child, perceive injection to be traumatic, which leads to a fear and avoidance of administering timely treatment. Further, the potentially life-threatening nature of a severe Type I allergic reaction is often accompanied with psychological stress and panic which can lead to delays or errors in proper intra-muscular injection, which can result in hospitalization or even death. In a meta-analysis of 32 studies evaluating epinephrine injectable administration techniques, 23% to 35% of participants failed to achieve the correct administration technique following training.

Further, there is variability with respect to whether auto-injector devices are able to reliably deliver a sufficient dose of epinephrine. The FDA has reported that EpiPen device failures lead to multiple deaths and dozens of hospitalizations annually.

The injection needle can be painful and dangerous not just due to the risk of skin lacerations and the possibility of the needle hitting a patient's bone during administration, but also the risk of serious, sudden cardiovascular events resulting from accidental blood vessel injection.

neffy can improve the management of severe Type I allergic reactions by addressing the current limitations of epinephrine intra-muscular injectable devices.

Clinical Development of *neffy* and our Intranasal Epinephrine Technology

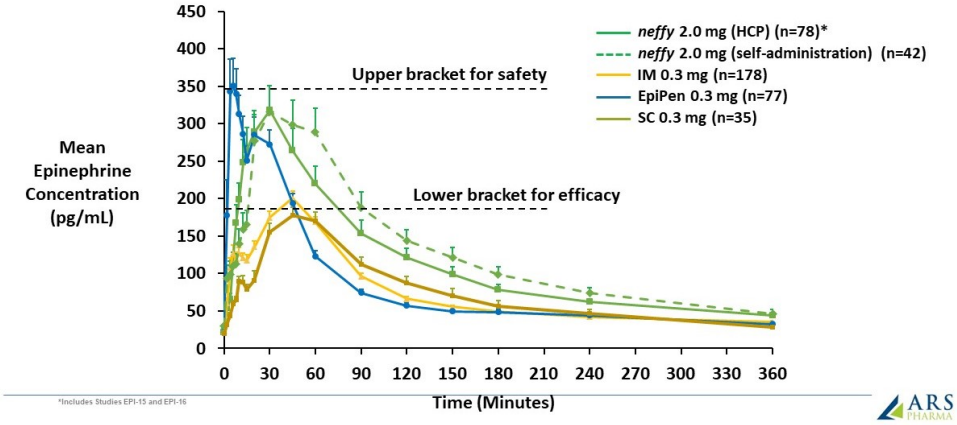
Our intranasal technology, including *neffy*, is designed to provide injection-like absorption of epinephrine at a 2.0 mg or 1.0 mg dose comparable to 0.3 mg or 0.15 mg injection, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray. On August 9, 2024, the FDA approved *neffy* 2 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater. As a result, we initiated the commercial launch of *neffy* 2 mg in the United States, with product becoming available in September 2024. On March 5, 2025, the FDA approved *neffy* 1 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in patients who are four years of age and older and weigh 15 kg to less than 30 kg. We initiated commercial launch of *neffy* 1 mg in the U.S., with product becoming available on May 7, 2025.

Based on our clinical studies completed to date and FDA labeling, we believe *neffy*'s "no needle, no injection" clinical profile supports differentiation over intra-muscular injections for the emergency treatment of Type I allergic reactions, including anaphylaxis.

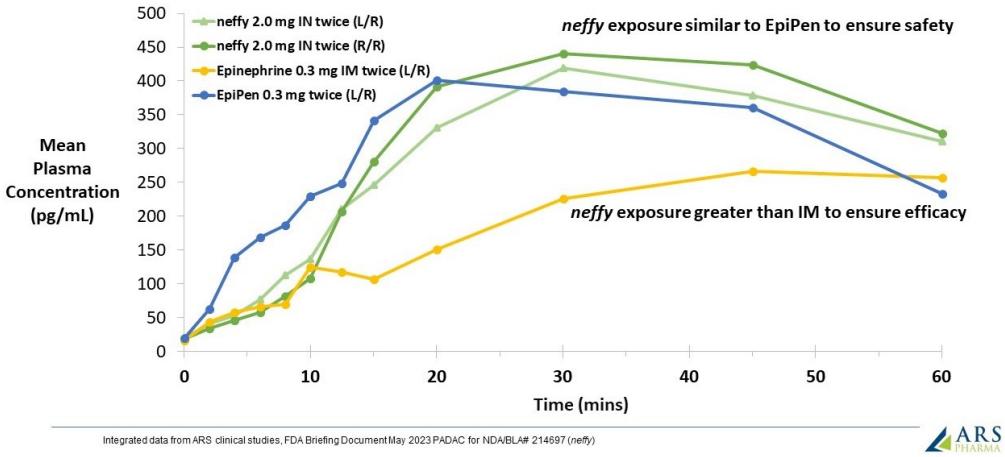
2.0 mg *neffy* is intended to be the dose that is comparable to approved 0.3 mg epinephrine intra-muscular injection products for persons 30 kg or greater in weight, which represents approximately 80% of the prescriptions in the United States. 1.0 mg *neffy* is intended to be the dose for persons 15 kg to less than 30 kg in weight.

In our clinical studies in both adults and children, 2.0 mg *neffy* gave comparable epinephrine exposures that were within the range of approved intra-muscular injection products (needle-in-syringe products and EpiPen) on key PK parameters (C_{max}, t_{max}, early partial AUCs, $AUC_{0\text{-}t}$). An integrated data analysis graph summarizing the key outcomes for registration for both single and repeat doses of *neffy* is shown below.

Single doses of 2.0 mg *neffy* compared to single doses of approved 0.3 mg injection products



Repeat doses of 2.0 mg *neffy* compared to repeat doses of approved 0.3 mg injection products



The hemodynamic response, measured by systolic blood pressure and heart rate, was observed as soon as 1 minute after administration of *neffy*, and was comparable to some injection products including EpiPen, and was greater than 0.3 mg intra-muscular needle-with-syringe. These hemodynamic responses were within normal physiologic ranges that are typically experienced during exercise or climbing stairs. Across all the clinical trials, a total of more than 700 subjects have been exposed to *neffy*. All doses of *neffy* ranging from 0.5 mg to 2.0 mg single doses, as well as repeat doses up to 4 mg within 10 minutes, were well-tolerated by patients. There is no meaningful pain upon administration of *neffy* with average scores of 5 to 8 as assessed on a 100 mm visual analogue scale, across studies. There was no irritation observed based on formal scoring in all studies. There were no serious treatment-related adverse events, and adverse events reported have generally not resulted in side effects more severe than grade 1, and were comparable to injection products. Since *neffy* is given without a needle, there was also no needle-related injuries or accidental blood vessel injections.

Furthermore, our registrational self-administration study of 2.0 mg *neffy* by adults with severe Type I allergies showed no critical dosing errors with *neffy* as evaluated by human factors professionals. Furthermore, *neffy* also showed zero dosing errors in two human factor validation studies involving 150 subjects when used by trained adults or trained children across multiple demographic groups, as well as when used by passers-byers with no prior experience or training with an epinephrine device.

Following FDA approval, we collected survey data through our *neffy* experience program to evaluate the clinical performance of *neffy* in patients experiencing anaphylaxis symptoms during oral food challenges and allergen immunotherapy. Nearly 90% (88.7%) of 680 patients experiencing anaphylaxis symptoms during oral food challenge and allergen immunotherapy were successfully treated with a single dose of *neffy* by a healthcare provider. Meta-analyses report a similar proportion of patients, 88.9%, being successfully treated with a single dose of epinephrine intramuscular injection or auto-injector by a healthcare provider for food-induced anaphylaxis. This highly similar treatment success rate supports that the real-world clinical effectiveness of *neffy* in anaphylaxis is consistent with epinephrine injection.

Key features of *neffy* demonstrated in our clinical, human factors or stability studies include:

Clinical Feature	Supporting Clinical Data
Comparable PKs to epinephrine	C_{max}, t_{max} and AUCs were within the range of approved intra-muscular injection products with a low intranasal dose of 2.0 mg *neffy* (people > 30 kg in weight) and 1.0 mg *neffy* (people 15 kg – 30 kg weight).
	Exposures with repeat doses of *neffy* were greater than IM to ensure efficacy, and comparable to EpiPen to ensure safety.
Low dose of epinephrine avoids side-effects that can be confused with anaphylaxis symptoms	Minimal to no gastrointestinal side effects with 1.0 or 2.0 mg *neffy* such as vomiting, diarrhea or abdominal pain that can occur if excess non-absorbed epinephrine is swallowed, confounding clinical monitoring since those same gastrointestinal side effects are symptoms of anaphylaxis during approximately 20% of events.
Robust pharmacodynamics ("PD") within a range comparable to injection products with no risk of accidental blood vessel injections	PD responses including systolic blood pressure and heart rate were within normal physiologic changes and comparable to auto-injector products, with maximum changes less than EpiPen.
	neffy has no potential for the accidental blood vessel injections observed with injection products such as EpiPen, which can lead to rapid and high epinephrine exposures that cause rapid increases in systolic blood pressure and can lead to cerebral hemorrhage or other cardiovascular side effects.
No meaningful pain or irritation after administration	Visual analogue scale scores were an average of 5 to 8 on a 100 mm scale, and show no meaningful pain (or burning or stinging sensation) after administration, attributable to *neffy* being an aqueous formulation. There is also no irritation observed based on formal scoring.
	Needle containing intra-muscular injection products are known to be painful and cause reluctance to dose.
Easy to use	No critical dosing errors during self-administration with 2.0 mg *neffy* by Type I allergy adult subjects.
	Zero percent error rate in human factor validation studies with intended commercial instructions for use and quick reference guide, when used by untrained adults or untrained children.
	Ability to dose *neffy* is not affected by any of the frequently observed anaphylaxis-related symptoms such as angioedema or swelling of the face, lips, tongue or larynx (~50% frequency), gastrointestinal symptoms such as vomiting or dysphagia (~20% frequency), or upper airway or breathing difficulty (~50% frequency).
Easy to carry	*neffy* is comparable in size to a wireless earbud case, and multiple *neffy* devices can fit in a patient or parent's pocket to satisfy guideline recommendations.
High reliability	*neffy*'s sprayer device is designed to deliver the effective dose more than 99.999% of the time, with no recalls or warnings among the millions of the same nasal sprayer devices sold to date.
No breathing or inhalation required	*neffy* is designed to be absorbed passively through the nasal mucosa without any inhalation, sniffing or breathing required, with its particles too large to enter the lungs.
Injection-like absorption even with nasal congestion	*neffy* reaches exposures comparable to approved injectable products even after induction of moderate to severe nasal rhinitis and/or edema (e.g., nasal congestion)
Shelf-life at least comparable to injection products, but also with high temperature stability	Drug stability studies show that *neffy* has a shelf-life at room temperature greater than the volume-weighted average shelf-life of 22 to 23 months for epinephrine injectable products based on stability data from the 2.0 mg dose of *neffy* for 30 months and from the 1.0 mg dose of *neffy* for 24 months.
	In addition, at high temperatures, *neffy* remains within specifications even when exposed to temperatures of 50°C (122°F) for at least three months, or temperatures of 40°C (104°F) for at least six months.

Planned Clinical Trials in Chronic Spontaneous Urticaria

Epinephrine has been used empirically by physicians and included in treatment guidelines for multiple allergy conditions that do not fall under the emergency treatment of Type I allergic reactions indication that epinephrine auto-injectors are labelled for. The needle-free, portable, easy-to-use and potentially safer clinical profile of our intranasal epinephrine technology product candidates supported by PK and PD data could enable the broader adoption of epinephrine in the outpatient setting for these other indications.

Development in Chronic Spontaneous Urticaria

There are approximately 1 million patients in the U.S. diagnosed with chronic spontaneous urticaria and treated with antihistamines or biologic treatments, such as Xolair, that still experience frequent flares, which is an indication for which epinephrine has never been formally developed as a prescription product, despite being used in-hospital to resolve such acute symptoms. Such patients experience multiple episodes each year, and we believe they would likely use multiple doses of our intranasal epinephrine technology product candidate each year to resolve their symptoms. Therefore, the market opportunity for treating flares in chronic spontaneous urticaria patients could be as large as the Type I allergy including anaphylaxis indication. Assuming that one sprayer device is used monthly to treat such flares in chronic spontaneous urticaria, we estimate that the market opportunity in the United States alone is greater than $2 billion in net sales in this indication, assuming a similar price and gross-to-net realizations as *neffy*, if approved. Although both patients treated with either antihistamines or biologic treatments, such as Xolair, can experience frequent flares that may be suitable for treatment with our intranasal epinephrine technology product candidates, our development strategy has focused first on patients treated with only antihistamines. Our intranasal epinephrine technology product candidates may offer significant pharmacoeconomic value to payors by reducing the likelihood of step-up therapy to a much more expensive biologic treatment.

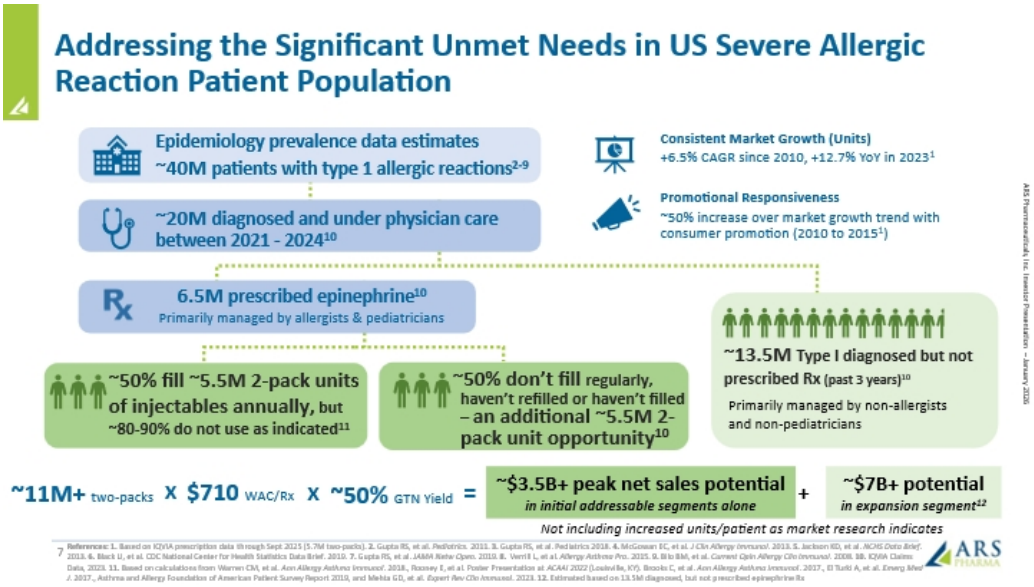
We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients. In the second quarter of 2025, we initiated a Phase 2b randomized, placebo-controlled outpatient clinical trial involving chronic spontaneous urticaria patients, on chronic treatment regimens, who still experience flares or exacerbations. Interim data from this clinical trial is anticipated in the second half of 2026, followed by the potential initiation of a single pivotal efficacy study in mid-2027.

Commercialization Opportunity and Commercialization Plan

Existing U.S. Market Opportunity

We believe *neffy* could address the needs of the approximately 3.2 million patients in the U.S. who currently fill intra-muscular injectable prescriptions, the approximately 3.3 million people in the U.S. that either refused to fill, or did not renew an intra-muscular injectable device prescription, and the more than 13.5 million eligible Type I allergy patients in the United States who are at risk of severe allergic reactions that are not prescribed an epinephrine product.

Based on the current list price of *neffy* and our target total gross-to-net yield, we estimate that the initial addressable potential market opportunity of 6.5 million patients who have been prescribed epinephrine during 2020-2022 is approximately $3.5 billion in annual net sales for *neffy*. We estimate the addressable market opportunity for the 13.5 million patients who have been diagnosed during 2020-2022, but were not prescribing epinephrine, is approximately $7.0 billion in potential annual net sales for *neffy*.



Key potential growth levers for *neffy* within the existing epinephrine market for the emergency treatment of Type I allergic reactions, which currently consists of only intra-muscular injectable products include:

- ***Consistent base market growth observed with the epinephrine intra-muscular injectable products.*** From 2010 to 2023, the number of epinephrine intra-muscular injectable devices sold in the U.S. has increased by approximately 6.5% annually based on IQVIA unit sales data, primarily due to the increasing size of the overall population affected by severe Type I allergies, led by food-based allergies.
- ***Potential promotional lift due to new marketing and education efforts by a branded product such as neffy***. The existing market for epinephrine intra-muscular injectable products is characterized by being highly promotionally sensitive, particularly from a consumer perspective. We estimate that branded marketing of EpiPen prior to generic entry contributed a promotional lift in sales of 31% over organic epinephrine intra-muscular injectable market growth trends. Our market research has indicated that *neffy's* user-friendly product profile has the potential to resonate significantly with consumers, and we are investing significantly into direct-to-consumer advertising to patients.
- ***Improving refill rates by patients.*** Based on IQVIA longitudinal claims data, only 31% to 39% of patients refilled their epinephrine intra-muscular injectable product prescription after 12 to 24 months from the initial prescription. In contrast, September 2025 survey we conducted of actual *neffy* users indicated that 95% were likely to refill *neffy*, which we believe indicates significant potential for market expansion through improved persistency and retention as *neffy* product expires and is re-filled by patients.
- ***Increased per patient device acquisition by patients and parents.*** In our market research conducted prior to FDA approval of *neffy* of 350 patients with an active intra-muscular injectable prescription, approximately 70% to 80% of patients reported an intention to acquire additional devices over time compared to their current injectable device. Currently, we estimate only between 20% to 30% of patients obtain more than one pack (containing two devices) per year today.

U.S. Market Expansion Opportunity

While we believe the existing epinephrine intra-muscular injectables market is a large commercial opportunity for *neffy* with multiple independent opportunities for further growth, IQVIA claims data indicates that many diagnosed, identifiable eligible patients do not receive prescriptions for intra-muscular injectables.

- In addition to the 3.2 million patients per year who fill their prescription for an epinephrine injectable device, there are approximately 3.3 million people who do not fill their epinephrine intra-muscular injectable prescription, or whose prescription has recently lapsed. In addition, there are 13.5 million patients who are under the care of physicians for potential severe allergic reactions per IQVIA claims data, but have not been prescribed an epinephrine intra-muscular injectable device.
- The poor refill rates of epinephrine autoinjectors have been attributed to a number of factors, including reduced promotional activities in recent years, limited adherence program effectiveness (lapsed prescriptions) and patient adversity to currently marketed products (i.e., fear of needles and concerns regarding poor reliability).
- Our September 2025 survey of actual *neffy* patients indicates that approximately 26% of patients are from market expansion segments that have either lapsed or never filled, which we believe supports that *neffy* is already expanding the market.

Ex-U.S. Market Opportunity

- Outside of the United States, we estimate that there are an additional 15 million patients in Europe, and 30 million patients in Asia including China and Japan, that experience Type I allergic reactions that are clinically appropriate for being prescribed *neffy*.
- We believe education around Type I allergic reactions and marketing of intra-muscular injectables has been limited in these regions, and that promotion and the availability of *neffy* would significantly expand the market.
- To target these opportunities outside of the U.S., we have entered into licensing, collaboration and partnership agreements, including with Alfresa for rights to *neffy* in Japan, Pediatrix for rights to *neffy* in China, Seqirus for rights to *neffy* in Australian and New Zealand, and ALK for, among other things, rights to *neffy* in all other territories outside of the U.S.
- ALK anticipates peak sales in excess of $425.0 million for its licensed regions alone, principally comprising Canada, the EU and the U.K.

Sales and Marketing

We believe that the epinephrine market is a highly consumer driven market. We expect this to be especially true for *neffy*, given that 99% of the physicians surveyed in our quantitative market research studies indicated that they would prescribe *neffy* if asked by a patient and approximately 70% of physicians would recommend *neffy* assuming equal market access conditions as epinephrine autoinjectors. As a result, we believe that driving consumer awareness, so that patients and parents ask their healthcare provider for *neffy*, while minimizing both access and educational barriers to acceptance is essential.

We have established robust marketing, sales, and distribution capabilities to support the launch of *neffy* in the U.S. through an experienced national sales force targeting healthcare providers. We believe we can successfully commercialize *neffy* in the U.S. with a focused sales force targeting high prescribers of epinephrine, particularly allergists and pediatricians. Our strategy is to target approximately 20,000 core high volume prescribers that represent between 50 to 55% of all epinephrine prescriptions. Our current sales force of 106 individuals is comprised of sales reps, area sales managers, and national sales directors, plus we have an additional 10 virtual sales reps and approximately 70 sales reps via our co-promotion partner, ALK U.S. We plan to expand our sales force to approximately 150 individuals beginning in the second quarter of 2026. In the U.S., we sell primarily to pharmaceutical wholesale distributors, which are the principal means of distributing our products to healthcare providers.

Our ongoing *neffy* experience program also allows healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenge, and obtain direct clinical experience using *neffy*. *neffy* market share among participants in the *neffy* experience program is more than three-fold higher than the typical healthcare provider.

We also market through direct-to-consumer channels, including across streaming platforms, traditional broadcast and cable television, and consumer-facing digital channels including Facebook, Instagram, waiting room TVs in doctors' offices, and digital banner ads. Since launch, the campaign has reached millions of allergy patients and is driving strong patient awareness, increasing prescription requests, and motivating patients to explore a non-injectable treatment option.

In November 2025, we also launched and began direct-to-consumer advertising of our *getneffy.com* website, which offers patients the option to obtain a *neffy* prescription the same day with a free visit with a virtual healthcare provider, eliminating the time-burden of an in-person visit. Patients may receive *neffy* with a $0 co-pay, if eligible with commercial insurance.

Competition

Our industry is highly competitive and subject to rapid technological changes. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approval of product candidates and the commercialization of those products. We believe that the key competitive factors that will affect the development and commercial success of *neffy*, our intranasal epinephrine technology product candidates and the other product candidates that we may develop are their efficacy, safety and tolerability profile, convenience in dosing, product labeling, value and price, in addition to whether there are alternative therapies approved for other indications and prescribed for off-label use and the availability of reimbursement from the government and other third parties. Our commercial opportunity could be reduced if our competitors have products which are better in one or more of these categories.

neffy competes with a number of existing products and other product candidates that target Type I allergic reactions, including certain products that are or may become generic products. Additionally, the development of new treatment methods for the diseases we are targeting could render our current or future product candidates non-competitive or obsolete.

neffy competes primarily against epinephrine intra-muscular injectable products, for the emergency treatment of Type I allergic reactions including EpiPen and its generics, which are marketed by Viatris, Inc. and Teva Pharmaceuticals, Inc., respectively; Adrenaclick, which is marketed by Amneal Pharmaceuticals, Inc.; Auvi-Q, which is marketed by Kaleo, Inc.; and Symjepi, which is marketed by Sandoz, Inc., a Novartis division.

We are not aware of any other company that has a "no needle, no injection" epinephrine product candidate in clinical development in the United States that has demonstrated a PK/PD profile bracketed by the approved injection products for all PK and PD parameters requested by the FDA across all relevant dosing conditions including single dosing, repeat dosing, self-administration and during allergen challenge.

We are aware of several companies developing higher dose spray candidates including Bryn Pharma, Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Nasus Pharma Ltd., Orexo AB, Insignis Therapeutics, Inc. and Belhaven BioPharma. Aquestive Therapeutics, Inc. is developing a sublingual candidate based on a prodrug of epinephrine, which recently received a Complete Response Letter ("CRL") from the FDA due to concerns with their application.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of *neffy* or our intranasal epinephrine technology product candidates nor do we have plans to develop our own manufacturing operations for clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturing organizations ("CMOs") for all of our required raw materials, drug substance and drug product for our preclinical research and clinical trials.

We currently rely on suppliers for raw materials including drug substance and multiple manufacturers for our product candidates and expect to rely on third-party suppliers and manufacturers for the commercial supply of any approved products. We currently employ internal resources and third-party consultants as needed to manage our CMOs. These CMOs offer a comprehensive range of contract manufacturing and packaging services and have successfully handled the scale up of *neffy* in connection with its commercialization.

neffy is presented as a nasal spray in aqueous solution with epinephrine as the active pharmaceutical ingredient ("API") filled into glass vials and closed with a rubber stopper and assembled into the unit dose sprayer device. Over time, epinephrine is oxidized and loses potency resulting in a finite shelf-life, and the *neffy* solution inside the unit dose sprayer changes to an amber to brown color.

Epinephrine is the API used in *neffy*. We use Cambrex Profarmco ("Cambrex") as one of our commercial sources for epinephrine API. Cambrex holds a U.S. drug master file for epinephrine produced at its facility in Italy, and its manufacturing process is fully validated. We have entered into a commercial supply agreement with Cambrex, and while we believe that Cambrex has sufficient capacity to satisfy our long-term requirements, there are several sources of API available.

Dodecyl maltoside or Intravail is purchased through our license agreement with Aegis Therapeutics, LLC ("Aegis") from two manufacturers, Dr. Reddy Laboratories and Inalco, which are based in India and Italy, respectively.

The unit dose sprayer device used to delivery drug product in *neffy* is produced by Aptar Pharma ("Aptar") and Silgan Dispensing Systems ("Silgan"). Aptar produces devices in France and the U.S., while Silgan produces devices in Germany, and both have sufficient capacity to satisfy our long-term requirements. The patent for the Aptar unit dose nasal spray device expired in early 2020.

Manufacturing drug product for *neffy* and our intranasal epinephrine technology product candidates is conducted by Renaissance Lakewood, LLC ("Renaissance"), which has been actively involved in supporting the manufacture of *neffy* and our intranasal epinephrine technology product candidates. We use its facility in Lakewood, New Jersey as our primary source for drug product manufacturing and final packaging. We have entered into a commercial supply agreement with Renaissance, and believe they have sufficient capacity to satisfy our long-term requirements, although we are evaluating alternative sourcing options.

Our registration stability studies demonstrate that *neffy* is stable at room temperature for up to 30 months, based on stability data meeting specifications with the 2 mg dose of *neffy* for 30 months and the 1 mg dose of *neffy* for 24 months. Epinephrine injectable products have a reported shelf-life range from the date of product manufacture of 18 to 24 months, with a volume-weighted average shelf-life of approximately 22 to 23 months. Our FDA and EC label indicates that *neffy* 2 mg is stable at room temperature for 30 months at 25°C. We have also conducted studies indicating that *neffy* is also stable at temperature excursions including 40°C for up to six months, and at 50°C for up to three months, without labeling permitting excursions up to such temperature, or *neffy* not requiring any special storage conditions.

Manufacturing Agreement with Renaissance

In September 2020, we entered into a manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"), which was subsequently amended in July 2023, September 2024 and July 2025 (the "Renaissance Agreement"). Pursuant to the agreement, Renaissance agreed to manufacture for, and provide to us, *neffy* nasal unit dose sprays ("Renaissance Products"). We are obligated to provide Renaissance with certain supplies to manufacture the Renaissance Products and to purchase from Renaissance a mid-double-digit percentage of our annual aggregate Renaissance Product requirements in the EU, and a high-double-digit percentage of our annual aggregate Renaissance Product requirements in the U.S. The agreement contains conventional commercial pharmaceutical manufacturing provisions including certain minimum purchase amounts to be determined in the future based on forecast needs and minimum batch size projections. We may also request Renaissance to perform certain services related to the Renaissance Product, for which we will pay reasonable compensation to Renaissance.

The initial term of the Renaissance Agreement commenced on September 17, 2024 and will terminate on (a) December 31, 2029 for Renaissance Product designated for commercial sale in the U.S. ("U.S. Initial Term"), and (b) December 31, 2030 for Renaissance Product designated for commercial sale in the EU ("EU Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and EU Initial Term automatically renew for successive two-year terms ("Renewal Term"). Either party may elect not to renew the U.S. Renewal Term and/or the EU Renewal Term by providing the requisite prior notice to the other party. Either party may terminate the agreement (1) for uncured material breach of the other party, (2) upon notice for insolvency-related events of the other party that are not discharged within a defined time period, (3) on a product-by-product basis if the manufacture, distribution or sale would materially contravene any applicable law, (4) by providing the requisite notice if (a) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before a specified date, (b) the authorization and approval representing more than a certain number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (c) we decided in our sole discretion to cease commercializing the Renaissance Product in the U.S., (5) in the case of a force majeure event that continues for six months or more, or (6) a violation by the other party of trade control or anti-corruption laws.

Intellectual Property

We strive to protect our intranasal epinephrine product candidates by seeking, maintaining, and defending our patent rights in the U.S. and internationally. Our policy is to pursue, maintain and defend patent rights in strategic areas, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

We own, co-own or exclusively license the patents and patent applications relating to our intranasal epinephrine product candidates. As of December 31, 2025, our patent portfolio consisted of issued patents and pending patent applications that we own, co-own or exclusively license from Aegis in the U.S. and other countries throughout the world. In total, as of that date, our patent portfolio consisted of eight issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, and over thirty member states of the European Patent Organization, including the U.K., directed to *neffy* and its uses, among other things, three pending U.S. patent applications, one pending international patent application and sixteen pending foreign patent applications, directed to *neffy* and its uses, among other things, and a pending U.S. provisional patent application directed to intranasal epinephrine formulations and methods of their use, among other things. These issued patents and pending patent applications provide patent protection for *neffy* and are expected to expire as early as 2038, absent any patent term adjustments.

In addition to patent protection, we also rely on trademarks, trade secrets, know how, and other proprietary information to develop and maintain our competitive position. We seek trademark protection in the U.S. and in certain other jurisdictions where available and when we deem appropriate. We currently have registrations and pending applications for our "*neffy*" mark in the U.S. as well as in certain foreign jurisdictions and for our "*EURneffy*" mark in the EU, U.K., and other foreign jurisdictions.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates and processes. For this and more comprehensive risks related to our intellectual property, please see "*Risk Factors—Risks Related to Our Intellectual Property.*"

We also seek to protect our intellectual property in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators, and other collaborators and contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to Our Intellectual Property.*"

The patent positions of specialty pharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the U.S. Patent and Trademark Office (the "USPTO") to determine priority of invention. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to Our Intellectual Property.*"

Our Collaboration and Licensing Agreements

License Agreement with Aegis

In June 2018, we entered into a license agreement (the "Aegis Agreement") with Aegis Therapeutics, LLC ("Aegis"), which was amended in July 2020 and January 2021. Pursuant to the Aegis Agreement, Aegis granted us an exclusive, worldwide, sublicensable license under patents and know-how relating to the Intravail drug delivery technology to research, develop, make (subject to Aegis supplying the Intravail drug delivery technology to us under a supply agreement), use, sell, offer for sale, import, and otherwise commercialize products incorporating epinephrine compounds ("Aegis Licensed Compounds"), including the *neffy* nasal spray. During the term of the Aegis Agreement, we are required to use commercially reasonable efforts to obtain regulatory approval for products containing one or more Aegis Licensed Compounds and using the excipient (including Intravail) ("Aegis Licensed Products") and to thereafter maximize sales of the Aegis Licensed Products. Aegis may not directly or indirectly exploit an Aegis Licensed Product or Aegis Licensed Compound or derivatives thereof without our consent.

Under the Aegis Agreement, Aegis received an upfront license fee of $50,000 in 2018 and is entitled to receive development milestone payments of up to $3.95 million in the aggregate and commercialization milestone payments up to $16.0 million in the aggregate for each Aegis Licensed Product. We made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone in 2019, a $1.0 million payment to Aegis upon the FDA's acceptance of our U.S. NDA filing in 2022, a $2.5 million milestone payment to Aegis for achieving FDA approval of *neffy* 2 mg in September 2024, $5.0 million milestone payment to Aegis for the first commercial sale of *neffy* 2 mg in October 2024, and a $2.0 million milestone payment to Aegis for achieving a certain annual net sales of *neffy* 2 mg in September 2025. Additionally, Aegis is entitled to receive a low- to mid-single-digit percentage royalty, subject to reductions under certain conditions including due to generic competition or below threshold levels of profitability in specific countries around the world, on net sales of all Aegis Licensed Products during the applicable royalty term, which commences on the first commercial sale of a Aegis Licensed Product in a country and ends upon the later of the expiration of all licensed patents covering such Aegis Licensed Product in such country or 15 years after the date of the first commercial sale of the Aegis Licensed Product in such country ("Aegis Royalty Term").

The Aegis Agreement will continue until the expiration of the last-to-expire Aegis Royalty Term, unless sooner terminated. We have the right to terminate the Aegis Agreement at any time after a specified notice period to Aegis. Either party may terminate the Aegis Agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

Collaboration and License Agreement with Alfresa

In April 2020, we entered into a collaboration and license agreement (the "Alfresa Agreement") with Alfresa Pharma Corporation ("Alfresa"). Pursuant to the Alfresa Agreement, we granted Alfresa (i) an exclusive, sublicensable license under our patents relating to *neffy* to develop, use and import epinephrine compositions ("Alfresa Licensed Compositions") and related products ("Alfresa Licensed Products") in Japan (the "Alfresa Territory") and to promote, distribute, offer for sale and sell Alfresa Licensed Products in the Alfresa Territory, and (ii) a non-exclusive, sublicensable license to manufacture and commercialize Alfresa Licensed Products under the license described in clause (i), under our technology to make and have made Alfresa Licensed Compositions and Alfresa Licensed Products in and outside the Alfresa Territory solely for the purpose of exercising the license described in clause (i) in the Alfresa Territory. We expressly reserved all rights to practice and grant licenses under our technology outside the scope of the licenses granted to Alfresa, including the right to manufacture Alfresa Licensed Compositions and Alfresa Licensed Products in the Alfresa Territory. During the term of the Alfresa Agreement, (1) we and Alfresa are obligated to use commercially reasonable efforts to develop a Alfresa Licensed Product throughout the Alfresa Territory, and (2) Alfresa is obligated to use commercially reasonable efforts to (A) seek pricing and reimbursement approval, (B) seek and maintain regulatory approval for the Alfresa Licensed Products through the Alfresa Territory, and (C) market, promote and otherwise commercialize Alfresa Licensed Products in the field throughout the Alfresa Territory.

Under the Alfresa Agreement, we received a one-time upfront payment of $2.0 million in 2020, earned $5.0 million upon the achievement of a clinical milestone in 2021, earned $6.0 million upon the completion of a regulatory milestone in Japan in November 2024, and earned $2.0 million upon the achievement of a commercial milestone in Japan in November 2025. We shared the cost of any additional clinical studies required for approval of *neffy* in Japan.

The Alfresa Agreement will continue until the later of (i) expiration of the last-to-expire valid claim of our patents or joint patent with Alfresa covering the composition, method of manufacture or method of use in the field of any Alfresa Licensed Product in the Alfresa Territory, and (ii) 10 years after the first commercial sale of any Alfresa Licensed Product in the Alfresa Territory. Alfresa has the right to terminate the Alfresa Agreement (1) at any time after a specified notice period to us, or (2) upon notice to us if a binding decision is rendered invalidating any of our patents. Either party may terminate the Alfresa Agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

In December 2025, in connection with the Alfresa Agreement, ARS and Alfresa also entered into a commercial supply agreement (the "Alfresa Supply Agreement"), under which we will supply Alfresa's requirements (and Alfresa will purchase from ARS its requirements) for a transfer price in the low-double-digit percentage on net sales of *neffy* in Japan. The Alfresa Supply Agreement is coterminous with our Alfresa Agreement. Pursuant to the Alfresa Agreement, at any time, Alfresa may elect to manufacture its own supply of drug product. In the event Alfresa elects to do so, Alfresa is obligated to pay us a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value we would receive by supplying drug product to Alfresa at the transfer price.

Collaboration and Distribution Agreement with Pediatrix

In March 2021, we entered into a collaboration and distribution agreement (the "Pediatrix Agreement") with Pediatrix Therapeutics ("Pediatrix"). Pursuant to the Pediatrix Agreement, we granted Pediatrix (i) an exclusive, royalty-bearing, sublicensable license under our patents relating to *neffy* to develop, use, register and import epinephrine compositions ("Pediatrix Licensed Compositions") and related products ("Pediatrix Licensed Products") in China, Macau, Hong Kong and Taiwan (the "Pediatrix Territory") and to promote, offer for sale and sell Pediatrix Licensed Products in the Pediatrix Territory; and (ii) an exclusive, royalty-bearing, sublicensable license to manufacture Pediatrix Licensed Compositions and Pediatrix Licensed Products solely for the purpose of exercising the license described in clause (i) in the Pediatrix Territory. We expressly reserved all rights to practice and grant licenses under our technology outside the scope of the licenses granted to Pediatrix. During the term of the Pediatrix Agreement, Pediatrix is obligated to use commercially reasonable efforts to (1) develop the Pediatrix Licensed Products throughout the Pediatrix Territory, (2) prepare, obtain, maintain and renew all necessary regulatory approvals for the Pediatrix Licensed Products in the Pediatrix Territory, and (3) market, promote and otherwise commercialize the Pediatrix Licensed Products throughout the Pediatrix Territory.

Under the Pediatrix Agreement, we received a one-time upfront payment of $3.0 million in 2021 and earned a regulatory milestone payment of $4.0 million in December 2025, and are eligible to receive net sales milestone payments of up to $80.0 million in the aggregate. We will receive a per unit supply price for any sale of commercial supply to Pediatrix. Additionally, we are eligible to receive a tiered royalty on the net sales of all Pediatrix Licensed Products during the applicable royalty term, which is less than one percent below a minimum annual sales threshold, and increasing to low- to mid-double-digit percentages above the minimum annual sales threshold, subject to reductions under certain conditions including due to generic competition. Pediatrix's obligation to pay us royalties continues on a Pediatrix Licensed Product-by- Pediatrix Licensed Product and region-by-region basis in the Pediatrix Territory, until the latest of (i) expiration of the last-to-expire valid claim of our patents covering such Licensed Product in such region; (ii) the expiration of all regulatory exclusivities that cover such Licensed Product in such region; or (iii) ten years after the first commercial sale of such Pediatrix Licensed Product in such region (the "Pediatrix Royalty Term").

The Pediatrix Agreement will continue until the expiration of the last-to-expire Pediatrix Royalty Term. Pediatrix has the right to terminate the Pediatrix Agreement at any time after a specified notice period to us. Either party may terminate the Pediatrix Agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

Seqirus Agreement

In March 2024, we entered into a license and distribution agreement (the "Seqirus Agreement") with Seqirus Pty Ltd. ("Seqirus"), which was amended in December 2025, for the exclusive license to commercialize *neffy* in Australia and New Zealand (the "Seqirus Territory"). Under the Seqirus Agreement, we are responsible for the transfer of know-how, which includes regulatory materials, regulatory data, and commercialization data, and also for the manufacturing of product for commercial supply which is available to Seqirus at a negotiated price. Seqirus is solely responsible for all regulatory and commercialization activities in the Seqirus Territory. Either party may terminate the Seqirus Agreement for certain breaches. Unless terminated earlier by either or both parties, the initial term of the Seqirus Agreement is 15 years from the first commercial sale of neffy in the Seqirus Territory. The Seqirus Agreement will automatically renew for two-year periods unless either party gives a notice to terminate at least 12 months prior to the end of the initial or any renewal term.

Under the Seqirus Agreement, we received an upfront payment of $0.5 million in May 2024, earned a regulatory milestone payment of $1.5 million in August 2024, and earned a regulatory milestone payment of $0.6 million in December 2025. In addition, we are eligible to receive up to $2.3 million of milestone payments upon achievement of certain event milestones. Subject to regulatory approval in Australia and New Zealand, we will also receive a per unit supply price for the sale of commercial supply to Seqirus.

ALK Collaboration Agreement

In November 2024, we entered into a collaboration, license and distribution agreement (the "ALK Collaboration Agreement") with ALK. Pursuant to the ALK Collaboration Agreement, we granted to ALK a worldwide (other than the United States, Japan, mainland China, Hong Kong, Taiwan, Macau, Australia and New Zealand) ("ALK Territory"), exclusive license under certain of our patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including *EURneffy* (the tradename for *neffy* 2 mg in the European Union) (epinephrine nasal spray) ("Products"), for all human uses, including the immediate or emergency treatment of allergic reactions (including Type I) and anaphylaxis and urticaria, and other future indications as agreed by the parties. If we develop any new intranasally administered product that contains epinephrine and files a new drug application in the United States for such product ("New Product"), upon ALK's request such New Product will be included as a Product under the ALK Collaboration Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Collaboration Agreement, we are obligated to transfer to ALK the existing marketing authorizations for the Products in the ALK Territory. We are also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in the ALK Territory, and will transfer such regulatory approvals to ALK. ALK is obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for Products through the European Commission and within specified countries within the ALK Territory. Following such approval for a Product in each indication within specified countries within the ALK Territory, ALK is obligated to use commercially reasonable efforts to commercialize such Product in such indication in such countries and to achieve first commercial sale of a Product in certain countries in accordance with a timeline specified in the ALK Collaboration Agreement.

Under the ALK Collaboration Agreement, ALK made an upfront payment to us of $145.0 million in November 2024 and earned a commercial milestone payment of $5.0 million for the first commercial sale of *neffy* in June 2025. We are eligible to receive regulatory and development milestones of up to $15.0 million and commercial sales-based milestones of up to $300.0 million, provided that $55.0 million of such sales-based milestones are contingent upon us obtaining regulatory approval for the Product in Canada by a specified time. We are entitled to receive tiered royalty payments on net sales in the mid- to high-teens, subject to certain standard reductions and offsets. Royalties will be payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the licensed patents covering such Product in such country, 15 years from first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

The contract will expire upon the expiration of the last to expire royalty term for all Products in the ALK Territory, unless terminated earlier. Either we or ALK may terminate the ALK Collaboration Agreement in the case of the other party's insolvency or in the event of an uncured material breach of the other party, except that we may not terminate the ALK Collaboration Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Collaboration Agreement for convenience upon prior written notice or for a safety or regulatory concern. We may terminate the ALK Collaboration Agreement in the event ALK makes certain challenges to certain of our patents. Prior to a change of control and outside of a set period of time after which we commence change of control negotiations, we may terminate the ALK Collaboration Agreement with respect to all countries in the European Economic Area ("EEA") upon prior written notice to ALK and payment of a termination fee that is the higher of an agreed mid-nine digit amount and the fair market value of the Products business in the EEA at the time of such termination. We may also terminate the ALK Collaboration Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

ALK Supply Agreement

On November 9, 2024, in connection with the ALK Collaboration Agreement, ARS and ALK also entered into a commercial supply agreement (the "ALK Supply Agreement"), under which ARS will supply ALK's requirements (and ALK will purchase from ARS its requirements) of Products for five years for a specified supply price, after which ALK may elect to transition to itself or its contract manufacturer the manufacture and supply of Products. Either we or ALK may terminate the ALK Supply Agreement in the event of an uncured material breach of the other party.

ALK Co-Promotion Agreement

In May 2025, we entered into a co-promotion agreement with ALK U.S., which was subsequently amended in October 2025 and March 2026 (as amended, the "ALK Co-Promotion Agreement"), to co-promote *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. Under the ALK Co-Promotion Agreement, we granted ALK U.S. a non-exclusive, royalty-free license to use the *neffy* trademarks and copyrights and the ARS house marks in the U.S. solely in connection with promoting *neffy* pursuant to the terms of the ALK Co-Promotion Agreement.

ALK U.S. commenced its promotion activities in May 2025 and is obligated to meet specified ramp-up milestones and minimum detail requirements using qualified sales representatives. In addition, during the term of the ALK Co-Promotion Agreement and for 180 days thereafter, ALK U.S. will not market, sell or manufacture any injection product containing epinephrine in the U.S.

We record all sales of *neffy* in the U.S. and, subject to the terms of the ALK Co-Promotion Agreement, continue to have sole responsibility for all U.S. commercialization activities, including marketing, medical affairs, market access, production, distribution, pharmacovigilance, quality and safety.

We will pay ALK U.S. a base fee to compensate ALK U.S. for its promotion activities. Payments for the first year of the partnership will be deferred and paid in the second year of the partnership. In addition to the base fee, ALK U.S. will be eligible to receive performance-based bonus payments from us starting in May 2026 equal to 30% of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified initial market share threshold in year two or a 50% market share threshold during years three and four of the partnership.

The ALK Co-Promotion Agreement expires in May 2029. Either party may terminate the ALK Co-Promotion Agreement in the event of an uncured material breach of the other party or for either party's change of control. We may terminate the ALK Co-Promotion Agreement in the case of ALK U.S.'s insolvency, if ALK U.S. fails to meet specified ramp-up timelines, or if ALK U.S. markets, sells or commercializes any non-injection product containing epinephrine in the U.S. We may terminate the ALK Co-Promotion Agreement if minimum detail requirements are not met for a consecutive three-month period. After the first year, we may terminate the ALK Co-Promotion Agreement for any reason or no reason for a fee (as described below). After the first year, ALK U.S. may terminate the ALK Co-Promotion Agreement for any reason or no reason, and we may terminate the ALK Co-Promotion Agreement in the event ALK U.S. restructures its sales force.

Upon termination of the ALK Co-Promotion Agreement by us for convenience, so long as ALK U.S. has met specified performance thresholds during the term, we are obligated to pay ALK U.S. a specified mid-to-low double-digit percentage of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified mid-quartile market share threshold that increases over time up to 50% for a specified period after termination, which period decreases in duration the later that the termination occurs. Upon termination of the ALK Co-Promotion Agreement by us in connection with a change of control of the Company, we are obligated to pay ALK U.S. a one-time mid-seven digit to low eight-digit termination fee in an amount that increases the later that the termination occurs.

Government Regulation and Product Approval

As a pharmaceutical company that operates in the U.S., we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Product candidates that we develop must be approved by the FDA, before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Regulation of Combination Products in the United States

Our intranasal epinephrine technology, including *neffy*, is comprised of drug and delivery device components that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product.

A combination product with a primary mode of action attributable to the drug component, such as *neffy* and our intranasal epinephrine technology product candidates, generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA. In reviewing the New Drug Application ("NDA") for such a product, however, FDA reviewers would consult with their counterparts in the device center to ensure that the device component of the combination product – the sprayer - met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products such as *neffy* and our intranasal epinephrine technology product candidates are subject to current Good Manufacturing Practice ("cGMP") requirements applicable to both drugs and devices, including the Quality Management System Regulations applicable to medical devices.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations and other applicable regulations;
- submission to the FDA of an investigational new drug ("IND"), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP regulations;
- satisfactory completion of an FDA PADAC review, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP requirements. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1.** The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- **Phase 2.** The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- **Phase 3.** The drug is administered to an expanded patient population to further evaluate dosage and clinical efficacy at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human subjects. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows such committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. The FDA may also determine that a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Post-Approval Requirements

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification to the FDA, the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other Healthcare Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback laws, false claims laws, data privacy and security laws, and other healthcare fraud and abuse laws, such as transparency laws regarding payments or other items of value provided to healthcare providers.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal healthcare program anti-kickback statute has been violated. Additionally, the intent standard under the federal anti-kickback statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the federal civil monetary penalties law, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including significant fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Some third-party payors require pre-approval of coverage for new drugs before they will reimburse healthcare providers who use such therapies. Generally, third-party payors limit coverage and reimbursement for new medication prior to a formal review by the payors' pharmacy and therapeutics committees. As such, several third-party payors have indicated that our products may be subject to denial or limited coverage prior to formal review. There may be significant delays in obtaining reimbursement for newly-approved drugs, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. There can be no assurance that our product candidates will be considered medically necessary or cost-effective.

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we are subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price ("AMP"), and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. In addition, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize neffy and any product candidates for which we receive approval.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. Furthermore, there can be no assurance that a product will be considered medically reasonable and necessary for a specific indication, that a product will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability to sell a product profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. For example, implementation of the ACA substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry.

Since its enactment, there have been amendments and judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how such challenges and the healthcare reform measures of the current administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken. Further, there may be additional health reform measures.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, the American Taxpayer Relief Act of 2021, effective January 1, 2024, eliminated the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program ("MDRP"), previously capped at 100% of the AMP for a covered outpatient drug.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Data Privacy and Security Laws

Numerous state, local, federal and foreign laws, including consumer protection laws and regulations related to data privacy, security, and protection, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. Such obligations may include, without limitation, HIPAA, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 ("CCPA"), the Canadian Personal Information Protection and Electronic Documents Act, Canada's Anti-Spam Legislation, the EU's General Data Protection Regulation 2016/679 ("EU GDPR"), and the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the EU (Withdrawal) Act 2018 ("UK GDPR"). HIPAA, as amended by HITECH, imposes obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, certain state and non-U.S. laws, such as the CCPA, the CPRA and the GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

In addition, Congress and various other states have enacted or are considering new laws and regulations regarding the privacy and security of health and other personal information to which we may become subject. Further, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We intend to continue to protect all personal information in our control and to comply with all applicable laws regarding the protection of such information.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information, including requiring covered companies to provide new disclosures to California residents, and affords such residents new abilities to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. Moreover, the California Privacy Rights Act, or the CPRA, – a consumer privacy ballot initiative that amends and expands the CCPA became effective on January 1, 2023, and expands the CCPA. The CPRA affords California residents significantly more control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcement agency dedicated to consumer privacy. While aspects of the CCPA and CPRA and its interpretation remain to be determined in practice, they create further uncertainty and may result in additional costs and expenses in an effort to comply.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of an application for a clinical trial authorization ("CTA") much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to each country's national health authority and an application made to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed.

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization ("ICH"), guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

At the EU level, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 ("CTD"). The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

EU Review and approval process

In the EU, medicinal products can only be commercialized after a related marketing authorization ("MA"), has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application ("MAA"), either under a centralized procedure administered by the European Medicines Agency ("EMA") or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the CHMP of the EMA conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMDh"), for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing Regulation in the EU

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

The EU also provides opportunities for market exclusivity. For example, upon receiving an MA, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Orphan Designation in the EU

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization Requirements in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Combination Products in the EU

The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which of the components of the combination has the primary mode of action.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal product is principal to that of the medical device are governed by the regulatory framework applicable to medicinal products. However, the General Safety and Performance Requirements ("GSPRs"), of Annex I to Regulation (EU) 2017/745 on Medical Devices ("MDR"), will be applicable to the safety and performance of the medical device part of the product in the context of its use with the medicinal product. In these circumstances, an MAA must be submitted to the competent authorities responsible for evaluating the safety and effectiveness of medicinal products. As part of the MAA, the applicant must also submit, where available, the results of the assessment of the conformity of the medical device part of the product with the MDR contained in the manufacturer's EU Declaration of Conformity of the device or the relevant Certificate of Conformity issued by a Notified Body. If the MAA does not include the results of the conformity assessment, and where the conformity assessment of the device, if used separately, requires the involvement of a Notified Body, the competent authorities must require the applicant to provide a Notified Body Opinion on the conformity of the device with the relevant GSPRs. Based on this approach, the competent authorities responsible for medicinal products will review the specific aspects of the medical devices part of the product which are relevant to the safety and efficacy of the medicinal product and the Notified Body – where applicable – will evaluate the relevant GSPRs of the device.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to medical devices in accordance with the MDR. However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an EU Member State or from the EMA, depending on its nature and therapeutic intention, must be sought regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where a medical device incorporates a medicinal product as an integral part as a single use drug delivery system, which is intended exclusively for use in the given combination and which is not reusable, it is regulated as a medicinal product. In this case, the relevant General Safety and Performance Requirements, or GSPRs of the MDR will apply to the safety and performance of the device element.

By contrast, drug-device combination products which do not form a single integral product will be regulated separately. This may include, for example a drug-device combination product where a medical device and a medicinal product are co-packaged and the medical device is intended solely to be used for the administration of the co-packaged medicinal product. In these circumstances, the medicinal product will be governed by the regulatory framework applicable to medicinal products and the medical device will be governed by the MDR. However, the characteristics of a medical device used for the administration of a medicinal product may impact the quality, safety and efficacy profile of the medicinal product. As a result, as part of the MAA submitted to the competent authorities for the medicinal product, the applicant may need to provide additional information regarding the characteristics of the co-packaged medical device that may impact on the quality, safety and/or efficacy of the medicinal product. Similar requirements may apply where the products are not co-packaged but the medicinal product information makes an explicit reference to a specific medical device.

Medicinal Products in the United Kingdom

The United Kingdom's ("UK"), withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency ("MHRA") is now the UK's standalone regulator for medicinal products and medical devices. The UK is no longer subject to EU regulations (Northern Ireland continues to follow certain limited EU regulatory rules, including in relation to medical devices, but not in relation to medicinal products).

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the UK MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023, confirming that it would bring forward changes to the legislation and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment with the EU CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU but have been tailored for the market. This includes the criterion that prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the UK.

Drug-device combination products in the UK

Similarly to the EU, the UK regulates medical devices and medicinal products separately and through different legislative instruments. Medical devices are governed by the Medical Device Regulations (UK MDR) 2002, as amended which are based on the (now superseded) EU Medical Devices Directive, as opposed to the EU MDR which does not apply in the UK. Products that are a combination of a medicinal product and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules depending on the type of drug-device combination.

Devices that are used to administer medicinal products that are included separately in a pack with the medicine or that can be refilled with medication contained in the same pack as the device are regulated as medical devices. Devices that are used for administering medicinal products where the device and medicinal product form a single integral product designed to be used exclusively in the given combination and which are not re-usable or refillable are regulated as medicinal products but certain requirements of the UK MDR apply with respect to safety and performance related features of a device. Devices that incorporate, as an integral part, a substance which if used separately, may be considered to be a medicinal product and where the substance is liable to act upon the body with action ancillary to that of the device are regulated are subject to the UK MDR but the body carrying out relevant conformity assessment procedures must consult with the MHRA on the medicinal aspects of the device. The MHRA can provide guidance to a company that is unsure which set of regulatory rules to follow.

Pricing, Coverage and Reimbursement

Reimbursement authorities in Europe may be more restrictive than payors in the United States. In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. In addition, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA"), process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA Regulation"), was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation began to apply on January 12, 2025 through a phased implementation and is intended to harmonize the clinical benefit assessment of HTA across the EU.

In light of the fact that the UK has left the EU, Regulation No 2021/2282 on HTA will not apply in the UK. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of 31 March 2025, relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

Ex-Europe

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, variation or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of December 31, 2025, we had 158 full-time employees and 5 part-time employees. Of these employees, 4 held Ph.D. or M.D. degrees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We incorporated in Delaware in January 2016. Our corporate headquarters are located at 11682 El Camino Real, Suite 300, San Diego, California 92130, and our telephone number is (858) 771-9307. Our corporate website address is *ars-pharma.com*. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K. Our periodic and current reports are available on our website, free of charge, as soon as reasonably practicable after filing. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Related to Our Business

We are highly dependent on the successful commercialization of neffy. To the extent neffy and EURneffy are not commercially successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock would likely decline.

neffy is our only product that has been approved for sale. Currently, *neffy* has been approved for the emergency treatment of allergic reactions (anaphylaxis) in the United States, EU, United Kingdom, Japan and Australia (in the case of *neffy* 2 mg and 1 mg) and China (in the case of *neffy* 2 mg). We are focusing a significant portion of our activities and resources on *neffy*, and we believe our near-term revenues are highly dependent on, and a meaningful portion of the value of our company relates to, our ability to successfully commercialize *neffy* in the United States and abroad through our collaboration partners. Successful commercialization of *neffy* is subject to many risks. Prior to *neffy*, we have not, as an organization, commercialized any product, and there is no guarantee that we will be able to do so successfully with *neffy*. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have. The commercial success of *neffy* depends on the extent to which patients and physicians accept and adopt *neffy* as a treatment of Type I allergic reactions, including anaphylaxis, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the population of patients who may suffer a Type I allergic reaction is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to use *neffy* for any reason, the commercial potential of *neffy* will be limited. It is too soon to tell how physicians, patients and payors will respond to the pricing of *neffy*. Physicians may not prescribe *neffy* and patients may be unwilling to use *neffy* if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for *neffy* in post-approval trials or potential additional indications, including urticaria, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of *neffy*. Thus, significant uncertainty remains regarding the commercial potential of *neffy*. If the commercialization of *neffy* is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

If we are unable to fully develop and maintain our sales, marketing and distribution capabilities on our own or through collaborations with marketing partners, we may not be successful in commercializing neffy.

We have built a sales force and entered into the ALK Co-Promotion Agreement to commercialize *neffy* in the United States. In order to successfully commercialize *neffy*, we must, among other things, continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Factors that may hinder our ability to successfully market and commercially distribute our products include:

- inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits and safety of prescribing *neffy*;
- inability to recruit, retain and effectively manage adequate numbers of effective sales personnel, including ALK U.S. sales personnel;
- lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and
- unforeseen delays, costs and expenses associated with maintaining our sales organization and receive the intended benefits to be provided by the ALK Co-Promotion Agreement.

If we are unable to maintain an effective sales force, including through the ALK Co-Promotion Agreement, for *neffy*, we may not be able to generate significant product revenue in the United States. In addition, until the commencement of our commercial launch in September 2024, no one in our sales force had promoted *neffy*. We are required to expend significant time and resources to train our sales force, including through the ALK Co-Promotion Agreement, to be credible in educating physicians and pharmacists on the benefits of *neffy*. In addition, we must continually train our sales force, including through the ALK Co-Promotion Agreement, to ensure that a consistent and appropriate message about *neffy* is being delivered to our potential customers. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market *neffy* and any additional products we may develop or acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

We have entered into the ALK Co-Promotion Agreement with ALK U.S. for the co-promotion of *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. The commercial success of *neffy* in the United States, will be influenced in part by the efforts and allocation of resources by ALK U.S. Currently, ALK U.S. has limited experience promoting *neffy*, and while we will continue to work with ALK U.S. to optimize their commercialization activities, we cannot guarantee that such efforts will be successful. We also depend on ALK U.S. to comply with all applicable laws relative to the promotion of *neffy*. Because we do not control the individual efforts of ALK U.S., they may take actions or fail to take actions in a manner that is inconsistent with our interests. As a result, we may not realize the full potential benefits from the ALK Co-Promotion Agreement, and such actions or inactions could result in more limited or reduced sales, reputational harm, or regulatory or other adverse legal implications, any of which could adversely affect our business and results of operations.

We entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Alfresa Pharma Corporation in Japan; Pediatrix Therapeutics, Inc. in China, Macau, Hong Kong and Taiwan; Seqirus in Australia and New Zealand; and ALK in all other unpartnered geographies outside the United States. If these third parties do not effectively engage or maintain their sales force for *neffy* if approved in the applicable territories, our ability to recognize milestone payments and royalties from the sales in such territories will be adversely affected.

We will need to continue to expend significant time and resources to train our sales forces to be credible in discussing *neffy* with the specialists treating the patients indicated under the product's label. In addition, if we are unable to effectively train our sales force and equip them with effective marketing materials our ability to successfully commercialize *neffy* could be diminished, which would have a material adverse effect on our business, results of operations and financial condition.

neffy and our current and future intranasal epinephrine technology product candidates 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, in which case we may not generate significant revenues or profits.

We have never commercialized a product before our U.S. commercial launch of *neffy* in September 2024, and *neffy* may fail to gain sufficient market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community. Physicians may be reluctant to prescribe *neffy* or our current and future intranasal epinephrine technology product candidates in place of well-established epinephrine intra-muscular injectable devices or other available treatments. Further, patients and caregivers may be reluctant to switch unless their physicians recommend switching products or are required to switch due to lack of coverage and adequate reimbursement. In addition, even though *neffy* has been determined to be safe and effective by the FDA and the EMA, safety or efficacy concerns in the medical community may hinder market acceptance.

The degree of market acceptance of *neffy* and any future intranasal epinephrine technology product will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the potential advantages of the product compared to competitive therapies and our ability to successfully publicize these advantages or highlight them in any marketing materials;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the prevalence and severity of any adverse side effects;
- the availability of alternative treatments and products from our competitors;
- pricing and cost effectiveness, which may be subject to regulatory control;
- changes in the standard of care for the targeted indications for the product;
- effectiveness of our or our collaborators' sales and marketing strategy; and
- our ability to obtain sufficient third-party insurance coverage or adequate reimbursement levels.

The market for neffy and our intranasal epinephrine technology may be smaller than we expect.

We have focused our development of our intranasal epinephrine technology initially for the emergency treatment of Type I allergic reactions. We base our market opportunity estimates on a variety of factors, including our estimates of the number of people who have experienced severe Type I allergic reactions and are at risk of anaphylaxis, the continued growth rate of our patient population, the number of those in our patient population who we expect will fill a prescription for *neffy*, including those that currently do not fill prescriptions for epinephrine intra-muscular injectable devices or whose prescriptions have lapsed, the estimated increase in per patient device acquisition of *neffy* as compared to epinephrine intra-muscular injectable devices and the net sales of epinephrine intra-muscular injectable devices. These estimates are based on many assumptions and may prove incorrect, and new studies or market research may reduce our estimated patient population and potential sales. If our market opportunities are smaller than we expect, our future product revenues may be smaller than anticipated, which would adversely affect our business, financial condition, results of operations and prospects.

If we are unable to achieve and maintain adequate levels of third-party payor coverage and reimbursement for neffy on reasonable pricing terms, its commercial success may be severely hindered.

Successful sales of any approved products, including *neffy*, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even with coverage for *neffy*, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use *neffy* if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost of those products.

Payors may require documented proof that patients meet certain eligibility criteria in order to be reimbursed for *neffy*. Payors may even require that pre-approval, or prior-authorization, be obtained from the payor for reimbursement of *neffy*. Patients are unlikely to use *neffy* unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of *neffy*.

In addition, the market for *neffy* may depend significantly on access to third-party payors' medical policies, drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies, and we will be required to offer discounted rates to state Medicaid programs to ensure Medicaid coverage of our drugs. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, even if not approved for the indication(s) for which *neffy* is approved.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize *neffy* and any product candidates for which we receive approval, which could have an adverse effect on our operating results and our overall financial condition. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling *neffy* at less than an optimized price could impact our revenues and overall success as a company. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for *neffy* may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of *neffy* to each payor separately, with no assurance that coverage will be obtained, or that payment levels will be adequate for *neffy* or any other products we may market. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for *neffy* or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, physicians may limit how much or under what circumstances they will prescribe or administer *neffy*, or any other products we may market, and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize *neffy*, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition and future success.

neffy has only been studied in a limited number of patients. neffy is now available to a much larger number of patients, and we do not know whether the results of neffy's use in such larger number of patients will be consistent with the results from our clinical studies.

Prior to commercialization, *neffy* had been administered only to a limited number of patients in clinical studies. While the FDA and European Commission granted approval of *neffy* based on the data included in the NDA and marketing authorization application ("MAA"), respectively, we do not know whether the results when a large number of patients are exposed to *neffy*, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of *neffy* that served as the basis for the approval of *neffy*. New data relating to *neffy* may result in changes to the product label and may adversely affect sales, or result in withdrawal of *neffy* from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing *neffy*'s marketing applications for additional indications and/or in other jurisdictions, or impose post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

Competitive products may reduce or eliminate the commercial opportunity for neffy or our current and future intranasal epinephrine technology product candidates. If our competitors develop technologies or product candidates more rapidly than us, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize neffy and our current and future intranasal epinephrine technology product candidates may be adversely affected.

The clinical and commercial landscape for the emergency treatment of Type I allergic reactions is highly competitive and subject to significant technological change. Existing products have name recognition, are marketed by companies with established commercial infrastructures, and are marketed with greater financial, technical and personnel resources than we have. We also face competition with respect to our current indications for our intranasal epinephrine technology, including *neffy*, and will face competition with respect to any future indications of our intranasal epinephrine technology or other product candidates that we may seek to develop or commercialize in the future from large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Based on the initially approved indications for *neffy*, we anticipate that *neffy* will compete primarily against epinephrine intra-muscular injectable products, for the emergency treatment of Type I allergic reactions including EpiPen and its generics, which is marketed by Viatris, Inc. and Teva Pharmaceuticals, Inc.; Adrenaclick, which is marketed by Amneal Pharmaceuticals, Inc.; Auvi-Q, which is marketed by Kaleo, Inc.; and Symjepi, which is marketed by Sandoz, Inc., a Novartis division. Several other companies are also clinically developing larger dose intranasal epinephrine product candidates that may compete with *neffy*, including Bryn Pharma, Nasus Pharma, Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Orexo AB and Belhaven BioPharma. Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine (Anaphylm), but received a Complete Response Letter in January 2026 regarding its new drug application for Anaphylm due to concerns with their application. If our current and future intranasal epinephrine technology product candidates are approved for other indications, they would also compete with a range of other therapeutic treatments that are well established such as antihistamines or in development.

Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approval of product candidates and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, safer, or more effectively marketed and sold, than any product candidate we may commercialize and may render *neffy* or our current and future intranasal epinephrine technology product candidates obsolete or non-competitive before we can recover development and commercialization expenses. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than *neffy* or our current and future intranasal epinephrine technology product candidates, which could render such products or product candidates obsolete and noncompetitive.

We face competition based on many different factors, including the efficacy, safety and tolerability of *neffy* and our current and future intranasal epinephrine technology product candidates, the ease with which *neffy* and our current and future intranasal epinephrine technology product candidates can be administered, the scope of regulatory approval for *neffy* and our current and future intranasal epinephrine technology product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or regulatory approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our products that receive regulatory approval. We will also be competing with respect to marketing capabilities and manufacturing efficiency for *neffy* as an early commercial stage product. We expect competition among future products, if any, will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product or future products cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early commercial stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our activities.

If the FDA, the European Commission or other comparable foreign regulatory authorities approve generic versions of neffy or our current or future intranasal epinephrine technology product candidates that receives regulatory approval, or such authorities do not grant our products appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.

In the United States, once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. The FDA may not finally approve an ANDA for a generic product or a Section 505(b)(2) NDA of a competitor until any applicable period of non-patent exclusivity and patent exclusivity for the reference listed drug in the Orange Book has expired. We have not received U.S. non-patent marketing exclusivity for *neffy*, which was approved by the FDA under the 505(b)(2) regulatory pathway. We have 8 patents with claims covering *neffy* listed in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of *neffy* or an NDA submitted under the 505(b)(2) regulatory pathway referencing *neffy* must make one of the following certifications to the FDA concerning the patents listed in the Orange Book for *neffy*: (a) the patents that are listed have expired; (b) the date on which such patents will expire; or (c) such patents are invalid or will not be infringed upon by the manufacture, use or sale of the generic equivalent version of *neffy* or the drug product submitted under the 505(b)(2) regulatory pathway referencing *neffy*. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to us for each patent to which the ANDA or 505(b)(2) application refers. Following receipt of a paragraph IV notice, we may bring a lawsuit for patent infringement against the paragraph IV filer, and we may be entitled to a statutory 30-month stay of approval of the proposed product of the paragraph IV filer. We received paragraph IV certification notice letters from Lupin in August 2025 and February 2026, providing notification to us that Lupin submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 2 mg and 1 mg, respectively. In February 2026, we filed a lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. See Note 10 – Commitments and Contingencies to the consolidated financial statements in this Form 10-K for additional discussion. There is no guarantee that we will be successful in our lawsuit against Lupin. Patent litigation is expensive and time consuming, requires significant resources, may absorb significant time of our management and has an unpredictable outcome. If we are unsuccessful in the lawsuit or if a generic competitor is found not to infringe our patents, the resulting generic competition will likely negatively affect our business, financial condition and results of operations.

In support of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and adequate labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning, in part, that it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Moreover, third-party insurers require, and many states allow or require, substitution of therapeutically equivalent generic drugs at the pharmacy level even if the branded drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be lost to the generic product.

Upon receiving a marketing authorization in the EU from the European Commission, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity. Comparable regimes to those in the U.S. and EU exist in some other major markets, including the United Kingdom.

Obtaining regulatory approval of neffy or our current or future intranasal epinephrine technology product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Even though we have obtained regulatory approval of *neffy* in the United States, the EU, and other foreign jurisdictions, including but not limited to the United Kingdom, China, Japan, and Australia, there is no guarantee that we will be able to maintain these regulatory approvals or obtain or maintain regulatory approval in any other jurisdiction. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even though the FDA and European Commission have granted marketing approval of *neffy*, comparable regulatory authorities in other foreign jurisdictions must also approve the manufacturing, marketing and promotion of *neffy* before it can be marketed in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EU including additional nonclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States including certain jurisdictions in the EU, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We have submitted and plan to submit additional or supplemental marketing applications in the United States and in the EU. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional nonclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We have one product approved for sale. We have limited experience in obtaining regulatory approval in domestic and international markets. If we or our collaboration partners fail to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of *neffy* will be harmed.

If we are unable to successfully develop our current or future intranasal epinephrine technology product candidates, or neffy for additional indications, or experience significant delays in doing so, the commercial potential of our current or future intranasal epinephrine technology product candidates or neffy will be more limited.

Successful continued development and ultimate regulatory approval of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications is important to the future success of our business. The future regulatory and commercial success of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications is subject to a number of risks, including the following:

- successful completion of nonclinical studies and clinical trials;
- successful patient enrollment in clinical trials;
- successful data from our nonclinical studies and clinical trials that support an acceptable risk-benefit profile of our intranasal epinephrine technology in the intended populations and indications;
- satisfaction of applicable regulatory requirements, including to satisfy applicable rules governing combination products;
- potential unforeseen safety issues or adverse side effects;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- remaining in compliance with post-marketing regulatory requirements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our intranasal epinephrine technology;
- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our intranasal epinephrine technology;
- entry into collaborations to further the development of *neffy* and our current and future intranasal epinephrine technology product candidates in other jurisdictions or for additional indications;
- continuing to grow our sales, marketing and distribution capabilities and commercializing any approved products, whether alone or in collaboration with others;
- successfully commercializing *neffy* and our current and future intranasal epinephrine technology product candidates;
- acceptance by patients, the medical community and third-party payors of *neffy* and our current and future intranasal epinephrine technology product candidates;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- products, following approval, maintaining a continued acceptable safety profile;
- effectively competing with other therapies;
- ensuring that we promote and distribute our products consistent with all applicable healthcare laws; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission and review process, maintaining regulatory approval, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any current or future collaboration partner. If we or a collaboration partner are unable to develop, receive regulatory approval for our intranasal epinephrine technology for the additional indications we are developing it for, including urticaria, or if we experience delays as a result of any of these risks or otherwise, our ability to grow our business will be limited.

If the FDA does not conclude that our current or future intranasal epinephrine technology product candidates, or neffy for additional indications, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates or additional indications under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates or additional indications will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

The Hatch Waxman Act added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if available to us, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for any additional indications by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval. This pathway does not, however, expedite the FDA review process timelines.

If the FDA does not allow us to proceed under the Section 505(b)(2) regulatory pathway for our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, we may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for any such product candidates or additional indications, including for urticaria, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates we develop, which could adversely impact our competitive position and prospects. We cannot assure you that our current or future intranasal epinephrine technology product candidates or *neffy* for additional indications will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Finally, a competitor might receive FDA approval and obtain non-patent market exclusivity before we obtain approval of any such product candidates or additional indications, including urticaria, which could delay approval of potential additional indications, including urticaria, for our intranasal epinephrine technology.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, further development and the commercialization of our current and future intranasal epinephrine technology product candidates.

To obtain the requisite regulatory approvals to market and commercialize our current and future intranasal epinephrine technology product candidate, including for urticaria, we must demonstrate through extensive nonclinical studies and clinical trials that such product candidates are safe and effective for their intended use in humans. Nonclinical and clinical testing are expensive and can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or nonclinical studies and initiating or completing additional studies or clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize for our current and future intranasal epinephrine technology product candidates, including for urticaria, including:

- regulators, IRBs, ethics committees or other reviewing bodies may not authorize or issue positive opinions permitting us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach an agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- a delay in receiving study or clinical trial material from outside the United States;
- the number of subjects or patients required for clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing *neffy* or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocol(s) submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB or ethics committee and regulatory authorities for re-examination;
- unforeseen safety events may occur during the course of a clinical trial and these events may result in the temporary suspension or termination of a clinical trial, or require urgent safety measures or restrictions to protect human subjects during the conduct of a clinical trial;
- regulators, IRBs, ethics committees or other reviewing bodies may fail to approve or issue positive opinions or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we have entered and may enter into agreement for clinical and commercial supplies, or the supply or quality of our current and future intranasal epinephrine technology product candidates or other materials necessary to conduct clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for policies or regulations of the FDA, the EMA, the EU or any other applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs and ethics committees of the institutions in which clinical trials are being conducted, or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to appear to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive impressions of the results from our earlier clinical trials of *neffy* for the emergency treatment of Type I allergic reactions or any other clinical trial or nonclinical studies in animals that we have conducted, could mandate repeated or additional nonclinical studies or clinical trials and could delay marketing approvals or result in changes to or delays in nonclinical studies or clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria. While data from our studies of our intranasal epinephrine technology product candidates demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products, we do not know whether any future clinical trials or studies that we may conduct will demonstrate adequate efficacy and safety necessary to result in obtaining regulatory approval to market our current and future intranasal epinephrine technology product candidates, including for urticaria. If later stage clinical trials do not produce favorable results that meet regulatory authority criteria, our ability to obtain regulatory approval for our current and future intranasal epinephrine technology product candidate, including for urticaria, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our current and future intranasal epinephrine technology product candidates, including for urticaria, would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our current and future intranasal epinephrine technology product candidates, including for urticaria, or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize such product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our current and future intranasal epinephrine technology product candidates, including urticaria.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate intranasal epinephrine technology in the future or by developing or acquiring new products or product candidates. We may expend our limited resources to pursue a particular indication or formulation for our intranasal epinephrine technology and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Although *neffy* is approved for the emergency treatment of allergic reactions (anaphylaxis) in the United States, EU, United Kingdom, Japan and Australia (in the case of *neffy* 2 mg and 1 mg) and China (in the case of *neffy* 2 mg), as part of our longer-term growth strategy, we are evaluating and plan to continue to evaluate our intranasal epinephrine technology, including *neffy*, for use in other potential indications. We may evaluate opportunities to in-license or acquire other development programs, product candidates, as well as commercial products, including for the treatment of other indications like Type I allergic reactions. Other than our intranasal epinephrine technology, we do not currently have any other programs in development. Our development of our intranasal epinephrine technology for other indications remains at an early clinical development stage and will require significant further investment and regulatory approvals prior to commercialization in such indications. Because we have limited financial and managerial resources, we are focused on specific indications for our intranasal epinephrine technology. As a result, we may fail to generate additional clinical development opportunities for our intranasal epinephrine technology for a number of reasons, including, that our intranasal epinephrine technology may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. In addition, we may forgo or delay pursuit of opportunities with other indications that could have had greater commercial potential or likelihood of success. We may not be able to develop our intranasal epinephrine technology for any additional indications based on resource allocation decisions and other reasons. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable products.

Research activities to identify additional indications for our intranasal epinephrine technology require substantial technical, financial and human resources. Additionally, any future potential indications for our intranasal epinephrine technology will require the selection of suitable patients for our clinical trials and additional clinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, continued build out of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales in such additional indications, if approved. We are not permitted to market or promote any future indications before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. By such time, if ever, as we may receive necessary regulatory approvals for any potential additional indications for our intranasal epinephrine technology, including urticaria, the standard of care for such treatments may have evolved such that it would be necessary to modify our plans for full approval and commercial acceptance of such products may be limited by a change in the standard of care. Additionally, if we receive the necessary approval for any additional indications for our intranasal epinephrine technology, we may not realize the full potential benefits from the sale of our intranasal epinephrine technology for such indications due to our existing collaboration and marketing arrangements.

Even if we develop, license, or otherwise acquire potential product candidates or development programs, and obtain the required financing or establish a collaboration to enable us to conduct pre-clinical and clinical development of such product candidates, we cannot be certain that such development would be successful, or that we will obtain regulatory approval or be able to successfully commercialize any other product candidates and generate revenue. Further, even if any product candidate we develop or acquire was to receive marketing approval, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke, vary or suspend approval of our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such product candidate.

The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial data in our clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In addition, initial data in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our ongoing, planned or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of our current or future intranasal epinephrine technology product candidates. There is a high failure rate for drugs and biologics candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

neffy or our current or future intranasal epinephrine technology product candidates may cause undesirable side effects, adverse events, or have other properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects or adverse events caused by *neffy* or our current or future intranasal epinephrine technology product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial, or withdrawal of regulatory approval by the FDA, the European Commission or comparable foreign regulatory authorities. Although our clinical studies to date have demonstrated that *neffy* is well-tolerated by patients with no serious treatment-related adverse events, and reported adverse events generally no more severe than grade 1 and comparable with injection products, and with no meaningful pain or irritation based on formal scoring, results of our ongoing or future clinical trials for *neffy* or our current or future intranasal epinephrine technology product candidates could reveal a high and unacceptable severity and prevalence of side effects, adverse events, or unexpected characteristics. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects or adverse events that prevented further development of the compound.

If unacceptable side effects or adverse events are observed following the commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates, including for urticaria, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, or the independent safety monitoring committee could suspend or terminate our clinical trials or regulatory authorities could order us to cease clinical trials, restrict us or *neffy* or our current or future intranasal epinephrine technology product candidates, including withdrawing the marketing approval of *neffy* or our current or future intranasal epinephrine technology product candidates or deny approval for or all targeted indications. Treatment-emergent side effects and adverse events that are deemed to be drug-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims, an unwillingness of physicians to prescribe *neffy* or our current or future intranasal epinephrine technology product candidates for approved indications, patients' unwillingness to purchase *neffy* or our current or future intranasal epinephrine technology product candidates, or payors' willingness to cover *neffy* or our current or future intranasal epinephrine technology product candidates. Undesirable side effects or adverse events resulting from the use of *neffy* or our current or future intranasal epinephrine technology product candidates (whether by patients in our clinical studies or through the commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates) could adversely affect enrollment in clinical trials, regulatory approval and commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates. Additionally, there may be negative findings regarding components of *neffy* or our current or future intranasal epinephrine technology product candidates by other parties. Any negative findings by third parties may impact *neffy* for its initially approved indications and labeling, or the future approvability or labeling of our current or future intranasal epinephrine technology product candidates, including for urticaria. In addition, all side effects and adverse events may not be appropriately recognized or managed by the treating medical staff. Inadequate training in recognizing or managing the potential side effects and adverse events of *neffy* or our current or future intranasal epinephrine technology product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

In addition, clinical trials of our intranasal epinephrine technology product candidates are and have been conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of our intranasal epinephrine technology product candidates that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Finally, our intranasal epinephrine technology product candidates are comprised of epinephrine and Intravail that is delivered via an intranasal device. Intra-muscular injection of epinephrine has been approved by the FDA and other regulatory authorities for the emergency treatment of Type I allergic reactions. In addition, Intravail has previously been included in the formulations of FDA approved products such as VALTOCO and TOSYMRA nasal sprays. The intranasal apparatus we use to deliver our intranasal epinephrine technology product candidates has been used to deliver several drugs approved by the FDA and other regulatory authorities, including VALTOCO, TOSYMRA and NARCAN. Even though *neffy* has received marketing approval for its initial indication, we are subject to the risks that the FDA, European Commission or similar regulatory authorities could revoke approval of intra-muscular epinephrine injection products, other drug formulations containing Intravail or utilizing the same intranasal apparatus, or that efficacy, manufacturing or supply issues could arise with epinephrine API, Intravail or our intranasal apparatus. This could result in our own products being removed from the market or being less commercially successful.

We may seek priority review by the FDA for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may in the future request priority review designation for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, however, we cannot assume that any application for priority review will meet the criteria for that designation. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to standard FDA review and approval. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Product liability lawsuits against us or any of our current and future licensing and collaboration partners could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of neffy or our current or future intranasal epinephrine technology product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, commercialization, and use of pharmaceutical products. Currently, we have one product, *neffy*, that has been approved for commercial sale. The sale of *neffy* and the use of *neffy* by us and any current and future licensing and collaboration partners in clinical trials may expose us to liability claims. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our current and future licensing and collaboration partners or others using, administering, or selling any of our future products, if approved. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for *neffy* or our current or future intranasal epinephrine technology product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs, including with respect to potential class action lawsuits;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to successfully commercialize *neffy* or our current or future intranasal epinephrine technology product candidates.

We face an inherent risk of product liability as a result of the commercialization and clinical testing of *neffy* or our current or future intranasal epinephrine technology product candidates. Although the clinical trial process is designed to identify and assess potential side effects and adverse events, clinical development does not always fully characterize the safety and efficacy profile of a new drug, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If *neffy* or our current or future intranasal epinephrine technology product candidates causes adverse events or side effects, we may be exposed to substantial liabilities. Physicians may not prescribe or patients may not use *neffy* or our current or future intranasal epinephrine technology product candidates for its approved indications or in accordance with *neffy*'s our current or future intranasal epinephrine technology product candidates' instructions or any warnings that identify known potential adverse effects, side effects, and patients who should not use *neffy* or our current or future intranasal epinephrine technology product candidates. We are highly dependent upon consumer perceptions of us regarding the safety and efficacy of *neffy* and our current or future intranasal epinephrine technology product candidates. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage in the amount of up to $10.0 million in the aggregate, including commercial product liability and clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of *neffy* or our current or future intranasal epinephrine technology product candidates, which could harm our business, financial condition, results of operations and prospects.

If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information (collectively, "sensitive data"). As a result, we and such third parties face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to conduct our business.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new or heightened cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on our licensing and collaboration partners, our CROs, third-party logistics providers, distributors and other contractors and consultants to utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities, including in connection with our clinical trials.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third-parties with whom we work experience a security incident or other interruption, we could, and in certain cases have, experienced adverse consequences. While we may be entitled to damages if the third-parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, as well as successful phishing attempts that did not have a material adverse effect, and expect such attempts will continue in the future. In addition, we have become aware of certain security incidents whereby vendor email accounts have been hacked and the bad actors impersonated our vendors in email communications with us. None of these incidents have had a material adverse effect on our business. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Vulnerabilities could be exploited and result in a security incident. Any unremediated critical or high risk vulnerabilities could pose material risks to our business. Further, we have and may in the future experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to operate our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials for *neffy* could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Relatedly, our contracts with third parties with whom we work may limit the types and/or amounts of damages that we can recover from those third parties, even where the third party is responsible for a privacy or cybersecurity incident or violation. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive data could be leaked, disclosed, or revealed as a result of or in connection with the use of generative AI technologies by our employees, personnel, or vendors, which may constitute a cybersecurity incident or data breach, and which may adversely affect our business, operations, reputation, or financial condition.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of *neffy*, and for the advancement of our clinical development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source raw materials, active pharmaceutical ingredient ("API") and other important components related to the manufacture of *neffy* and our intranasal epinephrine technology product candidates, including Intravail and our nasal sprayer apparatus, from international suppliers located in the European Union. Although we anticipate that our current supply of materials for *neffy* and our product candidates will be sufficient for at least the next 18-24 months, tariff policies, particularly those affecting the Europe Union and pharmaceutical products could materially increase our costs and reduce our margins, including as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, particularly regarding pharmaceutical-specific tariffs, present material risks to our operations and financial performance.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Should additional tariffs be imposed, including those specifically targeting pharmaceutical imports, our production costs could rise significantly, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the United States, as developing and qualifying alternative sources typically requires at least 18-24 months and substantial investment and regulatory approvals. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. *neffy* is included in formularies with pricing established through annual or multi-year contracts with commercial, third-party payors and pharmacy benefit managers, and reimbursement methodologies established by government programs, such as Medicare. These arrangements typically include fixed pricing terms that were negotiated prior to the implementation of the recently announced tariffs. As a result, and depending on the timing and scope of the implementation of these tariffs, cost increases due to tariffs may be difficult or impossible to pass through to customers until the next negotiation cycle, which could be up to 36 months away.

Current or future tariffs may also result in increased research and development expenses, including with respect to increased costs associated with raw materials, API, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business, including our nonclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

We are subject to risks related to public health crisis and any efforts to halt the spread of any public health crises. For example, COVID-19 and policies and regulations implemented by governments in response to its outbreak, such as directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages occurred, supply chains were disrupted, facilities and production were suspended, and demand for certain goods and services, such as medical services and supplies, spiked, while demand for other goods and services fell. We experienced certain impacts of COVID-19, including inability to conduct clinical trial site monitoring for certain earlier phase clinical trials and delays in completing clinical trials, bioanalytical sample analysis and study reports. There can be no guarantee we will not experience other impacts from other pandemics, epidemics or infectious disease outbreaks, such as being forced to further delay or pause enrollment, experiencing potential interruptions to our supply chain, facing difficulties or additional costs in enrolling patients in future clinical trials or being able to achieve full enrollment of our studies within the timeframes we anticipate, or at all. Additionally, pandemics, epidemics or other infectious disease outbreaks could have extensive impacts in many aspects of society and could result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Other global health concerns could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

While we have been working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to the production of *neffy* or our current or future intranasal epinephrine product candidates as a result of pandemics, epidemics or other infectious disease outbreaks, if such a public health crisis were to persist for an extended period of time, there could be significant and material disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of *neffy* or our current or future intranasal epinephrine product candidates. Any such supply disruptions, including disruptions in procuring items that are essential for our development activities and securing manufacturing slots for the products needed for such activities, could adversely impact our ability to initiate and complete nonclinical studies or clinical trials and generate sales of and revenue from *neffy* or our current or future intranasal epinephrine product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

COVID-19 affected and other public health crises may in the future affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. If any future public health crisis is not contained, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in our commercialization efforts;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism that reduces site resources;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire a virus or illness while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from regulatory authorities to initiate our future clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as *neffy* used in our clinical trials;
- changes in local regulations as part of a response to the public health crisis which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in nonclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA, the EMA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States, the EU or other relevant local geographies.

Any negative impact a public health crisis has on patient enrollment or treatment, or the commercialization of *neffy* and the development of any additional indications could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, increase our operating expenses, which could have a material adverse effect on our financial results. COVID-19 caused significant volatility in public equity markets and disruptions to the United States and global economies and any future pandemic, epidemic, infectious disease outbreak or similar public health crisis could lead to market dislocation. Any such volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial conditions. To the extent a future pandemic, epidemic, infectious disease outbreak or other public health crisis adversely affects our business and financial results, it may also heighten many of the other risks described in this “Risk Factors” section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

The FDA and other regulatory agencies actively enforce the laws and regulations relating to the promotion of our products.

If we are found to have improperly promoted uses of our products in the U.S., we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug and device products. In particular, a product may not be promoted in a manner that results in the company making false or misleading claims. If the FDA determines that our or our partners' public disclosures, promotional materials or training constitutes promotion of false or misleading claims, it could request modifications to disclosure policies, training or promotional materials or subject us or our partners to regulatory or enforcement actions, including the issuance of an untitled letter, a Warning Letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including "Dear Doctor" letters. On September 9, 2025 and January 23, 2026, we received untitled letters from the Department of Human & Health Services regarding our television ("TV") advertisements. The letters raised concerns from the FDA that our advertisements made false or misleading claims, including with respect to suggesting the avoidance of injectable treatments for emergency treatment of allergic reactions and reducing needle-fear concerns. We have since withdrawn the cited TV advertisements and are working directly with the FDA to address its concerns. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our or our partners' promotional or training materials to constitute promotion of false or misleading claims which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of operations, any of which could adversely affect our or our partners' ability to operate and, thus, adversely impact our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product in the U.S., we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development activities and the indications our intranasal epinephrine technology product candidates has been approved to treat and is being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts for *neffy*. Advertising and promotional materials must comply with FDA rules concerning the advertising and promotion of our intranasal epinephrine technology product candidates and are subject to FDA review, in addition to other potentially applicable federal and state laws. Failure to comply with these regulations can result in warning letters and further liability if off-label promotion is involved. The FDA's Office of Prescription Drug Promotion has sent warning letters to sponsors for alleged violative labeling and promotional materials, including those disseminated through social media. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about any potential additional indications. There is also a risk of inappropriate disclosure of sensitive or confidential information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding us, our management or our current or future intranasal epinephrine technology product candidates. Moreover, information communicated on social media must take into consideration applicable rules governing the advertising and promotion of medicinal products. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks Related to Our Results of Operations and Financial Position

We expect that our timing of sales and our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods, especially in the near term as we continue our ongoing commercial launch of *neffy*. Some of the factors that could cause our operating results to fluctuate from period to period include the factors described elsewhere in the "Risk Factors" section of this report as well as in "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

We have incurred significant losses since our inception.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have one product approved for commercial sale and remain in the early stages of our commercialization efforts, and we will continue to incur significant expenses related to our commercialization activities, clinical development and ongoing operations. As a result, we have incurred significant losses in most periods since our inception. Since our inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, performing research and development activities, pre-commercialization activities, the commercial launch of *neffy* and providing general and administrative support for these operations. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss for the year ended December 31, 2025 was $171.3 million. As of December 31, 2025, we had an accumulated deficit of $294.6 million. We expect to continue to incur significant losses for the foreseeable future.

We anticipate that our expenses will increase substantially if and as we:

- maintain and expand our sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure to support the commercialization of *neffy* and any other product candidates for which we may obtain regulatory approval;
- continue to develop and conduct nonclinical studies and clinical trials for our current or future intranasal epinephrine technology product candidates and for *neffy* on a post-approval basis;
- seek regulatory approvals in the United States and in other geographic regions for our current or future intranasal epinephrine technology product candidates;
- seek to identify future product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, negative or mixed clinical trial results, safety issues or other regulatory challenges, the risk of which in each case may be exacerbated by tariffs, trade wars, geopolitical conflicts and a health epidemic or pandemic;
- add clinical, scientific, operational, sales, financial and management information systems and personnel, including personnel to support our product candidate development and commercialization efforts and help us comply with our obligations as a public company;
- incur and pay the interest expense under the Credit Agreement;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical trials or conduct nonclinical studies in addition to those that we currently expect, or if there are any delays in completing our clinical trials or the development of our current or future intranasal epinephrine technology product candidates, or if we choose to develop or acquire any future product candidates. Our expenses could also increase significantly as a result of tariffs, trade wars and geopolitical conflicts.

We may need additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.

Our operations have consumed significant amounts of cash since inception. Based upon our current operating plan, we believe that our cash and cash equivalents will fund our operating and capital expenses for at least three years. We expect to incur significant expenses related to commercialization, such as product sales, medical affairs, marketing, manufacturing and distribution of *neffy*. Further, we expect to incur additional costs associated with operating as a public company. We may require significant additional amounts of cash in order to commercialize *neffy* for its currently approved indications in the United States, or for our current or future intranasal epinephrine technology product candidates which receive regulatory approval. In addition, other unanticipated costs may arise in the course of our continued development and commercialization efforts. Because the outcome of our commercialization efforts and continued development of our current or future intranasal epinephrine technology product candidates is highly uncertain, we cannot reasonably estimate the actual amounts of cash necessary to commercialize *neffy* for its approved indications in the United States, or any other indications we are pursuing.

Our future capital requirements depend on many factors, including:

- the costs of commercialization activities for *neffy* for its approved indications and our current or future intranasal epinephrine technology product candidates that receives regulatory approval, to the extent such costs are not the responsibility of any current or future licensing and collaboration partners, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of *neffy* or any current or future intranasal epinephrine technology product candidates that receives regulatory approval;
- the scope, progress, results and costs of researching and developing our intranasal epinephrine technology for potential additional indications, including urticaria;
- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications;
- the amount and timing of potential royalty and milestone payments to our current or future licensing and collaboration partners;
- the receipt of licensing fees, royalties and potential milestone payments under our current or future out-licensing arrangements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our personnel, including personnel to support our product development and commercialization efforts and help us comply with our obligations as a public company;
- our ability to service our current credit facility under the Credit Agreement and access, if and when needed, additional amounts of principal provided for under the Credit Agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. The global credit and financial markets have experienced extreme volatility and disruptions and have been adversely impacted, and may continue to be adversely impacted or further adversely impacted, by macroeconomic factors such as tariffs, trade wars, inflation, high interest rates, recessionary concerns, recessions, bank failures, geopolitical conflicts and general economic uncertainty. If the equity and credit markets do not improve or further deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

We believe that our existing cash and cash equivalents will be sufficient to fund our planned operations for at least three years. This estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We have no committed source of additional capital other than potential milestone payments, potential draw-downs under the Credit Agreement, each subject to its own conditions, and royalties under our collaboration and licensing agreements. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development and commercialization of *neffy*. We may need to seek licensing and collaboration partners for *neffy* for commercialization in additional indications on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to *neffy* in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate.

We expect our expenses to increase in connection with our planned operations. Based upon our current operating plan, we believe that our cash and cash equivalents will fund our operating and capital expenses for at least three years. However, unless and until we can generate a substantial amount of revenue from our current or future intranasal epinephrine technology product candidates, we may seek to finance our future cash needs through public or private equity offerings, royalty-based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. On January 31, 2025, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the "ATM Sales Agreement") pursuant to which we may from time to time offer and sell our common stock to or through Cantor Fitzgerald & Co., acting as sales agent, in any manner deemed to be an "at-the market offering". We have filed a sales agreement prospectus with the SEC pursuant to which we may offer and sell up to $200.0 million of our common stock pursuant to the ATM Sales Agreement. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, stockholders' interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect our stockholders' rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, which could adversely impact our ability to conduct our business. On September 29, 2025, we entered into the Credit Agreement, which subjects us to a number of restrictive covenants, including among others (subject to certain qualifications and exceptions), limitations on our ability to incur additional debt; create liens and encumbrances; merge, dissolve, liquidate or consolidate; make acquisitions, investments, or advances, dispose of or transfer assets, pay dividends, and enter into transactions with affiliates. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect their ability to oversee the commercialization of *neffy* and the development and potential future commercialization of *neffy* or our intranasal epinephrine technology product candidates for additional indications.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Our Credit Agreement contains conditions and restrictions that limit our flexibility in drawing on the additional funds thereunder and in operating our business. We may be required to repay our outstanding indebtedness under the Credit Agreement earlier than we expect and possibly at a time when we do not have sufficient capital to meet such obligations if an event of default occurs (including a material adverse change affecting our business), which could have a material adverse effect on our financial condition and results of operations.

As of December 31, 2025, we had an outstanding principal balance under our Credit Agreement of $100.0 million. We may also draw, at our election, up to an additional (i) $25.0 million under the Term B Loan during the period commencing on the six-month anniversary of the Closing Date and ending no later than the one-year anniversary of the Closing Date, (ii) $25.0 million under the Term C Loan will be made available at our election during the period commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the satisfaction of a certain revenue requirement under the Credit Agreement, and (iii) $100.0 million under the Term D Loan, subject to the consent of the Lenders. If we are unable to achieve the revenue requirement by the applicable date, we would be unable to borrow additional funds under the Term C Loan under the Credit Agreement, which could negatively impact our ability to fund our operations.

Furthermore, the Credit Agreement contains various covenants that limit or restrict our ability to engage in specified types of transactions. Subject to certain exceptions, these covenants limit our ability to, among other things, incur additional indebtedness; create liens and encumbrances; merge, dissolve, liquidate or consolidate; make acquisitions, investments, or advances, dispose of or transfer assets, pay dividends, and enter into transactions with affiliates. The Credit Agreement also contains a minimum liquidity covenant that requires us to maintain at all times at least $25.0 million of unrestricted cash and cash equivalents. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders. In the case of a continuing event of default under the Credit Agreement, including an event of default that arises due to our failure to comply with the covenants (subject to applicable notice and grace periods), the Lenders under the Credit Agreement could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted to the Lenders a security interest, or otherwise exercise the rights of a secured creditor. We are currently in compliance with the Credit Agreement covenants.

We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the Lenders could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business and financial condition. We cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance our debt to the Lenders or any other debt we may incur in the future. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department, and state and local taxing authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, legislation informally titled the One Big Beautiful Bill Act ("OBBBA") and the Inflation Reduction Act of 2022 ("IRA") enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to new and existing legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, realization of tax assets or results of operations.

Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. Unused federal net operating losses ("NOLs") for the tax years beginning before January 1, 2018, will carry forward to offset future taxable income, if any, until such unused losses expire. Unused federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is limited to 80% of taxable income. In addition, both current and future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Code if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. The Merger resulted in an ownership change of our company. The NOL carryforwards of pre-Merger, privately-held ARS Pharma may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our NOL carryforwards. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. Consequently, even if we achieve profitability in the future, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our business, cash flow, financial condition or results of operations.

Risks Related to our Legal and Regulatory Environment

neffy and our current or future intranasal epinephrine technology product candidates are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. neffy and our current or future intranasal epinephrine technology product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any current or future licensing and collaboration partners, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

neffy and our current or future intranasal epinephrine technology product candidates, as well as, among other things, the manufacturing processes, post-approval studies, labeling, post-approval pharmacovigilance monitoring, advertising and promotional activities for *neffy*, is subject to ongoing requirements of and review by the FDA, the EMA and other applicable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA and comparable foreign regulatory authorities of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States or relevant territory. We and our contract manufacturers will also be subject to user fees and periodic inspection by regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indications or uses for which the product may be marketed or to the conditions of approval, including the requirement in the United States to implement a Risk Evaluation and Mitigation Strategy or the inclusion of a Boxed Warning, which highlights a specific life-threatening safety risk, or comparable foreign strategies and requirements.

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. For example, the FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use. However, companies generally may share truthful and not misleading information that is otherwise consistent with a product's approved labeling. If we, or any current or future licensing and collaboration partners, do not market *neffy* or our current or future intranasal epinephrine technology product candidates, for only its approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that we are doing so. Violation of laws and regulations relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act and any comparable foreign laws. In the EU, the direct-to-consumer advertising of prescription-only medicinal products is prohibited. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public, and may also impose limitations on our promotional activities with health care professionals.

In addition, later discovery of previously unknown side effects, adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- exclusion from federal health care programs such as Medicare and Medicaid or comparable foreign programs;
- suspension, variation or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory agencies also closely regulate and monitor the post-approval marketing and promotional claims that may be made about drug products to ensure that the product is not promoted in a manner that results in the company making false or misleading claims. If the FDA or other agency determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize neffy or our current or future intranasal epinephrine technology product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including cost-containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, prevent or delay marketing approval of *neffy* or our current or future intranasal epinephrine technology product candidates for potential additional indications, including urticaria, restrict or regulate post-approval activities and affect our ability to profitably sell *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), was signed into law. The ACA was intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been amendments and judicial, executive and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how any such challenges, and the healthcare reform measures of the current administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, additional changes include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example: (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing "Most-Favored-Nation" pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical product; and (4) as part of the Make America Healthy Again Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. If implemented, a "Most-Favored-Nation" pricing policy that is determined to apply to us and neffy based on a reference to the lowest ex-U.S. list price for our intranasal epinephrine product could significantly reduce the U.S. list price for neffy and likewise reduce our annual market opportunity for neffy in the United States. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand orphan drug exclusions, and reduce Medicaid enrollment and funding.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresaw a three-year transition period which ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. On April 10, 2024, the Parliament adopted its related position and on June 4, 2025, the European Council agreed on its position. The Council, the Parliament and the European Commission have begun trilogue negotiations with a view to reaching an agreement on the package. A decrease in data and market exclusivity opportunities for our current or future intranasal epinephrine technology product candidates in the EU could make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

Following Brexit, the UK and the EU signed an EU-UK Trade and Cooperation Agreement ("TCA") which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement sets out some aspects of the UK and EU's relationship post-Brexit. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that the UK is treated as a "third country", a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement (Northern Ireland continues to follow certain limited EU regulatory rules, including in relation to medical devices, but not in relation to medicinal products). As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework". The Windsor Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023, and the arrangements under the Windsor Framework relating to medicinal products took effect on January 1, 2025. As it relates to marketing authorizations, the United Kingdom has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continued, until January 1, 2025, to be covered by the marketing authorizations granted by the European Commission but the Windsor Framework provides that the UK MHRA is the sole regulatory body responsible for granting marketing authorizations for Northern Ireland as of January 1, 2025.

A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our product candidates in the UK or the EU.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK and restrict our ability to generate revenue and achieve and sustain profitability in the future. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

These laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize *neffy* or our current or future intranasal epinephrine technology product candidates.

Disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies.

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel. Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, government shutdowns and reductions in the FDA's workforce and budgetary pressures could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the marketing of our products which could have a material adverse effect on our business.

Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any.

In some countries, including certain Member States of the EU, the pricing of prescription drugs is, in part, subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. The EU provides options for the EU Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our current or future intranasal epinephrine technology product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and began to apply on January 12, 2025 through a phased implementation, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

We cannot be sure that such prices and reimbursement will be acceptable to us. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of our current or future intranasal epinephrine technology product candidates in those countries would be negatively affected.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which we may operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer *neffy* in one or more countries and could materially damage our reputation, brand, international activities, ability to attract and retain employees, and business, prospects, operating results and financial condition.

In addition, *neffy* or our current or future intranasal epinephrine technology product candidates may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of *neffy* or our current or future intranasal epinephrine technology product candidates, or our failure to obtain any required import or export authorization for *neffy* or our current or future intranasal epinephrine technology product candidates, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of *neffy* or our current or future intranasal epinephrine technology product candidates may create delays in the introduction of any additional indications in international markets or, in some cases, prevent the export of *neffy* or our current or future intranasal epinephrine technology product candidates to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of *neffy* or our current or future intranasal epinephrine technology product candidates by, or in our decreased ability to export *neffy* or our current or future intranasal epinephrine technology product candidates to existing or potential customers with international operations. Any decreased use of *neffy* or our current or future intranasal epinephrine technology product candidates or limitation on our ability to export or sell *neffy* or our current or future intranasal epinephrine technology product candidates would likely adversely affect our business.

Our relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

- the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including: allegedly providing free items and services, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to government healthcare programs for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- HIPAA which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, of any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless or the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations of each of the laws described above, such as anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws that require biotechnology companies to report information on the pricing of certain drug products; and laws require the registration or pharmaceutical sales representatives. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities from *neffy* or our current or future intranasal epinephrine technology product candidates that have been approved for marketing in the United States or elsewhere, could be subject to legal challenge and enforcement actions. If our operations, or those of our partners and collaborators, are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM") and the Telephone Consumer Protection Act of 1991 ("TCPA") impose specific requirements on communications with customers. The TCPA, for example, imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to $1,500 per violation imposed through private litigation or by state authorities.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide any product that receives regulatory approval. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase compliance costs and potential liability for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Additionally, we are subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR") and Australia's Privacy Act, impose strict requirements for processing personal data.

For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR. 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Furthermore, we also conduct clinical trials in Asia and have operations in Japan and are subject to new and emerging data privacy regimes in Asia, including China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act. China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. However, evolving privacy and security laws and regulations may impact our ability to transfer personal data from Europe and other jurisdictions to the United States or other countries, or may require us to take additional actions in order to continue or resume such cross-border data flows (such as implementing new processes or additional safeguards). Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals(i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements. with certain third parties in the future.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data, including clinical trials. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

We publish privacy policies, marketing materials, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy, and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

In addition, we are contractually subject to industry standards adopted by industry groups and, we are and may become in the future, directly subject to such obligations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Further, our employees and personnel, and those of any third parties involved in our operations, including vendors, service providers, collaborators, contractors, and consultants, develop and/or use artificial intelligence or machine learning technologies, including generative artificial intelligence or automated decision-making tools (collectively, "AI technologies") in the course of performing work for us. The disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations and the disclosure and use of sensitive data in AI technologies may subject us to various legal, contractual, and reputational risks and liabilities. Governments have passed and are likely to pass additional laws and regulations regulating AI technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use or limited in our use of AI technologies, it could make our business less efficient and result in competitive disadvantages.

However, use of AI technologies in connection with our confidential, proprietary, or otherwise sensitive information, including personal data, may result in leaks, disclosure, or otherwise unauthorized or unintended access to or use or other processing of such information, including incorporation of such information into the applicable AI technology system or use of such information to further refine and train the AI technology models. Any such access or use, or any improper or inappropriate use, of AI technologies could, for example, reveal trade secrets or other confidential information that may enable third parties to replicate or improve upon our technologies and programs, advance their technologies or programs more rapidly than we do, or otherwise negatively impact the value of, or our ability to obtain or maintain, intellectual property rights. Access to and use and other processing of personal data may subject us to risks and potential liability and obligations under applicable data privacy laws. Further, we may use the output of AI technologies in our technologies, programs, and other aspects of our business, and such output could incorporate third-party intellectual property, or we may otherwise be unable to own, protect, further develop, or ultimately use such output, which could significantly harm our business to the extent such technologies, programs, or other aspects of our business rely upon such output. Such output may also be false, non-sensical, biased, or otherwise harmful to our operations and business if incorporated therein. Further, our ability to use AI technologies or further develop or use its output may depend on access to specific third-party software and infrastructure, such as processing hardware or third-party artificial intelligence models, and we cannot control the availability or pricing of such software and infrastructure, especially in a highly competitive environment. We may also face novel and urgent cybersecurity risks and emerging ethical risks relating to the use of AI technologies, which could adversely affect our operations, assets, including intellectual property and data, and reputation, as well as those of any third parties involved in our operations. Use of AI technologies in general, and generative AI in particular, in our business could subject us to additional costs and expenses, litigation, regulatory actions and investigations, and other negative consequences. There is significant uncertainty with respect to the nature of the laws and regulations that have been and may in the future be adopted, including how such laws and regulations will be interpreted and applied, both within and outside of the U.S., with respect to the use of AI technologies in general, and generative AI in particular, including the ownership of or right to use the output of generative AI. We may need to expend significant resources to modify and maintain our business practices to comply with such laws and regulations and to otherwise ensure appropriate and lawful use of artificial intelligence technologies, including generative AI and its output, in our technologies, programs, and other aspects of our business.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal or sensitive data on our behalf. In addition, these obligations may require us to change elements of our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses associated with being a public company, including public company reporting requirements, costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new requirements implemented by the SEC and Nasdaq. These rules and regulations are expected to continue to result in meaningful legal and financial compliance costs and to make some activities more time consuming and costly. These rules and regulations also may make it expensive for us to obtain directors' and officers' liability insurance.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We rely completely on third parties to manufacture and warehouse both our domestic and international supply of neffy and our current and future intranasal epinephrine technology product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or warehouse commercial quantities of *neffy* or our current or future intranasal epinephrine technology product candidates. Our ability to commercially supply *neffy* and our current or future intranasal epinephrine technology product candidates depends, in part, on the ability of third-party manufacturers to supply, manufacture and warehouse the raw materials, API and other important components related to the manufacture of our intranasal epinephrine technology product candidates, including Intravail and our nasal sprayer apparatus. We also rely on third parties to label and package the finished product. These third-party manufacturers currently have limited experience manufacturing our intranasal epinephrine technology product candidates, the raw materials and API for our intranasal epinephrine technology product candidates to be supplied to patients. While we will continue to work with our third-party suppliers and manufacturers to optimize the manufacturing process for *neffy* and our current or future intranasal epinephrine technology product candidates, we cannot guarantee that such efforts will be successful. If we fail to develop and maintain supply relationships with these third parties, we may be unable to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates.

In particular, we rely on third parties for the supply of our intranasal epinephrine technology product candidates unit dose nasal spray devices and glass microvials. We have entered into a manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"), which has been actively involved in supporting the manufacture of our intranasal epinephrine technology product candidates in our clinical development, and we will continue to rely on Renaissance as the primary source for drug product manufacturing and final packaging. Unless and until we can secure alternative sources, drug product manufacturing and final packaging, our dependence on Renaissance will subject us to the possible risks of shortages, interruptions, and price fluctuations.

If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption effect on our business, condition (financial and otherwise). For example, drug application processes require specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA or comparable foreign regulatory authority approval of a new supplier would be required. The amount of time required for the FDA or a comparable foreign regulatory authority to qualify a new supplier and confirm that our manufacturing processes meet the necessary standards could cause delays in the manufacturing and marketing of *neffy* and our current or future intranasal epinephrine technology product candidates and could, depending on the particular product, have a material adverse effect on our results of operations and financial condition.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture *neffy* or our current or future intranasal epinephrine technology product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our intranasal epinephrine technology product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the delay or interruption of the production of *neffy* or our current or future intranasal epinephrine technology product candidates due to a third-party contractor or supplier discontinuing the sale of certain products, requiring us to obtain substitute materials or products;
- the reduction or termination of production, raw materials, or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, whether related to our intranasal epinephrine technology product candidates or another product;
- the failure of the third party to manufacture our intranasal epinephrine technology product candidates, or the raw materials associated therewith, according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, including without limitation due to a change in raw materials supply, and the strict regulatory requirements of the FDA and other foreign regulatory authorities, this could affect the sales of *neffy* and our current or future intranasal epinephrine technology product candidates. In addition, other than to conduct audits, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our current or future intranasal epinephrine technology product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, and/or raw material suppliers, which would significantly impact our ability to develop, obtain or maintain marketing approvals for and commercialize *neffy* or our current or future intranasal epinephrine technology product candidates. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, application review delays, suspension, variation or withdrawal of approvals, license revocation, import alerts, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of *neffy* or our current or future intranasal epinephrine technology product candidates and harm our business and results of operations. Our current and anticipated future dependence upon others for the raw materials associated with, and the manufacture of *neffy* and our current or future intranasal epinephrine technology product candidates may adversely affect our profit margins and our ability to successfully commercialize *neffy* or our current or future intranasal epinephrine technology product candidates on a competitive basis.

We are dependent on international third-party licensees and assignees for the development and commercialization of neffy and our current and future intranasal epinephrine technology product candidates outside the United States. If these third parties are not successful in their development and commercialization efforts or if these third parties fail to meet their contractual, regulatory or other obligations, our business and results of operations could be adversely affected.

We have entered into exclusive licensing and collaboration agreements with third-party partners for the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates worldwide, excluding the United States. As a result, we are dependent on these parties to, at times, achieve regulatory approval of *neffy* and our current or future intranasal epinephrine technology product candidates for marketing and, if approval is obtained, commercialize *neffy* and our current or future intranasal epinephrine technology product candidates outside the United States. The timing and amount of any milestone and royalty payments we may receive under these agreements, as well as the commercial success of *neffy* and our current or future intranasal epinephrine technology product candidates in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources and successful commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates by our licensing and collaboration partners. We also depend on such licensing and collaboration partners to comply with all applicable laws relative to the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates in those countries. They may take actions or fail to take actions that result in safety issues with *neffy* and our current or future intranasal epinephrine technology product candidates in their licensed territory, and such safety issues could negatively impact *neffy* and our current or future intranasal epinephrine technology product candidates in countries outside of the licensed territory. We do not control the individual efforts of our licensing and collaboration partners and have limited ability to terminate these agreements or have assigned assets returned to us if such licensing and collaboration partners do not perform as anticipated.

The failure of our licensing and collaboration partners to devote sufficient time and effort to the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates; to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; to adequately respond to the adverse impact of military action, sanctions and market disruptions; and/or to satisfactorily resolve significant disagreements with us or address other factors could have an adverse impact on our financial results and operations. In addition, if these third parties violate, or are alleged to have violated, any laws or regulations during the performance of their obligations for us, including with respect to safety, patient and data privacy, antitrust, and bribery and corruption, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences and liabilities. We may not be successful in enforcing the terms and conditions of our licensing and collaboration agreements in court or via agreed upon dispute resolution mechanisms, and even if we were to prevail in any such dispute, the remedies may not be adequate to compensate us for the losses. Any termination, breach or expiration of some of these licensing or collaboration agreements could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive license fees, milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing regulatory approval and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates. Alternatively, we may attempt to identify and transact with a new assignee or licensee, but there can be no assurance that we would be able to identify a suitable partner or transact on terms that are favorable to us.

neffy and our current or future intranasal epinephrine technology product candidates are developed and produced at a few locations, and a business interruption at one or more of these locations or within our supply chain could have a material adverse effect on our business, financial position, and results of operations.

neffy and our current or future intranasal epinephrine technology product candidates are developed and produced at our third-party's manufacturing facilities in Lakewood, New Jersey. Disruptions of these facilities or within our supply chain can occur for many reasons, including events unrelated to us or beyond our control, such as fires and other industrial accidents, floods and other severe weather events, natural disasters, environmental incidents or other catastrophes, utility and transportation infrastructure disruptions, shortages of raw materials, pandemic diseases or viral contagions, and acts of war or terrorism. Natural disasters and adverse weather conditions can be caused or exacerbated by climate change, and the spate of extreme weather events experienced during 2021 presents an alarming trend. During 2021, for example, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to local businesses. Such events could compromise our inventory, resulting in significant costs. Furthermore, work stoppages, whether union-organized or not, can also disrupt operations. Business interruption could also be caused by compliance failures. A significant disruption at any of these facilities or otherwise within our supply chain, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis or at all, which could have a material adverse effect on our business, financial position, and results of operations.

We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to commercialize neffy and our current or future intranasal epinephrine technology product candidates may be delayed.

We are dependent on third parties to conduct our nonclinical studies and any clinical trials. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our nonclinical studies and past clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these studies and trials. While we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products or potential products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or a comparable regulatory authority concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit or of comparable applicable submitted to foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing *neffy* and our current or future intranasal epinephrine technology product candidates for potential additional indications, including urticaria.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our reliance on third parties requires us to share our trade secrets, know-how and other proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture *neffy* and our intranasal epinephrine technology product candidates and to perform quality testing, we must, at times, share our proprietary information, including trade secrets and know-how, with them. We seek to protect our proprietary information, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our current and future licensing and collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our proprietary information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how and other proprietary information increases the risk that such proprietary information become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. We rely, in part, on trade secrets, know-how and other proprietary information to develop and maintain our competitive position and a competitor's discovery of our proprietary information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for neffy, our current and future intranasal epinephrine technology product candidates and other proprietary technologies.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to *neffy* and our current or future intranasal epinephrine technology product candidates. If we are unable to obtain or maintain patent protection with respect to *neffy* and our current or future intranasal epinephrine technology product candidates, and its uses, our business, financial condition, results of operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing or in-licensing patents or patent applications in the United States and abroad related to *neffy* and our current or future intranasal epinephrine technology product candidates that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to obtain the intellectual property rights relating to our product could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our intellectual property by obtaining and defending patents. Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek adequate patent protection.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including United States Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the potential impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any future product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that any future product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Our patents or pending patent applications, or the patents or pending patent applications that we license, may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. We may, in the future, be subject to third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (“USPTO”) or become involved in post-grant review procedures, derivations, reexaminations, or inter partes review proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging our patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Patents are of national or regional effect. Although as of December 31, 2025 we own, co-own or exclusively license eight issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, and over thirty member states of the European Patent Organization, including the United Kingdom, directed to *neffy* and its uses, among other things, three pending U.S. patent applications, one pending international patent application and sixteen pending foreign patent applications directed to *neffy* and its uses, among other things, and a pending U.S. provisional patent application directed to intranasal epinephrine formulations and methods of their use, among other things, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Increased patent-related fees from the USPTO and patent offices in foreign countries may significantly increase our operating costs and limit our ability to protect our intellectual property. These increased costs may require us to be more selective in the inventions we choose to patent or the jurisdictions in which we seek protection. If we are unable to adequately fund our patent prosecution and maintenance, or if the costs of defending our patents against third-party challenges become prohibitive, our competitive position could be weakened. Furthermore, these fee structures may incentivize our competitors to adopt more aggressive litigation strategies, potentially increasing our legal expenses and the risk of being unable to exclude others from using our proprietary technology. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates in all of our expected significant foreign markets.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates in all of our expected significant foreign markets.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Further, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Many foreign countries could impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, Brazil enacted Law No. 15.122/2025 (known as the "Economic Reciprocity Law"), which provides a framework that allows for the suspension of obligations related to foreign entity's intellectual property rights. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law in the United States. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before we could therefore be awarded a patent covering any of our inventions even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology, or the technologies we license for our product, and the prior art allow the technology we use for *neffy* and our current or future intranasal epinephrine technology product candidates to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to *neffy* and our current or future intranasal epinephrine technology product candidates or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also included a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including Post Grant Review, Inter Partes Review, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect neffy and our current or future intranasal epinephrine technology product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to *neffy* and our current or future intranasal epinephrine technology product candidates. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws, rules and regulations in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in the patents we own, co-own or license from third parties. In addition, U.S. Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce the existing patents we own, co-own or license and patents we or our licensors might obtain in the future. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce the existing patents we own, co-own or license and patents that we or our licensors might obtain in the future.

As an example, beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the "UPC"). Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

In 2012, the European Union Patent Package (the "EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and various foreign patent agencies at various stages over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we or our licensors fail to maintain the patents and patent applications covering our product, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

Patent terms may be inadequate to protect our competitive position for neffy and our current or future intranasal epinephrine technology product candidates for an adequate amount of time and may adversely affect our anticipated future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of *neffy* and our current or future intranasal epinephrine technology product candidates. In particular, patent protection is important in the development and commercialization of our approved product candidates. Patents covering *neffy* and our current or future intranasal epinephrine technology product candidates normally provide market exclusivity, which is important in order for *neffy* and our current or future intranasal epinephrine technology product candidates to generate profits.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review, patents protecting any future indications or any product candidates might expire before or shortly after commercialization. Even if patents covering any future indications or any future product candidates are obtained, once the patent life has expired, we may be open to competition from generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patents we currently own, co-own or exclusively license for *neffy* and our intranasal epinephrine technology product candidates are expected to expire as early as 2038, absent any patent term adjustments. The API in *neffy* and our intranasal epinephrine technology product candidates is epinephrine, a generic API that is used in FDA-approved intra-muscular injectables. Since *neffy* was approved by the FDA under the 505(b)(2) regulatory pathway, our U.S. patents for *neffy* are not eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. While we are planning to seek additional patent coverage for *neffy*, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. Without patent protection, we may be open to competition from generic versions of *neffy*.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We own, co-own or exclusively license patent applications in our portfolio relating to *neffy* and our current or future intranasal epinephrine technology product candidates that are pending at the patent offices in the United States, Europe, Japan, and other foreign jurisdictions, however, we cannot predict:

- if and when patents may issue based on the patent applications we own, co-own or exclusively license;
- the scope of protection of any patent issuing based on the patent applications we own, co-own or exclusively license;
- whether the claims of any patent issuing based on the patent applications we own, co-own or exclusively license will provide protection against competitors,
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by the patent applications we own, co-own or exclusively license;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own, co-own or exclusively license will result in issued patents with claims that cover *neffy* and our intranasal epinephrine technology product candidates or uses thereof; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to any potential additional indications or any future product candidates.

We cannot be certain that the claims in our pending patent applications directed to *neffy* and our current or future intranasal epinephrine technology product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business. There is no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. Even if the patents do issue based on the patent applications we own, co-own or exclusively license, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to any potential additional indications or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, any additional potential indications or any future product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market neffy and our current or future intranasal epinephrine technology product candidates.

As the pharmaceutical industry expands and more patents are issued, the risk increases that *neffy* and our current or future intranasal epinephrine technology product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our operations or necessary for the commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents that will prevent, limit or otherwise interfere with our ability to make, use or sell *neffy* or our current or future intranasal epinephrine technology product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market *neffy* or our current or future intranasal epinephrine technology product candidates. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market *neffy* or our current or future intranasal epinephrine technology product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market *neffy* or our current or future intranasal epinephrine technology product candidates.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing on the intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing neffy or our current or future intranasal epinephrine technology product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell *neffy* and our current or future intranasal epinephrine technology product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. For example, on March 25, 2025, AptarGroup, Inc. and Aptar France SAS (collectively, "Aptar") filed a suit against us in the United States District Court for the Southern District of New York, alleging that we violated the Defend Trade Secrets Act (18 USC § 1836), misappropriated trade secrets under New York state law, and committed various breaches of contract (the "Aptar Litigation"). We dispute these allegations and intend to vigorously defend ourselves in the Aptar Litigation. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Additionally, delays caused by the federal agencies may increase the time period that we are subject to such claims.

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to *neffy* or our current or future intranasal epinephrine technology product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The pharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that *neffy* or our current or future intranasal epinephrine technology product candidates, or of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity of third-party patents may be difficult and uncertain. Stricter procedural rules and increased discretionary denials at the USPTO may limit our ability to use inter partes review to challenge third-party patents, potentially increasing our litigation costs and risk of infringement liability. These changes may result in our inability to invalidate patents asserted against us by third parties, our increased legal expenses, the need to pay significant licensing fees by us, or us being enjoined from selling certain products. Furthermore, our inability to invalidate questionable third-party patents through the Patent Trial and Appeal Board could adversely affect our product development timelines and market share. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in defending our rights in these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing *neffy* or our current or future intranasal epinephrine technology product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and could result in a court or administrative body finding our patents to be invalid or unenforceable.

Even if the patent applications we own, co-own or license are issued, third parties may challenge or infringe upon our patents. To counter infringement, we may be required to file infringement claims, which can be expensive and time-consuming. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness (or inventive step), written description or enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution.

Third parties may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our current or future products or provide any competitive advantage. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose part or all of the patent protection on one or more of our current or future products, which could result in our competitors and other third parties using our technology to compete with us. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, cash flows and prospects. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced staff and budgets experienced by the USPTO Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents.

We may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company.

In an infringement proceeding, even one initiated by us, there is a risk that a court will decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions they describe. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our research programs and product candidates, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own, co-own or have exclusively licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of our patents is upheld, the court will construe the claims of our patents narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks and pay for damages.

Even if we establish infringement by competitors, a court may decide not to grant an injunction against further infringing activity by competitors and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such infringement claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

neffy or our current or future intranasal epinephrine technology product candidates may face competition from generic intranasal epinephrine products sooner than expected, and our patents may be challenged.

Our success will depend in part on our ability to obtain and/or maintain patent protection for *neffy* and our current or future intranasal epinephrine technology product candidates and related technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. Moreover, the patent applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain additional patent coverage and/or maintain existing patent protection for our formulations, methods of treatment, and/or technologies would limit our protection against generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce substantially similar products or use technologies substantially similar to those we own, co-own, or exclusively license.

We have not received U.S. non-patent marketing exclusivity for *neffy*, which was approved by the FDA under the 505(b)(2) regulatory pathway. Without non-patent marketing exclusivity for *neffy*, we may face competition by third parties seeking to market generic versions of *neffy*. Upon approval of *neffy* by the FDA, we listed 7 patents with claims covering *neffy* in the Orange Book. An eighth patent with claims covering *neffy* was subsequently listed in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of *neffy* or an NDA submitted under the 505(b)(2) regulatory pathway referencing *neffy* must make one of the following certifications to the FDA concerning the patents listed in the Orange Book for *neffy*: (a) the patents that are listed have expired; (b) the date on which such patents will expire; or (c) such patents are invalid or will not be infringed upon by the manufacture, use or sale of the generic equivalent version of *neffy* or the drug product submitted under the 505(b)(2) regulatory pathway referencing *neffy*. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to us for each patent to which the ANDA or 505(b)(2) application refers. Following receipt of a paragraph IV notice, we may bring a lawsuit for patent infringement against the paragraph IV filer, and we may be entitled to a statutory 30-month stay of approval of the proposed product of the paragraph IV filer. We received paragraph IV certification notice letters from Lupin in August 2025 and February 2026, providing notification to us that Lupin submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 2 mg and 1 mg, respectively. In February 2026, we filed a lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. See Note 10 – Commitments and Contingencies to the consolidated financial statements in this Form 10-K for additional discussion. There is no guarantee that we will be successful in our lawsuit against Lupin. Patent litigation is expensive and time consuming, requires significant resources, may absorb significant time of our management and has an unpredictable outcome. If we are unsuccessful in the lawsuit or if a generic competitor is found not to infringe our patents, the resulting generic competition will likely negatively affect our business, financial condition and results of operations. In general, although we expect to vigorously defend our patents from infringement by third parties, there can be no assurances that we will be successful with respect to such defense or any other legal proceedings which may arise in the ordinary course of our business. Such a failure may have a material impact on our business, our results of operations, and our financial condition in the future.

In the EU, we received non-patent marketing exclusivity for *EURneffy*, which received marketing authorization grounded on Article 8(3) of Directive 2001/83/EC by the European Commission. *EURneffy* received an eight-year period of data protection whereby another applicant cannot rely the data submitted as part of the *EURneffy* marketing authorization application, and a ten-year period of marketing protection during which a generic, hybrid or biosimilar cannot be placed on the market in the EU.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any one of our issued patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such an infringement claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. Such announcements could harm our reputation, the perceived value of our intellectual property or the market for our existing or future products, which could have a material adverse effect on our business.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing *neffy* or our current or future intranasal epinephrine technology product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have registered and pending trademarks in the United States, as well as in several foreign jurisdictions, including but not limited to the United Kingdom, EU, and Japan. We may not be able to obtain applicable corresponding health regulatory approval to use these trademarks for our product. Our trademarks or trade names may be refused, challenged, infringed, circumvented, declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. We may not be able to register or use our trademarks in all relevant jurisdictions. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to or appeal those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to register or use, or obtain corresponding health regulatory approval for, a particular trademark in a given jurisdiction, we may need to adopt a different trademark in that territory, which could entail additional costs and diminish our brand equity. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to *neffy* or our current or future intranasal epinephrine technology product candidates but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own, co-own or exclusively license;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or co-own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using *neffy* or our current or future intranasal epinephrine technology product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of *neffy* or our current or future intranasal epinephrine technology product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and unpatented know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how and information. We further seek to protect our potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we have taken steps to protect our trade secrets and unpatented know-how, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of skilled personnel from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time-to-time we expect to rely on third parties, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We are and could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors, including, for example, the Aptar Litigation. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we are, and may in the future, become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged intellectual property, proprietary information, know-how or trade secrets of a current or former employer or competitor.

While we are, and may in the future, litigate to defend against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies that are essential to *neffy* and our current or future intranasal epinephrine technology product candidates, if such technologies are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time, we may be required to license technologies relating to our therapeutic programs from additional third parties to further develop or commercialize *neffy* and our current or future intranasal epinephrine technology product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell *neffy*, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of *neffy* or our current or future intranasal epinephrine technology product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Risks Related to Employee Matters and Managing Growth

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

Our success depends, and will likely continue to depend, upon our ability to hire and retain the services of our current executive officers and our other highly qualified personnel. We have entered into employment agreements with each of our executive officers but they may terminate their employment or engagement with us at any time. The loss of their services might impede the achievement of our research, development and commercialization objectives.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Our industry has experienced a high rate of turnover in recent years. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, which includes entities owned by our executive officers and directors, may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize *neffy* and our current or future intranasal epinephrine technology product candidates will be limited.

Our employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or comparable foreign programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth, which could disrupt our operations.

We expanded our organization following FDA approval of *neffy* in August 2024. Specifically, we increased our sales force and made additional hires in the areas of general and administrative, medical, commercial, sales and marketing, and operations. As a result, our headcount has increased from 23 full-time employees and 5 part-time employees as of July 31, 2024 to 158 full-time employees and 5 part-time employees as of December 31, 2025. We may need to further expand our headcount in the future to support our growth strategy. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of our attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such recent and anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If we are unable to effectively manage our recent and expected growth, our ability to generate revenues or achieve future profitability could be reduced and we may not be able to implement our business strategy, including the successful commercialization of *neffy*.

Risks Related to the Securities Markets and Ownership of Our Common Stock

The market price of our common stock could be volatile.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- our ability to maintain regulatory approval for *neffy*, or obtain regulatory approvals for additional indications;
- failure of *neffy* or our current or future intranasal epinephrine technology product candidates, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to *neffy* or our current or future intranasal epinephrine technology product candidates;
- any inability to obtain adequate supply of *neffy* or our current or future intranasal epinephrine technology product candidates or any of its components, or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for *neffy* or our current or future intranasal epinephrine technology product candidates;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions, including as a result of actual or threatened tariffs and trade wars;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- perceived and actual risks associated with our Credit Agreement;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies.

Additionally, a decrease in the stock price of our common stock may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law ("DGCL") may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of us more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chair of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of our voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we will be subject to Section 203 of the DGCL. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving us. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation designates the state courts of the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

We do not anticipate paying any cash dividends in the foreseeable future.

We plan to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any applicable legal restrictions on resale lapse, the trading price of our common stock could decline. We are not able to predict the effect that sales may have on the prevailing market price of our common stock.

General Risk Factors

Geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.

International and geo-political events could also have a serious adverse impact on our business. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions associated with geopolitical conflicts could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, and confidential information that is proprietary, strategic or competitive in nature, including clinical trial data ("Information Systems and Data").

Our Chief Executive Officer supervises our IT department (the "IT Department"), which coordinates with our cybersecurity incident management team, which consists of, among others, our Chief Financial Officer, Chief Legal Officer, Head of IT, and a third-party IT and cybersecurity consultant ("CSI Management Team") to identify, assess and manage our cybersecurity threats and risks. Members of our IT Department and CSI Management Team identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example manual tools, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, internal and external audits, conducting threat assessments for internal and external threats, third-party threat assessments, conducting vulnerability assessments to identify vulnerabilities, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: a cybersecurity incident response policy; incident detection and response; vulnerability management processes; a disaster recovery and business continuity plan; risk assessments; encryption of certain of our data; network security controls; segregation of certain of our data; access controls; physical security; asset management, tracking and disposal; systems monitoring; vendor risk management processes; employee training; penetration testing; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the IT Department works with the CSI Management Team to prioritize our risk management processes and mitigate cybersecurity threats that are expected to be more likely to lead to a material impact to our business. In addition, our management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which, together with the board of directors, evaluates our overall enterprise risk.

We use third-party service providers to assist us to identify, assess, and manage material risks from cybersecurity threats, including for example: a third-party IT and cybersecurity consultant; professional services firms, including legal counsel; threat intelligence service providers; cybersecurity software providers; managed cybersecurity service providers; penetration testing firms; and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as conducting nonclinical and clinical trials; supply and quality testing; development and manufacturing; and professional services firms, including legal counsel. Additionally, we rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology for certain environments and systems, employee email, and content delivery. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, which may include reputational due diligence and vendor risk evaluations.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I, Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*Risk Factors—If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*"

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including the CSI Management Team. Certain members of the CSI Management Team are information technology and security professionals, and we also rely on third-party security analysts who have certain certifications related to cybersecurity.

Our Chief Executive Officer, Chief Financial Officer and Chief Legal Officer are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Additionally, they are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Chief Executive Officer, Chief Financial Officer, and Chief Legal Officer. These members of management work with our CSI Management Team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our cybersecurity incident response policy includes reporting to the audit committee of our board of directors for certain cybersecurity incidents.

The audit committee periodically reviews and discusses with the appropriate members of our management material risks relating to data privacy, technology and information security, including cybersecurity, threats and back-up of information systems and our processes for assessing, identifying, and managing such risks, as well as our internal controls and disclosure controls and procedures relating to cybersecurity incidents. The board and audit committee are also provided with reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters are located in San Diego, California, where we lease approximately 9,254 square feet of office space. We believe that our facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. See Note 10 - Commitments and Contingencies of this Annual Report, which is incorporated by reference in this Item 3, for any required disclosure.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Global Market since December 4, 2020, and has been trading under the ticker symbol "SPRY" since November 9, 2022.

Holders of Common Stock

As of March 4, 2026, there were 13 holders of record of our common stock. Because most of our common stock is held by brokers, nominees, and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Use of Proceeds

None.

Item 6. [Reserved]

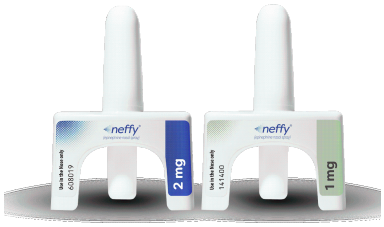
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with our financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward Looking Statements." Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

Overview

We are a biopharmaceutical company focused on the commercialization and development of *neffy* (currently identified in the European Union ("EU") and United Kingdom ("U.K.") by the trade name *EURneffy* and in China by the trade name 优敏速) for needle-free intranasal delivery of epinephrine for emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only U.S. Food and Drug Administration ("FDA") and European Commission-approved needle-free epinephrine product, also has approvals in the U.K., Japan, Australia, and China. It is the first new delivery method for epinephrine in more than 35 years. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail, which allows *neffy* to safely provide intranasal delivery of epinephrine at a low dose within the exposures of approved injectable products across a range of dosing conditions (including repeat dosing and allergen challenge). We believe the market opportunity for *neffy* in the United States is significant. At the current list price for *neffy* and our target total gross-to-net yield, the estimated 6.5 million patients currently prescribed an epinephrine autoinjector in the United States represents an initial addressable market opportunity of approximately $3.5 billion in annual net sales, while the remaining 13.5 million diagnosed patients that have not been prescribed an epinephrine product represent an additional addressable market opportunity of approximately $7.0 billion in annual net sales.

We believe *neffy*'s "no needle, no injection" approach addresses a significant unmet need in the use of epinephrine. There are approximately 40 million people in the U.S. who experience Type I allergic reactions. Of this group, approximately 20 million people are reported to have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million of those were prescribed an epinephrine autoinjector. However, in recent years, only an estimated one-half of those consistently carry their prescribed autoinjector with them. We believe the market opportunity for *neffy* in the U.S. is significant. Those estimated 3.2 million patients who currently fill their active epinephrine autoinjector prescription would represent approximately $1.8 billion in annual U.S. net sales at *neffy*'s target estimated gross-to-net yield based on epinephrine device unit volume in 2025.



In August 2024, the FDA approved *neffy* 2 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater, with *neffy* 1 mg subsequently approved in March 2025 for patients who are four years of age and older and weigh 15 kg to less than 30 kg. Our launch strategy for *neffy* in the United States involves direct outreach to high-volume prescribers of epinephrine accounting for approximately 55% of prescriptions in the last year through an efficient sales force. As of December 31, 2025, our sales force is comprised of approximately 106 ARS Pharma employees, who serve as sales reps, key account managers, area sales managers, and national sales directors, as well as 10 virtual sales reps, and approximately 70 sales reps via our co-promotion partner, ALK U.S., who began field operations in June 2025 and will target up to 9,000 specified pediatricians and other prescribers in the U.S. We plan to expand our internal sales force to approximately 150 individuals beginning in the second quarter of 2026. For more information regarding our partners and collaboration agreements, see "*Business—Our Collaboration and Licensing Agreements.*"

Our launch strategy is also supported by: active participation since November 2024 of approximately 2,800 healthcare professionals in our *neffy* experience program that allows healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenge as well as for the ongoing collection of real-world evidence that supports *neffy's* clinical equivalence to injection; extensive non-personal promotion including medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences; engagement and contracting with payors to obtain timely coverage with favorable gross-to-net discounting; our *neffyconnect* program that provides support to physicians and patients including our $25 co-pay savings card, $199 cash price and patient assistance programs; our *neffy*inSchools programs, where more than 9,000 schools to date have opted into receiving two cartons of *neffy* at no cost with accompanying school nurse education about *neffy*; partnerships with patient advocacy organizations including disease awareness campaigns; and multi-channel branded direct to consumer advertising including connected television, point of care, endemic and programmatic display, social media, and paid search that initiated in May 2025, as well as linear television advertising that started in June 2025. To reduce the time burden of an in-person healthcare provider visit, we also launched a new commercial initiative in November 2025 called "Get *neffy* on Us" that offers patients a free visit with a virtual prescriber, along with a $0 co-pay for eligible patients with commercial insurance. We also initiated a U.S. post-marketing registry-based study for *neffy* for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics in the second quarter of 2025, which is ongoing.

The EC has granted marketing authorization in the EU for *EURneffy* 2 mg (the trade name for *neffy* 2 mg in the EU and U.K.), for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater and on January 29, 2026, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion, recommending marketing authorization in the EU for *EURneffy* 1 mg for children who are four years of age and older and weigh 15 kg to less than 30 kg. Through our collaboration with ALK, *EURneffy* 2 mg was launched in Europe, beginning with Germany in June 2025, followed by the U.K. in October 2025. We received approval of *neffy* 2 mg and 1 mg in Japan in September 2025, which is expected to launch in the first quarter of 2026 by our collaboration partner, Alfresa. We also received approval of *neffy* 2 mg and 1 mg doses in Australia in December 2025, with commercial launch by our collaboration partner, Seqirus, initiated in February 2026. In December 2025, we received approval in China of 优敏速 (the trade name for *neffy* 2 mg in China), with commercial launch by our collaboration partner, Pediatrix, expected to start in the first half of 2026. *neffy* 2 mg is under review by Health Canada, with a regulatory decision expected in the second quarter of 2026 and if approved, with commercial launch by our collaboration partner, ALK, expected to start later in 2026. *neffy* has already been approved or is under regulatory review in countries representing approximately 98% of the current global epinephrine autoinjector sales.

Real-world data supports that *neffy* delivers similar response rates as injections for the emergency treatment of Type I allergic reactions. In September 2025, we reported survey results of anaphylaxis treatment outcomes in the *neffy* experience program, which provides 1 mg and 2 mg doses of *neffy* to allergists for in-office use if patients experience an anaphylactic event during oral food challenges or allergen immunotherapy. These results showed that approximately 90% of patients experiencing anaphylaxis symptoms were effectively treated with a single dose of *neffy*, which is consistent with that historically reported for epinephrine injection. The results were presented as an oral presentation at the American College of Allergy, Asthma and Immunology ("ACAAI") meeting in early November 2025 and was also published in the Annals of Allergy, Asthma and Immunology, the official peer-reviewed journal of the ACAAI, in December 2025.

We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients at the American Academy of Allergy and Immunology medical conference in February 2024. In the second quarter of 2025, we initiated a Phase 2b randomized, placebo-controlled outpatient clinical trial involving chronic spontaneous urticaria patients, on chronic treatment regimens, who still experience flares or exacerbations. Interim data from this clinical trial is anticipated in the second half of 2026, followed by the potential initiation of a single pivotal efficacy study in mid-2027.

Since our inception in 2015 as ARS Pharmaceuticals, Inc., we have devoted substantially all of our efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. We have funded our operations primarily with proceeds from the merger with Silverback Therapeutics, Inc. ("Silverback") in November 2022, private placement of convertible preferred stock, issuance of common stock, licensing, supply and distribution arrangements with our commercialization partners, debt, and net product sales. As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $245.0 million.

We have incurred net losses in most years since our inception. Net loss for the year ended December 31, 2025 was $171.3 million, and net income for the year ended December 31, 2024 was $8.0 million. As of December 31, 2025, we had an accumulated deficit of $294.6 million. Until we consistently generate positive net income, if ever, our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other development activities, the cost for regulatory filings, expenses for commercial activities to establish, maintain and enhance sales, marketing and distribution capabilities for *neffy*, the timing and volume of our product sales, and our ability to earn potential royalties and regulatory and commercial milestones under our license and collaboration arrangements.

Until such time, if ever, that we can generate substantial product revenue, we may finance our operations through our existing cash, cash equivalents, short-term investments, equity offerings, debt financings and other capital sources which may include collaborations, strategic alliances, marketing, distribution or licensing arrangements or other arrangements with third parties. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, any future debt agreements may limit our ability to enter into certain debt financings without the consent of the lenders thereunder. On September 29, 2025 we entered into a Credit Agreement (the "Credit Agreement") with RA Capital Agency Services, LLC (as the "Administrative Agent") and affiliates of OMERS Administration Corporation and RA Capital Management, L.P. as lenders (the "Lenders"), which provides for an aggregate principal amount of up to $250.0 million of term loans from the Lenders to us (the "Credit Facility"). Subject to limited exceptions, we are prohibited from incurring additional indebtedness and entering into certain strategic and licensing transactions without the prior written consent of the Lenders pursuant to the Credit Agreement. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and may require us to delay or reduce our marketing and sales efforts, or delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

We do not own or operate manufacturing facilities. We currently rely on third-party manufacturers and suppliers for *neffy* and our intranasal epinephrine technology product candidates, and we expect to continue to do so to meet our nonclinical, clinical and commercial activities. Our third-party manufacturers are required to manufacture our product under cGMP requirements and other applicable laws and regulations.

Financial Overview

Revenues

We have recognized net product sales in the United States since the commercial launch of *neffy* in September 2024. We have signed collaboration and license agreements for *neffy* for all geographies outside of the United States. The terms of these agreements may include payment to us of one or more of the following: non-refundable, upfront license fees; clinical, regulatory, and/or commercial milestone payments; clinical development fees; and royalties or a transfer price on net sales of licensed products if *neffy* receives marketing approval in these regions. We expect product revenues to fluctuate in future periods as we continue with the commercial launch of *neffy*. We expect revenues under collaboration agreements to fluctuate in future periods based on our ability to meet various regulatory milestones, and contingent on successfully obtaining regulatory approval for *neffy* in the licensed regions, commercial milestones, royalties or transfer price earned from our partner's net sales and the supply of commercial product as set forth in the agreements described earlier.

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs to manufacture *neffy* for commercial sale, including third-party manufacturing costs, raw material and component costs, excess or obsolete inventory adjustment charges, inventory write offs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, royalties on product sales, salaries and related expenses for personnel, and stock-based compensation. Prior to the FDA approval of *neffy* in August 2024, certain inventory components were purchased to manufacture *neffy* and recorded as research and development expenses, resulting in zero-cost inventory components. As a result, the cost of goods sold related to *neffy* will initially reflect a lower average per unit cost of materials, as previously expensed inventory components are consumed in commercial production and sold to customers.

As of December 31, 2025, we had $6.7 million in zero-cost inventory components remaining, and no zero-cost inventory components were determined to be obsolete. Based on our current forecast, we expect zero-cost inventory components to be substantially consumed in commercial production by mid-2026. The time over which the zero-cost inventory components are included in cost of goods sold will depend on several factors, but primarily the timing of future *neffy* sales.

Research and Development Expenses

To date, our research and development expenses have been related primarily to clinical development, process development, and manufacturing costs of *neffy* and our intranasal epinephrine technology product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- external research and development expenses incurred under agreements with contract research organizations ("CROs"), investigative sites and consultants and other third-party organizations to conduct our clinical studies and development activities;
- costs related to manufacturing *neffy* and our intranasal epinephrine technology product candidates for clinical trials and process validation studies, including fees paid to contract manufacturing organizations ("CMOs") and other third-party manufacturers;
- costs related to compliance with regulatory requirements and regulatory filings;
- indirect expenses including insurance and facility-related expenses; and
- salaries, payroll taxes, benefits and stock-based compensation charges for personnel engaged in research and development efforts.

Our external research and development expenses for *neffy* and our intranasal epinephrine technology product candidates consist primarily of fees, materials and other costs paid to CROs, CMOs, consultant and contractors. Our clinical, regulatory, manufacturing, and non-clinical development costs for the periods presented below reflect an allocation of expenses associated with personnel costs, stock-based compensation expense, and indirect costs incurred in support of overall research and development, such as facilities-related costs.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and the manufacturing costs of *neffy* and our intranasal epinephrine technology product candidates due to the inherently unpredictable nature of clinical development and manufacturing activities. Clinical development and manufacturing timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast to what degree our licensing, supply and distribution arrangements would affect our development plans and capital requirements.

The duration, costs and timing of clinical trials and development of *neffy* and our intranasal epinephrine technology product candidates for the treatment of additional indications will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- tariffs and international trade relations;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the efficacy and safety profile of *neffy* and our current and future intranasal epinephrine technology product candidates;
- the cost to seek regulatory approvals for our intranasal epinephrine technology product candidates in additional indications and any product candidates that successfully complete clinical trials;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of *neffy* and our intranasal epinephrine technology product candidates;
- establishing or maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of *neffy* and our intranasal epinephrine technology product candidates could significantly change the costs and timing associated with the development of that future product candidate. The process of conducting the necessary clinical research and manufacturing to obtain regulatory approval is costly and time-consuming. The actual probability of success for any future candidates may be affected by a variety of factors. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product's or any future candidates' development, which could increase our research and development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, stock-based compensation for personnel in executive, finance, business development, sales and marketing and other corporate administrative functions. Selling, general and administrative expenses also include pre-commercial launch activities prior to product launch, the initiation of commercialization activities in September 2024, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, and insurance costs.

Selling, general and administrative expenses have increased since the third quarter of 2024 due to the establishment of our sales force, the development and commencement of our marketing campaigns and initiatives, the ALK Co-Promotion Agreement, the hiring of additional sales and marketing personnel to support full commercialization activities, and the addition of infrastructure and programs to support commercialization activities. We expect to continue to incur audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director fees, investor relations costs associated with operating as a public company, patent costs and defense, and general and administrative personnel.

Other Income, net

Other income, net consists primarily of interest income from our cash, cash equivalents, and short-term investments, interest expense on our outstanding debt, and net amortization and accretion associated with our short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands, except percentages):

	Years Ended December 31,		Dollar Change	% Change
	2025	2024		
Revenue:				
Product revenue, net	$ 72,192	$ 7,255	$ 64,937	*
Revenue under collaboration agreements	9,716	81,529	(71,813)	(88%)
Revenue under supply agreements	2,370	365	2,005	*
Total revenue	84,278	89,149	(4,871)	(5%)
Operating expenses:				
Cost of goods sold	20,423	977	19,446	*
Research and development[(1)]	13,181	19,580	(6,399)	(33%)
Selling, general and administrative[(1)]	230,122	71,675	158,447	221%
Total operating expenses	263,726	92,232	171,494	186%
Loss from operations	(179,448)	(3,083)	(176,365)	*
Other income (expense), net:				
Interest income	10,669	11,369	(700)	(6%)
Interest expense	(2,599)	—	(2,599)	*
Total other income, net	8,070	11,369	(3,299)	(29%)
(Loss) income before income tax (benefit) expense	(171,378)	8,286	(179,664)	*
Income tax (benefit) expense	(80)	288	(368)	(128%)
Net (loss) income	$ (171,298)	$ 7,998	$ (179,296)	*

[*] Not meaningful

[(1)] Includes stock-based compensation expense as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 2,660	$ 2,955
Selling, general and administrative	19,435	11,579
Total	$ 22,095	$ 14,534

Revenues. Revenue for the year ended December 31, 2025 was $84.3 million, as compared to $89.1 million for the year ended December 31, 2024. Revenue for the year ended December 31, 2025 includes $72.2 million in net product revenues for sales of *neffy* in the United States, $9.7 million in revenue under collaboration agreements, and $2.4 million in revenue under supply agreements. Revenue under collaboration agreements consists of achievement of regulatory and commercial milestones under the Pediatrix Agreement of $4.0 million, ALK Collaboration Agreement of $2.6 million, Alfresa Agreement of $2.0 million, and Seqirus Agreement of $0.6 million, as well as the performance of development and regulatory services, and royalties attributable to the ALK Territory, excluding the EEA, under the ALK Collaboration Agreement of $0.3 million and $0.2 million, respectively.

Revenue for the year ended December 31, 2024 includes $81.5 million in revenues under collaboration agreements, $7.3 million in net product revenues for sales of *neffy* in the United States, and $0.4 million in revenue under supply agreements. Revenue under collaboration agreements consists of $73.1 million under the ALK Collaboration Agreement for the delivery of a license to develop, manufacture and commercialize products containing epinephrine administered intranasally in the ALK Territory excluding the EEA, $0.4 million under the ALK Collaboration Agreement for revenue recognized under the regulatory services performance obligations, $6.0 million from a regulatory milestone under the Alfresa Agreement, $1.5 million for the first event milestone under the Seqirus Agreement, and $0.5 million for the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how under the Seqirus Agreement.

Cost of Goods Sold. Cost of goods sold for the year ended December 31, 2025 was $20.4 million, as compared to $1.0 million for the year ended December 31, 2024. Prior to August 2024, costs incurred to manufacture *neffy* were recorded as research and development expenses, and product sales subsequent to August 2024 partially utilized zero-cost inventory components. Cost of goods sold consisted primarily of product costs and royalties, and during the year ended December 31, 2025, the establishment of an inventory reserve.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2025 were $13.2 million, as compared to $19.6 million for the year ended December 31, 2024. The decrease of $6.4 million was primarily due to decreases in IPR&D expense of $2.1 million from the achievement of the EMA regulatory milestone under the Recordati Termination Agreement during the year ended December 31, 2024, product-development related expense of $1.8 million, clinical trial costs of $0.8 million, personnel-related expenses of $0.8 million, and other research and development expenses of $0.9 million.

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Clinical and regulatory	$ 6,943	$ 8,033
Manufacturing and non-clinical development	6,238	11,547
Total	$ 13,181	$ 19,580

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2025 was $230.1 million, as compared to $71.7 million for the year ended December 31, 2024. The increase of $158.4 million was primarily due to increases in marketing-related expenses of $111.4 million, personnel-related expenses of $24.2 million, stock-based compensation expense of $7.9 million, outside services of $4.2 million, travel and meals expense of $3.6 million incurred mainly by our sales personnel, conference and seminar expense of $2.5 million, audit, tax and valuation fees of $1.5 million, legal fees of $0.6 million, and other general operating costs of $2.5 million.

Other Income (Expense), Net. Other income (expense), net for the year ended December 31, 2025 was $8.1 million, as compared to $11.4 million for the year ended December 31, 2024. The decrease of $3.3 million was primarily due to interest expense related to the term loan of $2.6 million and a decrease in net accretion of discounts on short-term investments of $2.1 million, partially offset by an increase in interest income from our cash, cash equivalents, and short-term investments of $1.4 million.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the merger with Silverback, private placement of convertible preferred stock, issuance of common stock, licensing, supply and distribution arrangements with our commercialization partners, debt, and net product sales. As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $245.0 million.

Cash flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Net cash and cash equivalents (used in) provided by operating activities	$ (170,866)	$ 13,548
Net cash and cash equivalents provided by (used in) investing activities	56,768	(106,101)
Net cash and cash equivalents provided by financing activities	104,598	72,399
Net decrease in cash and cash equivalents	$ (9,500)	$ (20,154)

Operating Activities

During the year ended December 31, 2025, net cash used in operating activities was $170.9 million. This consisted primarily of a net loss of $171.3 million, an increase in our operating assets and operating liabilities of $38.5 million and $18.5 million, respectively, and non-cash charges of $20.4 million. The increase in our operating assets was due to increases in inventories of $22.0 million and accounts receivable of $17.2 million, partially offset by a decrease in prepaid expenses and other assets of $0.7 million. The increase in our operating liabilities was primarily attributable to an increase in accounts payable and accrued expenses of $18.9 million, partially offset by a decrease in contract liability of $0.4 million. The non-cash charges consisted primarily of non-cash stock-based compensation of $22.1 million, establishment of an inventory reserve of $2.2 million, depreciation and amortization expense of $1.4 million, and other non-cash items of $0.3 million, partially offset by net accretion of discounts on short-term investments of $5.5 million.

During the year ended December 31, 2024, net cash provided by operating activities was $13.5 million. This consisted primarily of net income of $8.0 million, an increase in our operating assets of $20.3 million, an increase in our operating liabilities of $18.5 million, and non-cash charges of $7.4 million. The increase in our operating assets was primarily due to an increase in accounts receivable of $8.2 million, an increase in prepaid and other assets of $6.2 million, and an increase in inventories of $5.9 million. The increase in our operating liabilities was due to an increase in accounts payable and accrued liabilities of $16.4 million and an increase in contract liability of $2.1 million. The non-cash charges consisted primarily of non-cash stock-based compensation of $14.5 million, partially offset by net accretion of discounts on short-term investments of $7.3 million.

Investing Activities

During the year ended December 31, 2025, the cash and cash equivalents provided by investing activities was $56.8 million. This consisted of maturities of short-term investments of $307.0 million, partially offset by purchases of short-term investments of $242.0 million, payments of milestone obligations under license agreements of $7.9 million, and purchases of property and equipment of $0.3 million.

During the year ended December 31, 2024, the cash and cash equivalents used in investing activities was $106.1 million. This consisted primarily of purchases of short-term investments of $356.0 million, payments of milestone obligations under license agreements of $7.5 million, and purchases of property and equipment of $0.6 million, partially offset by maturities of short-term investments of $258.0 million.

Financing Activities

During the year ended December 31, 2025, the $104.6 million of cash and cash equivalents provided by financing activities was attributable to net proceeds from the term loan under the Credit Agreement of $96.3 million, proceeds from stock option exercises and issuance of common stock under the employee stock purchase plan of $5.7 million, and proceeds from milestone obligations met under license agreements of $2.7 million.

During the year ended December 31, 2024, the cash and cash equivalents provided by financing activities was $72.4 million. This consisted of $69.4 million from the upfront payment from ALK that was allocated to the EEA License and $3.0 million from stock option exercises and issuance of common stock under the employee stock purchase plan.

Term Loans

On September 29, 2025 (the “Closing Date”), we entered into the Credit Agreement with the Administrative Agent and the Lenders, which provides for an aggregate principal amount up to $250.0 million of term loans from the Lenders to us, including an initial tranche of $100.0 million under Term A Loan funded on the Closing Date, $25.0 million under Term B Loan that will be made available during the period commencing on the six-month anniversary of the Closing Date and ending no later than the one-year anniversary of the Closing Date, up to $25.0 million under Term C Loan will be made available at our election during the period

commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the satisfaction of a certain revenue requirement, and up to $100.0 million under Term D Loan, subject to the consent of the Lenders. The Term Loans will mature on the five-year anniversary of the Closing Date. The Credit Facility enhances our liquidity position and provides additional financial flexibility, subject to the satisfaction of certain customary conditions for future tranches and revenue-based requirements for the third tranche.

Future Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents, short-term investments, and revenues from product sales and cash proceeds from collaboration and out-licensing agreements will be sufficient to meet our anticipated cash requirements through at least the next three years. In particular, we expect our existing cash, cash equivalents, short-term investments, and revenues from net product sales and cash proceeds from collaboration and out-licensing agreements will allow us to fund commercial manufacturing and sales and marketing activities, general operating activities and working capital requirements, and proof of concept clinical trials of *neffy* for additional indications. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future funding requirements will depend on many factors, including:

- revenue received from commercial sales of *neffy*;
- the timing and amount of any milestone and royalty payments under the ALK Collaboration Agreement, ALK Co-Promotion Agreement, Pediatrix Agreement, Aegis Agreement, Alfresa Agreement, Recordati Termination Agreement, and the Seqirus Agreement;
- the scope, progress, results and costs of researching and developing our intranasal epinephrine technology for additional indications;
- the scope and costs of clinical and commercial manufacturing of *neffy* and our intranasal epinephrine technology product candidates;
- the timing of, and the costs involved in, obtaining marketing approvals for our intranasal epinephrine technology for additional indications;
- the number of additional indications for our intranasal epinephrine technology that we may pursue and their development requirements;
- the costs of commercialization activities for *neffy* and our intranasal epinephrine technology product candidates, to the extent such costs are not the responsibility of any collaborators, including the costs and timing of building and maintaining product sales, marketing, distribution and manufacturing capabilities;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies;
- our headcount growth and associated costs as we expand our employee headcount and building and maintaining a commercial infrastructure;
- our ability to service our current credit facility under the Credit Agreement and access, if and when needed, additional amounts of principal provided for under the Credit Agreement;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of our existing cash, cash equivalents, short-term investments, equity offerings, debt financings and other capital sources which may include collaborations, strategic alliances, marketing, distribution or licensing arrangements or other arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, our current or future debt agreements may limit our ability to incur additional debt. Subject to limited exceptions, we are prohibited from incurring additional indebtedness and entering into certain strategic and licensing transactions without the prior written consent of the Lenders pursuant to the Credit Agreement. If we raise funds through additional collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, development programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock.

Our ability to raise additional funds may be adversely impacted by macroeconomic factors that may result in worsening global economic conditions and disruptions to and volatility in the global credit and financial markets, including due to tariffs, trade wars, inflation, high interest rates, recessionary concerns, recessions, bank failures, geopolitical conflicts, and general economic uncertainty. Because of the numerous risks and uncertainties associated with product development and commercialization, we cannot predict the timing or amount of increased expenses and cannot assure you that we will generate profits or positive cash flows from operating activities in the future.

Future Contractual Cash Obligations

The total remaining unconditional purchase obligations related to the supply of raw materials is $55.3 million as of December 31, 2025. Our remaining payment obligations by year are as follows: 2026 ($9.1 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035.

Under the ALK Co-Promotion Agreement, the total remaining payment obligations under this agreement are $20.2 million as of December 31, 2025. Our remaining obligations by year are as follows: 2026 ($8.3 million), 2027 ($5.2 million), 2028 ($4.7 million), and 2029 ($2.0 million). In addition to the base fee, ALK U.S will be eligible to receive performance-based payments from us. Future performance-based payment amounts are indeterminate since they depend on future revenues, which are uncertain.

In August 2024, we entered into a corporate sponsorship agreement with Food Allergy Research and Education, Inc., which was subsequently amended in May 2025. Our remaining payment obligations as of December 31, 2025 are $6.0 million. Our remaining payment obligations by year are as follows: 2026 ($5.0 million), and 2027 ($1.0 million).

Under the Credit Agreement, the outstanding principal of $100.0 million as of December 31, 2025 is due upon maturity on September 29, 2030. Estimated interest payments are calculated based on the outstanding principal, the applicable interest rate and expected timing of scheduled payments as of December 31, 2025. As of December 31, 2025, based on the interest rate in effect at such date, total estimated remaining interest payments are $45.7 million, and our estimated remaining interest payments by year are as follows: 2026 ($9.6 million), 2027 ($9.6 million), 2028 ($9.6 million), 2029 ($9.6 million), and 2030 ($7.2 million).

Under the Aegis Agreement, remaining payment obligations to OrbiMed are contingent upon our achievement of certain commercial milestones and have been reduced to $9.0 million as of December 31, 2025. We are also required to make royalty payments to OrbiMed based on a mid-single-digit percentage of net product sales. Future royalty payment amounts are indeterminate since they depend on future revenues, which are uncertain.

In February 2023, we entered into a termination agreement (the "Recordati Termination Agreement") with Recordati Ireland, Ltd. ("Recordati") to reacquire the rights to *neffy* in Europe and certain European Free Trade Association, Russia/the Commonwealth of Independent States, Middle East and African countries (the "Recordati Territory"). Under the Recordati Termination Agreement, we are required to make royalty payments to Recordati of up to €5.0 million in the aggregate from sales of *neffy* in the Recordati Territory, of which up to €4.6 million (approximately $5.4 million in U.S. dollars) remain as of December 31, 2025. Future royalty payment amounts are indeterminate since they depend on future revenues, which are uncertain.

We enter into contracts in the normal course of business with third-party contract organizations and vendors for clinical studies, manufacturing and other services and products. These contracts generally provide for termination after a notice period.

As of December 31, 2025, we have not recognized any reserves related to uncertain tax positions and had no accrued interest or penalties related to uncertain tax positions.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, accrued expenses, stock-based compensation, and valuation allowances for deferred tax assets. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies and estimates are described in more detail in Note 2 – Summary of Significant Accounting Policies to our consolidated financial statements, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements.

Revenue Recognition

Product revenue, net

Product revenue is recorded net of estimates for variable consideration, including distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, co-payment assistance, and other incentives for certain indirect customers. Reserves for these estimates are recorded in the same period of the related sale and reflect amounts earned or expected to be claimed on those sales. Estimates of variable consideration require significant judgment and are based on factors such as contractual and statutory requirements, known market events, industry trends and data, forecasted customer buying and payment patterns, and historical experience. Variable consideration is included in net product revenue only to the extent it is probable that a significant reversal will not occur in a future period. Estimates are reassessed each reporting period, and actual amounts may differ from those estimates. Any adjustments are recorded in the period differences become known on a cumulative catch-up basis and may affect product revenue and net (loss) income in that period.

Revenue under collaboration agreements

Revenue from licenses to our intellectual property is recorded when the license is transferred and the licensee can use and benefit from it, provided the license is distinct from other obligations. For licenses bundled with other obligations, management evaluates whether performance obligations are satisfied over time or at a point in time and, if over time, determines the appropriate method to measure progress. Milestone payments are included in the transaction price only when it is probable that a significant revenue reversal will not occur, and are reassessed each reporting period. Sales-based royalties or commercial milestones based on product sales where a license is the predominant item are recorded at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Adjustments to estimates are recorded on a cumulative catch-up basis and may affect revenue under collaboration agreements and net (loss) income in that period.

Recent Accounting Pronouncements

See Note 2 – Summary of Significant Accounting Policies to our consolidated financial statements for information about recent accounting pronouncements, the timing of their adoption, and our assessment, if any, of their potential impact on our financial condition and results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required for a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act.

Item 8. Financial Statements and Supplementary Data

ARS Pharmaceuticals, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ARS Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ARS Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive (loss) income, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Rebates

Description of the Matter	As described in Note 2 to the consolidated financial statements, the Company records product revenue with each sale at the transaction price, net of reserves for variable consideration, including but not limited to commercial rebates owed to pharmacy benefit managers and managed care organizations. The Company estimates the rebate amounts owed based on the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel and any rebate amounts for product that has been dispensed to a patient but not invoiced to the Company at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the consolidated balance sheet. Auditing management's estimates of commercial rebates was especially challenging because the related accruals were dependent on certain significant assumptions including the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel and for which the product has been dispensed to a patient but has not been invoiced at the end of each reporting period.
How We Addressed the Matter in Our Audit	To test the commercial rebates, our audit procedures included, among others, understanding and evaluating the significant assumptions and the underlying data used in management's calculations. This included testing contractual arrangements and management’s estimates of expected claims for product that remains in the distribution channel and for which the product has been dispensed to a patient but the Company has not been invoiced at the end of the reporting period. In addition, we inspected the results of the Company's analysis of commercial rebates and evaluated the estimates made based on historical experience.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2019.

San Diego, California

March 9, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 41,317	$ 50,817
Short-term investments	203,669	263,205
Accounts receivable, net	25,347	8,175
Inventories	8,369	5,212
Prepaid expenses and other current assets	6,194	6,886
Total current assets	284,896	334,295
Inventories, noncurrent	23,053	5,307
Property, plant and equipment, net	2,465	1,066
Intangible assets, net	14,452	7,371
Other assets	2,786	3,114
Total assets	$ 327,652	$ 351,153
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $1,624 and $656, respectively)	$ 37,948	$ 22,841
Contract liability, current	609	557
Other current liabilities	588	42
Total current liabilities	39,145	23,440
Term loans, net (including related party amounts of $4,819 and $0, respectively)	96,374	—
Financing liability	72,140	69,383
Contract liability, net of current portion	1,130	1,532
Other accrued liabilities	4,605	—
Total liabilities	213,394	94,355
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2025 and 2024; 99,290,926 and 97,954,172 shares issued and outstanding at December 31, 2025 and 2024, respectively	10	10
Additional paid-in capital	408,726	379,873
Accumulated other comprehensive gain, net	125	220
Accumulated deficit	(294,603)	(123,305)
Total stockholders' equity	114,258	256,798
Total liabilities and stockholders' equity	$ 327,652	$ 351,153

The accompanying notes are an integral part of these consolidated financial statements.

ARS Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive (Loss) Income
(in thousands, except share and per share data)

	Years Ended December 31,	
	2025	2024
Revenue:		
Product revenue, net	$ 72,192	$ 7,255
Revenue under collaboration agreements	9,716	81,529
Revenue under supply agreements	2,370	365
Total revenue	84,278	89,149
Operating expenses:		
Cost of goods sold (including related party amounts of $4,781 and $241, respectively)	20,423	977
Research and development (including related party amounts of $2,255 and $2,066, respectively)	13,181	19,580
Selling, general and administrative (including related party amounts of $475 and $465, respectively)	230,122	71,675
Total operating expenses	263,726	92,232
Loss from operations	(179,448)	(3,083)
Other income (expense), net:		
Interest income	10,669	11,369
Interest expense (including related party amounts of $130 and $0, respectively)	(2,599)	—
Total other income, net	8,070	11,369
(Loss) income before income tax (benefit) expense	(171,378)	8,286
Income tax (benefit) expense	(80)	288
Net (loss) income	(171,298)	7,998
Unrealized (losses) gains on available-for-sale securities	(95)	171
Comprehensive (loss) income	$ (171,393)	$ 8,169
Net (loss) income per share:		
Basic	$ (1.74)	$ 0.08
Diluted	$ (1.74)	$ 0.08
Weighted-average shares outstanding used in computing net (loss) income per share:		
Basic	98,566,481	96,936,661
Diluted	98,566,481	102,390,828

The accompanying notes are an integral part of these consolidated financial statements.

ARS Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	96,414,963	$ 10	$ 362,004	$ 49	$ (131,303)	$ 230,760
Exercise of common stock options, release of restricted stock units, and issuance of common stock under the employee stock purchase plan	1,539,209	—	3,016	—	—	3,016
Stock-based compensation	—	—	14,853	—	—	14,853
Net income and comprehensive income	—	—	—	171	7,998	8,169
Balance at December 31, 2024	97,954,172	10	379,873	220	(123,305)	256,798
Exercise of common stock options, release of restricted stock units, and issuance of common stock under the employee stock purchase plan	1,336,754	—	5,681	—	—	5,681
Stock-based compensation	—	—	23,172	—	—	23,172
Net loss and comprehensive loss	—	—	—	(95)	(171,298)	(171,393)
Balance at December 31, 2025	99,290,926	$ 10	$ 408,726	$ 125	$ (294,603)	$ 114,258

The accompanying notes are an integral part of these consolidated financial statements.

ARS Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net (loss) income	$ (171,298)	$ 7,998
Non-cash adjustments to reconcile net (loss) income to net cash used in operating activities:		
Stock-based compensation expense	22,095	14,534
Provision for inventory reserve	2,160	—
Depreciation and amortization expense	1,367	79
Accretion on investments, net of amortization	(5,523)	(7,254)
Other non-cash items	337	—
Changes in operating assets and liabilities:		
Accounts receivable	(17,205)	(8,175)
Inventories	(21,986)	(5,945)
Prepaid expenses and other assets	656	(6,191)
Accounts payable and accrued liabilities	18,881	16,413
Contract liability	(350)	2,089
Net cash and cash equivalents (used in) provided by operating activities	(170,866)	13,548
Cash flows from investing activities:		
Purchases of short-term investments, available-for-sale	(242,033)	(356,038)
Maturities of short-term investments, available-for-sale	307,000	258,000
Payments of milestone obligations under license agreements	(7,860)	(7,500)
Purchases of property and equipment	(339)	(563)
Net cash and cash equivalents provided by (used in) investing activities	56,768	(106,101)
Cash flows from financing activities:		
Proceeds from term loan, net of issuance costs	96,257	—
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	5,681	3,016
Proceeds from milestone obligations met under license agreements recognized as an increase to the financing liability	2,660	69,383
Net cash and cash equivalents provided by financing activities	104,598	72,399
Net decrease in cash and cash equivalents	(9,500)	(20,154)
Cash and cash equivalents at beginning of period	50,817	70,971
Cash and cash equivalents at end of period	$ 41,317	$ 50,817
Supplemental cash flow information:		
Cash paid for interest	$ 2,452	$ —

The accompanying notes are an integral part of these consolidated financial statements.

ARS Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Description of Business

ARS Pharmaceuticals, Inc. ("ARS", "ARS Pharma" or the "Company") is a biopharmaceutical company focused on the commercialization and development of *neffy* (currently identified in the European Union and United Kingdom by the trade name *EURneffy* and in China by the trade name 优敏速) for needle-free intranasal delivery of epinephrine for emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only FDA and European Commission-approved needle-free epinephrine product, and the first new delivery method for epinephrine in more than 35 years.

The Company incorporated in Delaware in January 2016 and is located in San Diego, California. The Company has a wholly owned subsidiary, ARS Pharmaceuticals Operations, Inc., incorporated in Delaware in August 2015, through which it conducts substantially all its operations. ARS Pharmaceuticals Operations, Inc. has a wholly owned subsidiary in Ireland, ARS Pharmaceuticals IRL, Limited, to facilitate the filing of regulatory approval for *neffy* in European countries.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses in most years since its inception and had an accumulated deficit of $294.6 million as of December 31, 2025. The Company had cash, cash equivalents, and short-term investments of $245.0 million as of December 31, 2025 and has not generated positive cash flows from operations in most years. To date, the Company has funded its operations primarily with proceeds from the merger with Silverback Therapeutics, Inc. ("Silverback") in November 2022 (the "Merger"), the private placement of convertible preferred stock, the issuance of common stock, licensing, supply and distribution agreements, debt, and net product sales. The Company's currently available cash, cash equivalents, and short-term investments as of December 31, 2025 are sufficient to meet its anticipated cash requirements for at least the 12 months following the date these financial statements are issued.

From August 5, 2015 (inception) through December 31, 2025, the Company has devoted substantially all of its efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing the Company, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. Management expects operating expenses to increase for the foreseeable future, and there can be no assurance that the Company will achieve profitability in the future, or if achieved, that it will be sustained on a continuing basis.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB"). The Company's financial statements are presented on a consolidated basis, which include the accounts of ARS Pharmaceuticals, Inc., ARS Pharmaceuticals Operations, Inc. and ARS Pharmaceuticals IRL, Limited. All intercompany accounts and transactions have been eliminated in consolidation. The Company's functional and reporting currency is the U.S. dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income in the accompanying consolidated statements of operations and comprehensive (loss) income. All adjustments considered necessary for a fair presentation have been included.

Use of Estimates

The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements are revenue recognized under collaboration agreements and accruals for variable consideration of product revenue. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Fair Value of Financial Instruments

Cash, cash equivalents, and short-term investments are carried at fair value. The carrying amounts of all accounts receivable, prepaid expenses and other current assets, and accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Cash and Cash Equivalents

Cash and cash equivalents include cash readily available in checking, money market mutual funds, and short-term investments with remaining maturities when purchased of 90 days or less. The Company considers all highly liquid investments with remaining maturities when purchased of 90 days or less to be cash equivalents.

Investments

The Company invests excess cash in investment grade fixed income securities. These investments are included in short-term investments on the accompanying consolidated balance sheets, classified as available-for-sale, and reported at fair value with unrealized gains and losses included in accumulated other comprehensive gain, net. Realized gains and losses on the sale of securities are recognized in other income, net.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable includes trade accounts receivable from product sales to customers, partner receivables for reimbursable research and development costs, royalties, license fees, and milestone payments due under the Company's collaboration agreements and supply of *neffy* under the Company's supply agreements. Trade accounts receivables are recorded at wholesale acquisition cost ("WAC"), less purchase price discounts, prompt pay discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company determines the allowance for credit losses for accounts receivable based on each customer's or partner's accounts receivable balance and age, their financial condition, and the general economic environment.

When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists. The allowance for credit losses was immaterial at December 31, 2025, and no allowance for credit losses was deemed necessary at December 31, 2024.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with high credit quality financial institutions.

The Company reviews its financial instruments portfolio on a quarterly basis to determine if any unrealized losses have resulted from a credit loss or other factors. As part of the review, management considers factors such as historical experience, market data, issuer-specific factors, and current economic conditions. This review is subjective, as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may be related to credit issues.

The Company is also subject to credit risk related to its accounts receivable from product sales and revenue under collaboration and supply agreements. *neffy* is distributed primarily through wholesale distributors and pharmacies. These entities are not obligated to purchase any set number of units, and they distribute *neffy* on demand as orders are received. The Company enters into collaboration and supply agreements with pharmaceutical companies that have operations outside the U.S. under which the Company is entitled to receive payments for royalties, license fees, milestone achievements, reimbursable costs for research and development services, and supply of *neffy*. The Company extends credit to its customers and partners in the normal course of business after evaluating their overall financial condition.

Prior to August 2025, the Company operated under the Title Agreement (as defined in the Revenue Recognition policy), under which the Title Agent (as defined in the Revenue Recognition policy) retained all credit and collection risk on product sales to the Company's wholesale distributors and pharmacy customers. As of August 2025, the Company ceased operating under the Title Agreement and now retains all credit and collection risk on product sales.

At December 31, 2025, five customers accounted for 82% of accounts receivable with each individual customer ranging from 12% to 21%. As of December 31, 2024, one customer, the Title Agent, accounted for 93% of accounts receivable. For the years ended December 31, 2025 and 2024, four and six customers accounted for 79% and 89% of the Company's gross product sales, with each individual customer ranging from 15% to 22% and 11% to 23% of the Company's gross product sales, respectively. For the year ended December 31, 2025, three customers accounted for 94% and 90% of revenue under collaboration agreements, with each individual customer ranging from 18% to 43% of the Company's revenue under collaboration agreements. For the year ended December 31, 2024, one customer accounted for 90% of revenue under collaboration agreements. For the years ended December 31, 2025 and 2024, one customer accounted for 86% and 100% of revenue under supply agreements, respectively. To date, the Company has not experienced any credit losses from its trade and partner accounts receivable.

Inventories

Inventories consist of finished goods held for sale and distribution, raw materials and work in process, and include labor and overhead. Inventories are stated at the lower of cost or net realizable value, and are determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company periodically reviews its inventory to identify obsolete, slow-moving, or otherwise unsalable inventories, and establishes allowances for situations in which the cost of the inventory is not expected to be recovered. Such impairment charges, if any, are recorded in cost of goods sold on the accompanying consolidated statements of operations.

The Company capitalizes inventory costs after regulatory approval, when future commercialization is considered probable, and a future economic benefit is expected to be realized. Prior to regulatory approval, the Company records inventory costs as research and development expenses. As such, when regulatory approval is received, this may result in zero-cost inventory that does not have a carrying value. This inventory is available to the Company to utilize for commercial operations as well as ongoing research and development activities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Repair and maintenance costs are charged to expense as incurred.

Intangible Assets

Intangible assets are measured at fair value as of the acquisition date or, in the case of capitalized milestone payments, the date they become due. The evaluation of intangible assets includes assessing the amortization period for which the asset is expected to contribute to the future cash flows of the Company. Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis when the Company is unable to reliably estimate the pattern of cash flow.

Leases

The Company determines the initial classification and measurement of its right-of-use ("ROU") asset and lease liabilities at the lease commencement date and thereafter, if modified. The Company recognizes a ROU asset for its operating leases with lease terms greater than 12 months. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The lease liability is calculated by using the present value of all lease payments, with the present value determined by using the incremental borrowing rate for operating leases determined by using the incremental borrowing rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment as well as a review of peer companies. Variable charges for common area maintenance and other variable costs are recognized as expense as incurred. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in research and development and general and administrative expenses in the accompanying consolidated statements of operations and comprehensive (loss) income.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment, the ROU asset, and intangible assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate, including its eventual residual value. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. The Company has not recognized any impairment losses from inception through December 31, 2025.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The provisions of ASC 606 require the following steps to determine revenue recognition: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product revenue, net

The Company's product, *neffy*, was approved by the FDA in August 2024, and the Company began generating product revenue from sales of *neffy* in September 2024. The Company sells its product to its wholesale distributor and pharmacy customers in the United States. These customers subsequently resell the products to pharmacies and health care providers or dispense products directly to patients.

The Company uses a third-party logistics provider to support the warehousing, distribution, order processing, accounts receivable, and data management. From September 2024 to July 2025, the Company operated under a title model agreement (the "Title Agreement"), pursuant to which an affiliate of third-party logistics provider (the "Title Agent") purchased and took title of the Company's product, then resold it to the Company's customers. Beginning in August 2025, the Company discontinued the Title Agreement and now sells its products directly to customers. In accordance with ASC 606, the Company recognizes revenue at a point in time when the customers obtain control of the Company's products, typically upon delivery.

The Company also enters into consignment agreements with certain pharmacies, under which revenue is recognized when the product is sold to a patient and control transfers from the Company to the patient. Consignment agreements were not subject to the Title Agreement.

Product revenue is recorded at the net transaction price, which includes estimates for variable consideration such as distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, co-payment assistance, and other incentives for certain indirect customers. The Company establishes reserves for these estimates based on amounts earned or expected to be claimed on related sales. Reserves are recorded as a reduction to accounts receivable if payable to a customer or as an accrued expense if payable to a third-party or related to product returns.

The Company uses the expected value method to determine the appropriate amount of variable consideration, considering factors such as contractual and statutory requirements, known market events, industry trends and data, forecasted customer buying and payment patterns, and historical actual data. Estimates are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net (loss) income in the period of adjustment. Variable consideration is included in net product revenue only to the extent it is probable that a significant revenue reversal will not occur in a future period.

Distribution Service Fees. The Company pays distribution service fees to its wholesale distributors. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchased amount. These fees are recorded as other current liabilities on the accompanying consolidated balance sheets.

Commercial Pharmacy Discounts. The Company provides discounts to its pharmacy customers. These discounts are a contractually fixed percentage of WAC and are a direct reduction from the WAC price they are charged. They are calculated at the time of sale based on the amount purchased. These discounts are recorded as contra trade accounts receivable on the accompanying consolidated balance sheets.

Prompt Pay Discounts. The Company incentivizes on time invoice payments through prompt pay discounts. Prompt pay discounts are typically taken by customers, so an estimate of the discount is recorded at the time of sale based on the purchased amount. Prompt pay discount estimates are recorded as contra trade accounts receivable on the accompanying consolidated balance sheets.

Chargebacks. Certain government entities and covered entities (e.g. Veterans Administration, 340B covered entities) can purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and WAC will be charged back to the Company. The Company estimates the amount of chargebacks based on the expected number of claims and the related costs associated with the revenue recognized for product that remains in the distribution channel and any chargeback amounts not invoiced to the Company at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the accompanying consolidated balance sheets.

Rebates. The Company provides commercial rebates to pharmacy benefit managers and managed care organizations and is subject to mandatory discount obligations under the Medicare, Medicaid, and Tricare programs. The rebate amounts for these programs are determined by contractual arrangements or statutory requirements. Rebates are owed after the product has been dispensed to a patient and the Company has been invoiced. The Company estimates the amount of rebates based on the expected number of claims and the related costs associated with the revenue recognized for product that remains in the distribution channel and any rebate amounts for product that has been dispensed to a patient but not invoiced to the Company at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the accompanying consolidated balance sheets.

Co-payment Program. The Company offers co-payment assistance programs to commercially insured patients whose insurance requires a co-payment to be made when filling their prescription. The Company estimates the amount of co-payment assistance based on the expected volume and the average buy down rate associated with the revenue recognized for products that remain in the distribution channel and any co-payment assistance amounts not invoiced to the Company at the end of each reporting period. Co-payment programs estimates are recorded as other current liabilities on the accompanying consolidated balance sheets.

Product Returns. Customers have the right to return damaged product, product that is within six months or less of the labeled expiration date, or product that is past the expiration date by no more than twelve months. *neffy* was commercially launched in September 2024 and due to the limited returns data, the Company uses professional judgment and industry data to estimate returns. As time passes and additional historical sales and returns data becomes available, the Company will update the estimated returns as needed. A reserve for potential product returns is recorded as other current liabilities on the accompanying consolidated balance sheets.

Revenue under collaboration and supply agreements

The Company enters into collaboration agreements to license certain rights to *neffy* to third parties and supply *neffy* for distribution. At contract inception, the Company evaluates whether the collaboration agreement involves joint operating activities in which the parties are active participants and share significant risks and rewards in accordance with ASC Topic 808, *Collaborative Agreements* ("ASC 808"). Arrangements that meet these criteria are accounted for as collaborative arrangements under ASC 808. This assessment is updated over the life of the arrangement as roles and responsibilities change.

For collaboration agreements within the scope of ASC 808 that include multiple components, the Company determines which components are accounted for under ASC 808 and which components represent vendor-customer relationships accounted for under ASC 606. For components accounted for under ASC 808, the Company applies a consistent recognition approach based on applicable accounting guidance or a reasonable policy election. Amounts due from or payable to collaboration partners are presented in the income statement based on the nature of the underlying activity. When the Company is the principal in sales to third parties, revenues, cost of goods sold, and operating expenses are recorded on a gross basis. When the Company is not the principal, its share of results is recorded on a net basis as collaboration revenue or expense.

If the Company concludes that some or all components of the agreement are distinct and represent a transactions with a customer, the Company accounts for those elements of the arrangement in accordance with ASC 606 by applying the five-step model described above.

The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; clinical, regulatory, and/or commercial milestone payments; payment for clinical and commercial supply; and royalties or a transfer price on the net sales of licensed products.

Licenses of Intellectual Property. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, upfront payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license is subject to repurchase by the Company, at its option, control of the license is not considered transferred to the customer, and in such case, the Company would account for the proceeds allocated to such license as either a financing obligation or a lease in accordance with ASC 606. Future amounts received related to the license which is subject to the Company's repurchase, such as royalties or milestone payments, would be accounted for as additional financing proceeds and would increase the financing obligation in the accompanying consolidated balance sheet. The Company would record such financing obligation as revenue when the right to repurchase has lapsed or was exercised.

If the license is not a distinct performance obligation, the Company evaluates the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments. At the inception of each arrangement that includes clinical, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. In making the assessment of the constraint, the Company considers several factors, such as the stage of product development, the risks associated with the remaining activities required to achieve the milestones, as well as whether the achievement of the milestone is outside the control of the Company. Milestone payments that are not within the Company's control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized when the underlying performance obligation has been met.

Transaction Price Allocation. At the inception of each arrangement, the Company identifies its distinct performance obligations and allocates the transaction price to the performance obligations based upon their relative standalone selling prices. Standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. The best evidence of standalone selling price is an observable price of a good or service when sold separately by an entity in similar circumstances to similar customers. Since the Company typically does not have such evidence, the Company estimates standalone selling price so that the amount that is allocated to each performance obligation equals the amount that the Company expects to receive for transferring the promised goods or services. The methods that the Company uses to make such estimates include (1) the adjusted market assessment approach, under which the Company forecasts product sales in the appropriate market, considers probability of commercialization success, and estimates discount rates; and (2) the expected cost of satisfying the performance obligations inclusive of a reasonable margin, also known as the expected cost plus margin approach.

Research and Development Revenues. For arrangements that contain research and development commitments, any arrangement consideration allocated to the research and development work is recognized as the underlying services are performed over the research and development term, if the criteria for over time recognition are met. If the over time recognition criteria are not met, research and development performance obligations are recognized at a point-in-time, when the research and development work is completed.

Clinical and Commercial Supply. Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered customer options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. Revenue from product sales to the Company's collaboration partners is recognized at the point-in-time that the collaboration partner obtains control, which is typically based upon the terms of delivery of the product.

Royalty/Transfer Price Revenues. For arrangements that include sales-based royalties or transfer price, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Cost of Goods Sold

Cost of goods sold primarily consists of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including salaries and related expenses for personnel, stock-based compensation, third-party manufacturing costs, raw material and component costs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, supply agreement fees, and royalties on product sales. Prior to the FDA approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which resulted in zero-cost inventory. As a result, the cost of goods sold related to *neffy* initially reflects a lower average per unit cost of materials, as previously expensed zero-cost inventory is utilized for commercial production and sold to customers.

Research and Development Costs

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, external research and development costs incurred under agreements with contract research organizations, investigative sites and consultants to conduct clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates (including *neffy* prior to FDA approval in August 2024) for clinical trials, and other allocated expenses.

Payments for research and development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying consolidated balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company uses judgments and estimates to determine the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Selling, General and Administrative Costs

Selling, general and administrative costs are expensed in the period incurred. Selling, general and administrative costs primarily consist of marketing-related expenses, salaries and related expenses for personnel, including meals and travel-related expenses incurred by the sales team, stock-based compensation, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax, and other consulting services, and insurance costs.

Advertising

Costs for producing advertising are expensed when incurred. Costs for communicating advertising, such as search engine marketing, banner advertisements, social media advertisements, and print advertisements, are recorded as prepaid expenses and then expensed the first time the advertising takes place. For the years ended December 31, 2025 and 2024, advertising costs were $99.8 million and $12.5 million, respectively.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the statements of operations and expensed as incurred since recoverability of such expenditures is uncertain.

License Fees

Costs incurred to acquire technology licenses and milestone payments made under existing agreements are expensed prior to FDA approval and capitalized after FDA approval when technological feasibility has been achieved, based on management's assessment of the ultimate recoverability and the potential for alternative future use.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company recognizes expense for awards subject to performance-based milestones over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and recognizes forfeitures as they occur. In the event that stock-based awards are granted in contemplation of or shortly before a planned release of material non-public information, and such information is expected to result in a material increase in the share price of the Company's common stock, the Company may consider whether an adjustment to the observable market price is required when estimating the grant date fair value.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the statements of operations in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2025 and 2024, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2025, the Company had no accrued interest or penalties.

Comprehensive (Loss) Income

Comprehensive (loss) income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive (loss) income typically consists of the change in unrealized gains and losses on available-for-sale securities.

Segment Reporting

Operating segments are components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker for purposes of making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)–Improvements to Income Tax Disclosures* ("ASU 2023-09"). The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The Company adopted ASU 2023-09 on a prospective basis effective January 1, 2025. The adoption of ASU 2023-09 resulted in enhanced disclosures as included in Note 14 – Income Taxes.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standards setting bodies that are adopted as of the specified effective date. The Company believes the impact of recently issued standards, other than those noted below, and any issued but not yet effective standards will not have a material impact on our financial statements upon adoption.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40)* ("ASU 2024-03"). The amendments in this update require disclosure, in the notes to the financial statements, of specific expense categories present within expense captions presented on the face of the income statement within continuing operations of public business entities. The amendments in this update are effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any and all prior periods presented in the financial statements. The impact of adoption of this ASU on the Company's disclosures is currently being evaluated.

3. Net (Loss) Income Per Share

Basic net (loss) income per share attributable to common stockholders is calculated by dividing the net (loss) income attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net (loss) income per share attributable to common stockholders is the same as basic net (loss) income per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net (loss) income of the Company. For purposes of this calculation, stock options, warrants, and unvested restricted stock units, are considered to be common stock equivalents but are not included in the calculations of diluted net (loss) income per share for the periods presented as their effect would be antidilutive.

The following table provides the calculation of basic and diluted net (loss) income per share (in thousands, except share and per share information):

	Years Ended December 31,	
	2025	2024
Net (loss) income per share, basic:		
Net (loss) income attributable to common stockholders	$ (171,298)	$ 7,998
Shares used in computation:		
Weighted-average common shares outstanding, basic	98,566,481	96,936,661
Net (loss) income per share, basic	$ (1.74)	$ 0.08
Net (loss) income per share, diluted:		
Net (loss) income attributable to common stockholders	$ (171,298)	$ 7,998
Shares used in computation:		
Weighted-average common shares outstanding, basic	98,566,481	96,936,661
Weighted-average effect of potentially dilutive securities:		
Stock options	—	5,369,025
Shares to be purchased under Employee Stock Purchase Plan	—	47,237
Warrants	—	36,023
Restricted stock units	—	1,882
Weighted-average common shares outstanding, diluted	98,566,481	102,390,828
Net (loss) income per share, diluted	$ (1.74)	$ 0.08

The following securities are excluded from the calculation of weighted-average dilutive common shares because their inclusion would have been anti-dilutive:

	As of December 31,	
	2025	2024
Warrants to purchase common stock	45,456	—
Common stock options outstanding	16,744,639	6,265,948
Restricted stock units outstanding	1,382	—
Total	16,791,477	6,265,948

4. Collaboration, Out-Licensing and Related Agreements

Alfresa Agreement

In March 2020, the Company signed a Letter of Intent ("LOI") with Alfresa Pharma Corporation ("Alfresa") for the right to negotiate a definitive agreement for the exclusive license and sublicensable right to develop, register, import, manufacture and commercialize *neffy* in Japan in exchange for an upfront payment of $2.0 million. In April 2020, the Company entered into a collaboration and license agreement (the "Alfresa Agreement") for the rights pursuant to the LOI. Under the Alfresa Agreement, the Company delivered a license to *neffy* technology, completed a required clinical study, and remains obligated to use commercially reasonable efforts to develop and commercialize *neffy* in Japan. The parties agreed to share the cost of any additional clinical studies required for approval of *neffy* in Japan. Alfresa is solely responsible for regulatory and commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use in Japan. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the Alfresa Agreement will continue until the later of (i) expiration of the last-to-expire patent in Japan; or (ii) 10 years after the commercial sale of *neffy* in Japan.

In December 2025, in connection with the Alfresa Agreement, the Company also entered into a commercial supply agreement (the "Alfresa Supply Agreement") with Alfresa, under which ARS will supply Alfresa's requirements (and Alfresa will purchase from ARS its requirements) for a transfer price in the low-double-digit percentage on net sales of *neffy* in Japan. The Alfresa Supply Agreement is coterminous with the Alfresa Agreement. Either the Company or Alfresa may terminate the Alfresa Supply Agreement in the event of an uncured material breach of the other party. Pursuant to the Alfresa Agreement, at any time, Alfresa may elect to manufacture its own supply of drug product. In the event Alfresa elects to do so, Alfresa is obligated to pay the Company a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value the Company would receive by supplying drug product to Alfresa at the transfer price.

At inception of the Alfresa Agreement, the Company identified the following performance obligations: (i) the license for *neffy*; and (ii) research and development services, both of which have been satisfied. The initial transaction price was $7.0 million, which included the upfront payment of $2.0 million and a regulatory milestone of $5.0 million that was deemed not probable of significant reversal at the inception of the Alfresa Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was allocated to performance obligations based on their estimated stand-alone selling prices.

As of December 31, 2025, the Company has earned an aggregate of $15.0 million for the upfront payment and achievement of regulatory and commercial milestones, and there are no remaining regulatory or commercial milestone payments under the Alfresa Agreement. The Company is also entitled to receive a transfer price in the low double-digit percentage on future net sales of *neffy* in Japan.

For the years ended December 31, 2025 and 2024, the Company earned milestone payments of $2.0 million and $6.0 million for the achievement of regulatory and commercial milestones, respectively, which were recognized as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income.

Recordati Agreement

In September 2020, the Company entered into a License and Supply Agreement (the "Recordati Agreement") with Recordati Ireland, Ltd. ("Recordati") for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize *neffy* in Europe and certain European Free Trade Association, Russia/the Commonwealth of Independent States, Middle East and African countries (the "Recordati Territory"). Under the Recordati Agreement, the Company received an upfront payment of $11.8 million and a regulatory milestone payment of $6.0 million in 2020.

In February 2023, the Company and Recordati entered into a termination agreement (the "Recordati Termination Agreement"), pursuant to which, among other things, the Company and Recordati agreed to terminate the Recordati Agreement. Pursuant to the Recordati Termination Agreement, the Company reacquired all of the Recordati Rights, paid Recordati a one-time upfront payment of €3.0 million ($3.3 million in U.S. dollars), and agreed to pay additional payments upon achievement of certain milestones including: (i) an EMA regulatory milestone payment of €2.0 million, (ii) a milestone payment of €5.0 million upon first commercial sale of *neffy* in the Recordati Territory, and (iii) royalty payments of up to €5.0 million in the aggregate from sales of *neffy* in the Recordati Territory (collectively, the "Recordati Rights").

The Company determined that the Recordati Rights at the time of entering into the Recordati Termination Agreement had no alternative future use and therefore recorded the €3.0 million upfront payment to Recordati as an in-process research and development ("IPR&D") expense presented within research and development expense. The Recordati Termination Agreement ended the Company's performance obligations pursuant to the Recordati Agreement and consequently the existing contract liability of $3.1 million previously received from Recordati was recorded against IPR&D expense presented within research and development expense in the consolidated statements of operations for the year ended December 31, 2023. Accordingly, no revenue has been recognized subsequent to the Recordati Termination Agreement.

In June 2024, the EMA regulatory milestone was met and a €2.0 million ($2.1 million in U.S. dollars) expense was recorded in research and development expense in the accompanying consolidated statements of operations and comprehensive (loss) income. In June 2025, the first commercial sale milestone was met for the first commercial sale of *neffy* in the Recordati Territory. As a result, the Company capitalized the €5.0 million ($5.9 million in U.S. dollars) milestone for the first commercial sale of *neffy* in the Recordati Territory to intangible assets in the accompanying consolidated balance sheets. The intangible assets will be amortized through cost of goods sold in the accompanying consolidated statements of operations and comprehensive (loss) income on a straight-line basis over the estimated life of the intellectual property of 13.5 years.

For the year ended December 31, 2025, the Company recognized $0.5 million in royalty expense from the sale of *neffy* in the Recordati Territory, as cost of goods sold in the accompanying consolidated statements of operations and comprehensive (loss) income.

Pediatrix Agreement

In March 2021, the Company entered into a collaboration and distribution agreement (the "Pediatrix Agreement") with Pediatrix Therapeutics, Inc. ("Pediatrix") for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize *neffy* in the People's Republic of China, Taiwan, Macau, and Hong Kong (the "Pediatrix Territory"). Under the Pediatrix Agreement, Pediatrix is responsible, at its sole cost and expense, for all ongoing development work that is necessary for or otherwise supports regulatory approval in the Pediatrix Territory, including all clinical trials, and activities related to post-approval commitments and commercialization tests. In addition, Pediatrix is responsible for commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use. The Company is responsible for the manufacturing of product for clinical studies as well as commercial supply, all at a negotiated transfer price. Either party may terminate the Pediatrix Agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in the Pediatrix Territory, (ii) the expiration of all regulatory exclusivities that cover *neffy* in the Pediatrix Territory, or (iii) 10 years after the first commercial sale of *neffy* in the Pediatrix Territory.

At inception of the Pediatrix Agreement, the Company identified the performance obligations as: (i) the delivery of the license for *neffy* in the Pediatrix Territory; and (ii) the manufacturing of products for clinical studies and commercial supply, both of which have been satisfied. The license was considered distinct from potential supply obligations, which are effectively options for Pediatrix to purchase future goods and do not provide a material right. The initial transaction price was $3.0 million, which includes the upfront payment received at the inception of the Pediatrix Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was allocated to performance obligations based on their estimated stand-alone selling prices, and variable consideration is reassessed each reporting period.

As of December 31, 2025, the Company has earned an aggregate of $7.0 million for the upfront payment and achievement of regulatory and commercial milestones and is eligible to receive up to $80.0 million in sales-based milestone payments. There are no regulatory or commercial milestones remaining under the Pediatrix Agreement. Since receiving regulatory approval in the Pediatrix Territory, the Company is also entitled to tiered royalties in the low double-digits on future net sales in the Pediatrix Territory and will receive a per unit supply price for commercial supply sold to Pediatrix.

For the year ended December 31, 2025, the Company earned a milestone payment of $4.0 million for the achievement of regulatory and commercial milestones, which was recognized as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income.

Seqirus Agreement

In March 2024, the Company entered into a license and distribution (the "Seqirus Agreement") with Seqirus Pty Ltd. ("Seqirus"), which was amended in December 2025, for the exclusive license to commercialize *neffy* in Australia and New Zealand (the "Seqirus Territory"). Under the Seqirus Agreement, the Company is responsible for the transfer of know-how, which includes regulatory materials, regulatory data, and commercialization data, and also for the manufacturing of product for commercial supply which is available to Seqirus at a negotiated price. Seqirus is solely responsible for all regulatory and commercialization activities in the Seqirus Territory. Either party may terminate the Seqirus Agreement for certain breaches. Unless terminated earlier by either or both parties, the initial term of the Seqirus Agreement is 15 years from the first commercial sale of *neffy* in the Seqirus Territory. The Seqirus Agreement will automatically renew for two-year periods unless either party gives a notice to terminate at least 12 months prior to the end of the initial or any renewal term.

At inception of the Seqirus Agreement, the Company identified a single performance obligation: the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how, which has been satisfied. The license and know-how were considered distinct from potential supply obligations, which are effectively options for Seqirus to purchase commercial supply and do not represent a material right. The initial transaction price was $0.5 million, which includes the upfront payment received at the inception of the Seqirus Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was allocated to performance obligations based on their estimated stand-alone selling prices, and variable consideration is reassessed each reporting period.

As of December 31, 2025, the Company has earned an aggregate of $2.6 million for the upfront payment and achievement of regulatory and commercial milestones and is eligible to receive up to $2.3 million in remaining regulatory and commercial milestones. Since receiving approval in the Seqirus Territory, the Company is also entitled to receive a per unit supply price for commercial supply sold to Seqirus.

For the years ended December 31, 2025 and 2024, the Company earned milestone payments of $0.6 million and $2.0 million for the achievement of regulatory and commercial milestones, respectively, which was recognized as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income.

ALK Collaboration Agreement

In November 2024, the Company entered into a collaboration, license and distribution agreement (the "ALK Collaboration Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the ALK Collaboration Agreement, the Company granted to ALK a worldwide (other than the United States, Japan, mainland China, Hong Kong, Taiwan, Macau, Australia and New Zealand) ("ALK Territory"), exclusive license under certain of the Company's patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including *EURneffy* (the trade name for *neffy* in the European Union) (epinephrine nasal spray) ("Products"), for all human uses, including the immediate or emergency treatment of allergic reactions (including Type I) and anaphylaxis and urticaria, and other future indications as agreed by the parties. If the Company develops any new intranasally administered product that contains epinephrine and files a new drug application in the United States for such product ("New Product"), upon ALK's request such New Product will be included as a Product under the ALK Collaboration Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Collaboration Agreement, the Company is obligated to transfer to ALK the existing marketing authorizations for the Products in the ALK Territory. The Company is also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in the ALK Territory, and will transfer such regulatory approvals to ALK. ALK is obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for Products through the European Commission and within specified countries within the ALK Territory. Following such approval for a Product in each indication within specified countries within the ALK Territory, ALK is obligated to use commercially reasonable efforts to commercialize such Product in such indication in such countries and to achieve the first commercial sale of a Product in certain countries in accordance with a timeline specified in the ALK Collaboration Agreement.

Under the ALK Collaboration Agreement, ALK made a $145.0 million upfront payment to the Company in November 2024, and the Company earned $5.0 million for the first commercial sale of *EURneffy* in the ALK Territory in June 2025. The Company is eligible to receive regulatory and commercialization milestones of up to $15.0 million and sales-based milestones of up to $300.0 million, provided that $55.0 million of such sales-based milestones are contingent upon the Company obtaining regulatory approval for the Product in Canada by a specified time. The Company is entitled to receive tiered royalty payments on net sales in the mid- to high-teens, subject to certain standard reductions and offsets. Royalties will be payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the licensed patents covering such Product in such country, 15 years from first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

The contract will expire upon the expiration of the last to expire royalty term for all Products in the ALK Territory, unless terminated earlier. Either the Company or ALK may terminate the ALK Collaboration Agreement in the case of the other party's insolvency or in the event of an uncured material breach of the other party, except that the Company may not terminate the ALK Collaboration Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Collaboration Agreement for convenience upon 12 months' prior written notice or for a safety or regulatory concern. The Company may terminate the ALK Collaboration Agreement in the event ALK makes certain challenges to certain of the Company's patents. Prior to a change of control and outside of a set period of time after which the Company commences change of control negotiations, the Company may terminate the ALK Collaboration Agreement with respect to all countries in the European Economic Area ("EEA") upon prior written notice to ALK and payment of a termination fee that is the higher of an agreed mid-nine digit amount and the fair market value of the Products business in the EEA at the time of such termination (the "Repurchase Option"). The Company may also terminate the ALK Collaboration Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

In connection with the ALK Collaboration Agreement, the Company and ALK also entered into a commercial supply agreement (the "ALK Supply Agreement") in November 2024, under which the Company will supply ALK's requirements (and ALK will purchase from the Company its requirements) of Products for five years for a specified supply price, after which ALK may elect to transition to itself or its contract manufacturer the manufacture and supply of Products. The contract term for the ALK Supply Agreement is coterminous with the ALK Collaboration Agreement. Either the Company or ALK may terminate the ALK Supply Agreement in the event of an uncured material breach of the other party.

Accounting Assessment

The Company concluded that the ALK Collaboration Agreement and the ALK Supply Agreement qualify as a contract with a customer under ASC 606 as one combined arrangement. The Company identified the following performance obligations: (i) exclusive commercialization license in the European Economic Area (the "EEA License"); (ii) exclusive commercialization license in the rest of the ALK Territory (the "ROW License") and; (iii) five separate development and regulatory services performance obligations. The Company also evaluated the (i) promise to add a New Product and new indications to the ALK Collaboration Agreement, and (ii) the promises under the ALK Supply Agreement, and concluded that these promises did not meet the definition of a performance obligation nor did these promises convey a material right to ALK.

The Company determined that the non-refundable upfront payment of $145.0 million is the estimated transaction price at contract inception. The outstanding regulatory milestone payments (totaling $15.0 million) were fully constrained at contract inception and as of December 31, 2025 as a result of the uncertainty of whether any of the milestones will be achieved. In making the assessment of the constraint utilizing the most likely amount method, the Company considered the stage of development, and the risks associated with the remaining development required to achieve the milestones, as well as whether the achievement of the milestone is outside the control of the Company or ALK. The Company determined that the commercial milestone ($5.0 million) and the sales-based milestones and royalties will be recognized on the later of when the related sales occur or when control of the associated license has been transferred, as the Company determined that such sales-based consideration relates predominantly to the licenses granted to ALK. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and will include regulatory milestones in the transaction price if it is probable that a significant revenue reversal will not occur in future periods.

At contract inception, the Company determined the estimated standalone selling prices for each performance obligation in order to allocate the transaction price among the performance obligations. The standalone selling price for the licenses was estimated using the adjusted market assessment approach. Under this method, the Company forecasted future cash flows expected in the ALK Territory, the probability of commercialization success, and a market discount rate. To estimate the standalone selling prices of the development and regulatory services, the Company forecasted its expected costs of satisfying each performance obligation inclusive of an appropriate margin for that service.

The Company allocated the total transaction price to each performance obligation on a relative standalone selling price basis and determined whether revenue should be recognized at a point in time or over time. The Company allocated $69.4 million to the EEA License performance obligation; $73.1 million to the ROW License performance obligation; and $2.6 million to the development and regulatory services performance obligations.

In November 2024, the ROW License was transferred to ALK for immediate use and benefit from intellectual property, and the related revenue was recognized at a point in time. Accordingly, the Company recognized revenue under collaboration agreements of $73.1 million in the accompanying consolidated statements of operations and comprehensive (loss) income during the year ended December 31, 2024. In June 2025, ALK completed the first commercial sale of *EURneffy* in the ALK Territory and earned a $5.0 million commercial milestone, of which $2.6 million was allocated to the ROW License and recognized as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income. For the year ended December 31, 2025, the Company recognized $0.2 million of sales-based royalties for product sales in the ALK Territory, excluding the EEA Territory, as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income.

As of December 31, 2025, the Company has earned an aggregate of $150.0 million in milestone payments for the upfront payment and achievement of regulatory and commercial milestones, of which $72.1 million has been allocated to the EEA License and is accounted for as a financing liability. The Company is eligible to receive remaining regulatory milestone payments of up to $15.0 million and sales-based milestone payments of up to $300.0 million, of which $55.0 million in sales-based milestones are contingent upon regulatory approval of the Product in Canada by a specified date, as well as tiered royalties on net sales in the mid- to high-teens, subject to customary reductions and offsets. Royalties are payable on a Product-by-Product and country-by-country basis until the latest of: (i) the expiration of the licensed patents covering such Product in such country; (ii) 15 years from the first commercial sale of such Product in such country; or (iii) expiration of regulatory exclusivity for such Product in such country. The Company is also eligible to receive a per unit supply price for commercial supply sold to ALK under the ALK Supply Agreement.

Contract Liability

The development and regulatory services performance obligations under the ALK Collaboration Agreement each represent a separate performance obligation. The development and regulatory services, which are transferred to the customer over time, were provided to ALK beginning at the inception of the ALK Collaboration Agreement and are expected to continue through 2028. Development and regulatory service performance obligations were initially recorded as contract liabilities, and revenue earned under these performance obligations is recognized as services are performed based on the costs incurred through the end of each reporting period as a percentage of the estimated total costs to be incurred for these performance obligations. For the year ended December 31, 2025, the Company recognized $0.3 million of revenue related to the development and regulatory services performance obligations, which is recorded as revenue under collaboration agreements in the accompanying consolidated statements of operations and comprehensive (loss) income.

A reconciliation of the contract liability from the ALK Collaboration Agreement is as follows (in thousands):

Balance at December 31, 2024	$	2,089
Revenue recognized under the ALK Collaboration Agreement		(350)
Balance at December 31, 2025	$	1,739

Financing Liability

As discussed above, the Company retains a substantive Repurchase Option for the EEA License, which prevents control from transferring to ALK under ASC 606. As a result, the consideration allocated to the EEA License is accounted for as a financing liability because the repurchase price exceeds the original selling price. Accordingly, in November 2024, the $69.4 million allocated to the EEA License was recorded as a financing liability and will remain outstanding until the Repurchase Option lapses or is exercised. Commercial and sales-based milestones allocated to the EEA License are recognized as increases to the financing liability when earned.

A reconciliation of the Financing Liability from the ALK Collaboration Agreement is as follows (in thousands):

Balance at December 31, 2024	$	69,383
Commercial milestone allocated to the EEA License		2,435
Sales-based royalties earned under the EEA License		322
Balance at December 31, 2025	$	72,140

ALK Co-Promotion Agreement

In May 2025, the Company and ALK-Abelló, Inc. (“ALK U.S.”, an affiliate of ALK) entered into a co-promotion agreement, which was subsequently amended in October 2025 and March 2026 (the “ALK Co-Promotion Agreement”), to co-promote *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. Accordingly, the Company granted ALK U.S. a non-exclusive, royalty-free license to use the *neffy* trademarks and copyrights and the ARS house marks in the U.S. solely in connection with promoting *neffy* pursuant to the terms of the ALK Co-Promotion Agreement.

Under the ALK Co-Promotion Agreement, ALK U.S. commenced its promotion activities in May 2025 and is obligated to meet specified ramp-up milestones and minimum detail requirements using sales representatives that meet specific qualifications. In addition, during the term of the ALK Co-Promotion Agreement and for 180 days thereafter, ALK U.S. will not market, sell or manufacture any injection product containing epinephrine in the U.S.

The Company is the principal of all sales transactions of *neffy* in the U.S. and, subject to the terms of the ALK Co-Promotion Agreement, continues to have sole responsibility for all U.S. commercialization activities, including marketing, medical affairs, market access, production, distribution, pharmacovigilance, quality and safety.

The Company will pay ALK U.S. a base fee to compensate ALK U.S. for its promotion activities. Payments to ALK U.S. for the services performed during the first year of the arrangement will be deferred and paid in the second year of the arrangement. In addition to the base fee, ALK U.S. will be eligible to receive performance-based bonus payments from the Company starting in the second year of the arrangement equal to 30% of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified initial market share threshold in year two or a 50% market share threshold during years three and four of the arrangement.

The ALK Co-Promotion Agreement expires on the fourth anniversary of the commencement of promotion activities thereunder. Either party may terminate the ALK Co-Promotion Agreement in the event of an uncured material breach of the other party or for either party's change of control. The Company may terminate the ALK Co-Promotion Agreement in the case of ALK U.S.'s insolvency, if ALK U.S. fails to meet specified ramp-up timelines, or if ALK U.S. markets, sells or commercializes any non-injection product containing epinephrine in the U.S. After the first six months, the Company may terminate the ALK Co-Promotion Agreement if minimum detail requirements are not met for a consecutive three-month period. After the first year, the Company may terminate the ALK Co-Promotion agreement for any reason or no reason for a fee (as described below). After the first year, ALK U.S. may terminate the ALK Co-Promotion Agreement for any reason or no reason, and the Company may terminate the agreement in the event ALK U.S. restructures its sales force.

Upon termination of the ALK Co-Promotion Agreement by the Company for convenience, so long as ALK U.S. has met specified performance thresholds during the term, the Company is obligated to pay ALK U.S. a specified mid-to-low double-digit percentage of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified mid-quartile market share threshold that increases over time up to 50% for a specified period after termination, which period decreases in duration the later that the termination occurs. Upon termination of the ALK Co-Promotion Agreement by the Company in connection with a change of control of the Company, the Company is obligated to pay ALK U.S. a one-time mid-seven digit to low eight-digit termination fee in an amount that increases the later that the termination occurs.

The Company evaluated the terms of the ALK Co-Promotion Agreement and concluded it represents a vendor arrangement with ALK U.S. As a result, during the year ended December 31, 2025, the Company recognized $6.6 million in ALK-related selling, general, and administrative expense in the accompanying consolidated statements of operations and comprehensive (loss) income, and the corresponding liability is included in accounts payable and accrued liabilities and other accrued liabilities in the accompanying consolidated balance sheet as of December 31, 2025.

5. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 26,815	$ 4,674
Work in process	288	19
Finished goods	4,319	5,826
Total inventories, net	$ 31,422	$ 10,519
Reported as:		
Inventories	$ 8,369	$ 5,212
Inventories, noncurrent	23,053	5,307
Total inventories, net	$ 31,422	$ 10,519

Prior to FDA approval in August 2024, costs incurred for the manufacturing of *neffy* were recorded as research and development expenses, which upon approval resulted in zero-cost inventory. The Company held $6.7 million and $11.7 million in zero-cost inventory as of December 31, 2025 and 2024, respectively, none of which was determined to be obsolete as of each period end. The Company expects to fully utilize its zero-cost inventory in future periods.

6. Intangible Assets

Intangible assets, net, all of which are finite-lived, consisted of the following (in thousands):

	December 31,	
	2025	2024
Capitalized milestone payments[(1)]	$ 15,360	$ 7,500
Less accumulated amortization	(908)	(129)
Total	$ 14,452	$ 7,371

[(1)] As described in Note 4 – Collaboration, Out-Licensing and Related Agreements and Note 11 – In-Licensing and Supply, capitalized milestone payments were recognized from the Recordati Termination Agreement and Aegis License Agreement, respectively.

The amortization expense for the years ended December 31, 2025 and 2024 was $0.8 million and $0.1 million, respectively.

The weighted-average amortization period of intangible assets is 13.1 years. As of December 31, 2025, estimated future amortization expense for capitalized intangible assets for the next five years is as follows (in thousands):

Year Ended December 31,	Amount
2026	$ 1,105
2027	1,105
2028	1,105
2029	1,105
2030	1,105
Total	$ 5,525

7. Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 – Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and

Level 3 – Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The following table identifies the Company's assets that were measured at fair value on a recurring basis (in thousands):

	Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2025					
Cash and cash equivalents - Money market mutual funds	1	$ 41,030	$ —	$ —	$ 41,030
Short-term investments - U.S. Treasury securities	2	203,544	134	(9)	203,669
Total		$ 244,574	$ 134	$ (9)	$ 244,699
December 31, 2024					
Cash and cash equivalents - Money market mutual funds	1	$ 6,506	$ —	$ —	$ 6,506
Cash and cash equivalents - U.S. Treasury securities	2	42,382	5	—	42,387
Short-term investments - U.S. Treasury securities	2	262,990	223	(8)	263,205
Total		$ 311,878	$ 228	$ (8)	$ 312,098

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the periods presented. During the years ended December 31, 2025 and 2024, the Company purchased $242.0 million and $356.0 million in short-term investments, respectively, and there were $307.0 million and $258.0 million in maturities of short-term investments, respectively.

The Company's short-term investments portfolio contains investments in U.S. Treasury securities that have an effective maturity date that is less than one year from the respective balance sheet date. The Company's money market mutual fund holdings are highly liquid and invest primarily in cash and U.S. Treasury securities.

There was $0.1 million in net unrealized losses and $0.2 million in net unrealized gains on available-for-sale securities for the years ended December 31, 2025 and 2024, respectively. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of December 31, 2025 were primarily attributable to current economic and market conditions and not credit risk. As of December 31, 2025 and 2024, no allowance for credit losses was recorded for available-for-sale securities. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell any investments prior to recovery of its amortized cost basis, which is expected to be at maturity.

Accrued interest receivable on the Company's available-for-sale securities was $1.0 million at both December 31, 2025 and 2024 and is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

The Company's Term Loan (as defined in Note 9 – Term Loans) are carried at historical cost, adjusted for the debt discount and debt issuance costs, and are not required to be carried at fair value. The fair value of the Term Loan approximates fair value due to the use of current market rates that are repriced frequently.

As of December 31, 2025 and 2024, the Company did not have any liabilities that were measured at fair value on a recurring basis.

8. Balance Sheet Details

Accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accounts payable	$ 5,725	$ 9,870
Accrued gross-to-net liabilities	14,162	2,179
Accrued marketing related expenses	6,880	1,855
Accrued inventory	3,439	4,255
Accrued cost of goods sold	3,165	617
Other	4,577	4,065
Total	$ 37,948	$ 22,841

9. Term Loans

On September 29, 2025 (the "Closing Date"), the Company and certain direct and indirect subsidiaries of the Company who may become a party thereto from time to time, as guarantors (the "Guarantors"), and ARS Pharmaceuticals Operations, Inc., as the borrower (the "Borrower" and, collectively with the Guarantors, the "Credit Parties"), entered into a credit agreement (the "Credit Agreement") with RA Capital Agency Services, LLC (as the "Administrative Agent" and as the "Collateral Agent"), and affiliates of OMERS Administration Corporation and RA Capital Management, L.P., as lenders, and such other lenders who may become a party thereto from time to time (the "Lenders"), providing for an aggregate principal amount of up to $250.0 million of term loans from the Lenders to the Borrower (the "Term Loans"). The Term Loans will mature on September 29, 2030.

Pursuant to the terms of the Credit Agreement, the Term Loans may be advanced in four tranches. The first tranche (the "Term A Loan") was advanced in the principal amount of $100.0 million on the Closing Date. The second tranche (the "Term B Loan") in a principal amount of $25.0 million may be advanced at the Borrower's election during the period commencing on the six-month anniversary of the Closing Date and ending no later than the one-year anniversary of the Closing Date, subject to customary conditions. The third tranche (the "Term C Loan" and collectively with the Term B Loan, the "Delayed Draw Term Loans") in a principal amount of $25.0 million may be advanced at the Borrower's election during the period commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the Company achieving trailing 12-month ("TTM") net revenues for *neffy* of at least $100.0 million and customary conditions. The fourth tranche (the "Term D Loan") of up to $100.0 million is uncommitted and may be advanced at the Borrower's election, subject to the consent of all of the Term D Lenders and customary conditions. The total outstanding principal is due at maturity on September 29, 2030. The Term Loans require interest-only payments and do not require scheduled principal payments prior to maturity. The Borrower may prepay principal on the Term Loans, in whole or in part, subject to a prepayment premium and an exit fee.

The Company received $100.0 million in gross cash proceeds from Term A Loan on the Closing Date, less the upfront fees taken in the form of an original issue discount and third-party fees totaling $3.8 million. The debt discount and the debt issuance costs are recorded net of the Term A Loan balance and are amortized to interest expense over the term of the debt using the effective interest rate method.

The Term Loans will initially bear interest at a per annum rate of 5.50% plus the greater of (i) the three-month forward-looking term SOFR or (ii) 3.00%, which interest rate may be reduced by 25 to 50 basis points based on achieving certain TTM net revenue milestones. The Credit Agreement provides for interest-only payments on a quarterly basis until maturity. At Borrower's election and subject to certain conditions, 100% of accrued interest in the first two years, and 50% of accrued interest in the last three years, may be paid-in-kind, in which case the applicable interest rate for the Term Loans shall increase by 1.00% per annum for the portion of such Term Loans that is paid-in-kind. The weighted average interest rate for the year ended December 31, 2025 was 9.49% per annum.

The obligations of the Borrower under the Credit Agreement are guaranteed on a full and unconditional basis by the Company and the Guarantors and are secured by substantially all of the respective Credit Parties' tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

The Credit Agreement contains customary representations and warranties, covenants and events of default, including a requirement for the Borrower to maintain at all times, a minimum specified amount of unrestricted cash in deposit accounts. The Credit Agreement also includes customary events of default, including, among others, payment defaults, material misrepresentations, breaches of covenants following any applicable cure period, cross defaults with certain other indebtedness or material agreements, bankruptcy and insolvency events, judgment defaults, the occurrence of certain events that could reasonably be expected to have a "material adverse effect," and the occurrence of a change in control (as defined in the Credit Agreement). The occurrence of an event of default could result in the acceleration of the Company's obligations under the Credit Agreement and the exercise by the Administrative Agent of other rights and remedies provided for under the Credit Agreement.

The Administrative Agent and Collateral Agent, as well as a Lender, are affiliates of RA Capital Management, L.P. ("RA Capital"). Affiliates of RA Capital collectively hold in excess of 10% of the Company's outstanding common stock and are currently the Company's largest stockholder. One of the Company's board members is a controlling person of RA Capital's general partner. The Lender affiliated with RA Capital holds a portion of Term Loans in the principal amount of $5.0 million.

The following table summarizes the composition of the Term Loans as reflected on the accompanying consolidated balance sheet (in thousands):

	December 31, 2025
Gross proceeds	$ 100,000
Unamortized debt discount and debt issuance costs	(3,626)
Total	$ 96,374

10. Commitments and Contingencies

Contingencies

From time to time, the Company may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business.

On July 24, 2023, Aera A/S, an IP consultancy firm in Denmark representing an unidentified opponent, filed a notice of opposition with the European Patent Office (the "EPO") in respect of EP 3678649 (the "EP '649 Patent"), which is a patent directed to a nasal spray formulation of epinephrine, and uses thereof. Oral proceedings took place on October 7, 2025, and the Opposition Division (the "OD") of the EPO upheld the validity of all claims in the EP '649 Patent. The OD issued a written decision on November 4, 2025. The opponent filed a notice of appeal on December 17, 2025. The deadline to file a grounds of appeal is March 4, 2026.

On March 25, 2025, AptarGroup, Inc. ("AptarGroup") and Aptar France SAS (collectively, "Aptar") filed a suit against ARS Pharmaceuticals, Inc. and ARS Pharmaceuticals Operations, Inc. in the United States District Court for the Southern District of New York. Aptar alleges the Company violated the Defend Trade Secrets Act (18 USC § 1836), misappropriated trade secrets under New York state law, and committed various breaches of contract. The complaint was served to the Company, and the Company filed a motion to dismiss on June 12, 2025. Aptar subsequently filed opposition to the motion to dismiss on July 28, 2025. The Company intends to vigorously defend itself in this matter. On September 29, 2025, the Company filed a lawsuit against AptarGroup in the U.S. District Court for the Southern District of California, alleging that AptarGroup violated federal antitrust law in connection with its sale of certain constituent parts of *neffy*. On December 16, 2025, Aptar moved to dismiss or in the alternative transfer ARS's lawsuit to the Southern District of New York. On January 27, 2026, ARS filed an opposition to Aptar's motion to dismiss, and Aptar filed a reply brief on February 27, 2026.

On August 29, 2025, the Company filed a lawsuit against Lupin, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos.: 10,576,156, 10,682,414, 11,173,209, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838 and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. The lawsuit follows a Paragraph IV certification notice letter received from Lupin on August 13, 2025, advising the Company that Lupin submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture and sell a generic version of the Company's product *neffy*© 2 mg (epinephrine nasal spray) prior to the expiration of the patents referenced above.

On February 26, 2026, the Company filed a lawsuit against Lupin, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos.: 10,576,156, 10,682,414, 11,173,209, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838 and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. The lawsuit follows a Paragraph IV certification notice letter received from Lupin on February 6, 2026, advising the Company that Lupin submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture and sell a generic version of the Company's product *neffy*© 1 mg (epinephrine nasal spray) prior to the expiration of the patents referenced above.

Regardless of the outcome, involvement in legal proceedings may have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors. The Company cannot predict the outcome of these suits, and failure by the Company to obtain favorable resolutions could have a material adverse effect on its business, results of operations, and financial condition. The Company's chances of success on the merits of these suits are still uncertain and any possible loss or range of loss cannot be reasonably estimated and as such the Company has not recorded a liability as of December 31, 2025.

Except as described above, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or other body pending or, to the knowledge of the Company's executive officers, threatened against or affecting the Company, the Company's common stock, any of its subsidiaries or its subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Unconditional Purchase Obligations and Commitments

Unconditional purchase obligations and commitments are defined as agreements to purchase goods or services that are enforceable and legally binding (non-cancelable, or cancelable only in certain circumstances). In the normal course of business, the Company enters into arrangements with suppliers, manufacturers, and various other companies that supply goods or services. These arrangements can include unconditional purchase obligations and commitments. Unconditional purchase obligations and commitments are satisfied as services are performed or upon receipt of the related goods.

The total remaining unconditional purchase obligations related to the supply of raw materials is $55.3 million as of December 31, 2025. Purchase obligations by year are as follows: 2026 ($9.1 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035. During the years ended December 31, 2025 and 2024, the Company made $8.0 million and $0.2 million in payments under these agreements, respectively.

The total remaining commitments related to the ALK Co-Promotion Agreement is $20.2 million as of December 31, 2025. Commitments by year are as follows: 2026 ($8.3 million), 2027 ($5.2 million), 2028 ($4.7 million), and 2029 ($2.0 million). No payments were made under this agreement during the years ended December 31, 2025 and 2024.

The total remaining commitment related to a corporate sponsorship agreement with Food Allergy Research and Education, Inc. is $6.0 million as of December 31, 2025. Commitments by year are as follows: 2026 ($5.0 million) and 2027 ($1.0 million). During the years ended December 31, 2025 and 2024, the Company made $6.0 million and $2.0 million in payments under this agreement, respectively.

The amounts above do not represent the entire anticipated expenditure in the future but represent only those items for which the Company is contractually obligated. For this reason, these amounts do not provide an indication of the Company's expected future cash outflows related to purchases and commitments.

11. In-Licensing and Supply

License Agreement with Aegis

In June 2018, the Company entered into a License Agreement (the "Aegis Agreement") with Aegis Therapeutics, LLC ("Aegis"). Under the Aegis Agreement, the Company licensed the exclusive, worldwide, royalty-bearing, sublicensable, rights to certain proprietary Aegis technology, patent rights and know-how to develop and commercialize epinephrine products. The Company utilizes this technology in its sole commercial product, *neffy*. As consideration for the license, the Company paid an upfront license fee of $50,000, which was recorded in research and development expenses in the consolidated statements of operations for the year ended December 31, 2018.

The Company is required to make aggregate milestone payments of up to $20.0 million upon achievement of certain regulatory and commercial milestones. Regulatory milestone payments under the Aegis Agreement are recorded upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. Prior to the FDA approval of *neffy* in August 2024, regulatory milestone payments were recorded as research and development expenses in the accompanying consolidated statements of operations. The Company made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019, and a $1.0 million milestone payment to Aegis upon the FDA's acceptance of the Company's new drug application submission for *neffy*, which occurred in the third quarter of 2022. As of December 31, 2025, the Company's remaining milestone payment obligation is $9.0 million upon the achievement of certain annual net sales.

Since the FDA approval of *neffy* in August 2024, regulatory and commercial milestone payments have been capitalized as intangible assets in the accompanying consolidated balance sheets upon achievement. Amortization expense for capitalized milestone payments has been recognized as cost of goods sold in the accompanying consolidated statements of operations and comprehensive (loss) income on a straight-line basis over the estimated life of the intellectual property. In August and September 2024, milestone payments of $2.5 million and $5.0 million were recognized for achieving FDA approval of *neffy* and the first commercial sale of *neffy,* respectively. In September 2025, a milestone payment of $2.0 million milestone was recognized for achieving certain annual net product sales of *neffy*.

The Company also pays royalties based on a mid-single-digit percentage of net product sales on its or its sublicensees' net sales of the Licensed Products (as defined in the Aegis Agreement) on a product-by-product basis. Royalties are recorded to cost of goods sold in the period the related product revenue is recognized.

In November 2024, OrbiMed Advisors LLC ("OrbiMed") entered into an agreement with Aegis, to purchase the rights, royalty interests, and related sales milestone payments on net product sales of *neffy*. The Company will make all future payments under the Aegis Agreement to an affiliate of OrbiMed. As described in Note 15 – Related Party Transactions, a member of the Company's Board of Directors is a General Partner at OrbiMed.

The Company is responsible for reimbursing Aegis for certain patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. For the year ended December 31, 2025, the Company incurred legal patent expenses of $0.3 million under the Aegis Agreement. No legal patent expenses were incurred during the year ended December 31, 2024.

The Company may terminate the Aegis Agreement with 30 days written notice or either party may terminate the Aegis Agreement for certain breaches of the Aegis Agreement. Unless terminated earlier by either or both parties, the term of the Aegis Agreement will continue until the final expiration of all royalty obligations under the Aegis Agreement.

In conjunction with the Aegis Agreement, the Company also entered into a supply agreement (the "Aegis Supply Agreement") with Aegis that allows the Company to purchase materials for preclinical, development and commercial use at predetermined prices. The Company may elect to have Aegis supply minimum quantities but there are no minimum or maximum purchase obligations under the Aegis Supply Agreement unless this election is made. The parties may terminate the Aegis Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Aegis Supply Agreement in the event of certain breaches of the Aegis Supply Agreement or upon the earlier of the expiration or termination of the Aegis Agreement or June 2028. The Aegis Supply Agreement term may be extended by mutual written agreement.

Manufacturing Agreement with Renaissance

In September 2020, the Company entered into a manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"), which was subsequently amended in July 2023, September 2024, and July 2025 (the "Renaissance Agreement"). Pursuant to the Renaissance Agreement, Renaissance agreed to manufacture for, and provide to the Company, *neffy* nasal unit dose sprays ("Renaissance Products"). The Company is obligated to provide Renaissance with certain supplies to manufacture the Renaissance Products and to purchase from Renaissance a mid-double-digit percentage of the Company's annual aggregate Renaissance Product requirements in the EU, and a high double-digit percentage of the Company's annual aggregate Renaissance Product requirements in the U.S. The Renaissance Agreement contains conventional commercial pharmaceutical manufacturing provisions including certain minimum purchase amounts to be determined in the future based on forecast needs and minimum batch size projections. The Company may also request Renaissance to perform certain services related to the Renaissance Product, for which the Company will pay reasonable compensation to Renaissance.

Pursuant to the amendment in September 2024, the amended initial term of the Renaissance Agreement commenced on September 17, 2024, and will terminate on (a) December 31, 2029 for Renaissance Product designated for commercial sale in the U.S. ("U.S. Initial Term"), and (b) December 31, 2030 for Renaissance Product designated for commercial sale in the EU ("EU Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and EU Initial Term automatically renew for successive two-year terms ("Renewal Term"). Either party may elect not to renew the U.S. Renewal Term and/or the EU Renewal Term by providing the requisite prior notice to the other party, with the initial terms automatically renewing for successive two-year terms, unless either party gives notice pursuant to the Renaissance Agreement. Either party may terminate the Renaissance Agreement (1) for uncured material breach of the other party, (2) upon notice for insolvency-related events of the other party that are not discharged within a defined time period, (3) on a product-by-product basis if the manufacture, distribution or sale would materially contravene any applicable law, (4) by providing the requisite notice if (a) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before a specified date, (b) the authorization and approval representing more than a certain number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (c) the Company decided in its sole discretion to cease commercializing the Renaissance Product in the U.S., (5) in the case of a force majeure event that continues for six months or more, or (6) a violation by the other party of trade control or anti-corruption laws.

12. Common Stock and Stockholders' Equity

Authorized Shares

The Company's current Amended and Restated Certificate of Incorporation authorizes 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	December 31,	
	2025	2024
Common stock options granted and outstanding	16,744,639	15,161,180
Restricted stock units granted and outstanding	1,382	2,763
Common stock reserved for future awards or option grants	8,085,186	5,905,773
Common stock reserved for future employee stock purchase plan issuances	2,722,563	2,223,100
Warrants to purchase common stock	45,456	45,456
Total	27,599,226	23,338,272

Equity Offerings

In January 2025, the Company filed an automatic shelf registration statement on Form S-3ASR with the Securities and Exchange Commission which became effective upon filing (the "Shelf Registration Statement"). The Shelf Registration Statement allows the Company, from time to time, to offer and sell any combination of shares of the Company's common stock and preferred stock, various series of debt securities, and/or warrants to purchase any of such securities, either individually or in combination with other securities, in one or more offerings. The Company simultaneously entered into a Controlled Equity Offering^{SM} sales agreement (the "Equity Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to offer, sell and issue shares of the Company's common stock from time to time through Cantor acting as sales agent and up to a maximum aggregate offering price of $200.0 million. As of December 31, 2025, no securities have been sold pursuant to the Shelf Registration Statement or Equity Sales Agreement.

13. Stock-Based Compensation

Stock-based compensation expense recognized for all equity awards has been reported in the accompanying consolidated statements of operations and comprehensive (loss) income as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development expense	$ 2,660	$ 2,955
Selling, general and administrative expense	19,435	11,579
Total	$ 22,095	$ 14,534

During the years ended December 31, 2025 and 2024, $1.1 million and $0.3 million of stock compensation expense was capitalized into inventory, respectively.

As of December 31, 2025, the total unrecognized stock-based compensation expense related to outstanding employee options was $42.4 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.2 years.

As of December 31, 2025 and 2024, there were 1,382 and 2,763 restricted stock units outstanding, respectively.

Equity Incentive Plans

In September 2018, ARS Pharma adopted the 2018 Equity Incentive Plan. As a result of the Merger, on November 8, 2022 ARS Pharma assumed Silverback's 2016 and 2020 Equity Incentive Plans, and Employee Stock Purchase Plan ("ESPP"). There were 200,537 shares and 43,679 shares of common stock purchased under the ESPP during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, 25,737,116 shares were authorized under the 2016 and 2020 Equity Incentive Plans, of which 7,787,841 shares were available for future grant, and 12,822,226 shares were outstanding. As of December 31, 2025, 6,634,333 shares were authorized under the 2018 Equity Incentive Plan, of which 297,345 shares were available for future grant, and 3,923,795 shares were outstanding. The Company does not intend to grant future stock options or other equity awards under the 2016 or 2018 Equity Incentive Plans.

Stock Options

Stock options granted under the Company's equity incentive plans expire no later than 10 years from the date of grant and generally vest over a one- to four-year period. The Company issues new shares of common stock upon the exercise of stock options.

A summary of the Company's stock option activity for the year ended December 31, 2025 is as follows:

	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	15,161,180	$ 6.63		
Granted	3,363,850	$ 11.63		
Exercised	(1,134,836)	$ 3.62		
Forfeited	(645,555)	$ 11.29		
Outstanding at December 31, 2025	16,744,639	$ 7.66	7.3	$ 78,158
Exercisable at December 31, 2025	10,634,343	$ 6.40	6.6	$ 63,481

The exercisable shares subject to options outstanding at December 31, 2025 in the table above include vested and early exercisable awards. The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock for all options that were in-the-money at December 31, 2025. The aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $9.1 million and $14.7 million, respectively.

The weighted-average grant date fair value per share of option grants for the years ended December 31, 2025 and 2024 was $8.66 and $6.51, respectively. The total fair value of shares vested during the years ended December 31, 2025 and 2024 was $24.6 million and $14.1 million, respectively.

The fair value of stock options granted was estimated using a Black-Scholes option-pricing model ("Black-Scholes") with the following assumptions:

	Years Ended December 31,	
	2025	2024
Expected term (in years)	5.5 – 6.1	5.5 – 6.1
Expected volatility	83.2% – 87.3%	91.9% – 94.2%
Risk-free interest rate	3.8% – 4.4%	3.6% – 4.3%
Expected dividend yield	0%	0%

The fair value of stock options was determined using the Black-Scholes assumptions below.

Fair Value of Common Stock. The fair market value of the Company's common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded.

Expected Term. The expected term represents the period that the options granted are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility. Given the Company's limited historical stock price volatility data, the Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Company has limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free Interest Rate. The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

Expected Dividend Yield. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company uses an expected dividend yield of zero.

14. Income Taxes

The components of (loss) income before income tax (benefit) expense consisted of the following (in thousands):

	Years Ended December 31,	
	2025	2024
United States	$ (171,372)	$ 8,281
Foreign	(6)	5
(Loss) income before income tax (benefit) expense	$ (171,378)	$ 8,286

Income tax (benefit) expense consisted of the following (in thousands):

	Years Ended December 31,	
	2025	2024
Current:		
Federal	$ (97)	$ 260
State	17	28
Foreign	—	—
Total current income tax (benefit) expense	(80)	288
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred income tax (benefit) expense	—	—
Income tax (benefit) expense	$ (80)	$ 288

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate, after the adoption of ASU 2023-09 on a prospective basis, is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
Tax computed at federal statutory rate	$ (35,989)	21.0%
State income taxes, net of federal income tax effect[(1)]	135	-0.1%
Foreign tax effects	1	0.0%
Non-taxable or non-deductible items		
Stock-based compensation	93	-0.1%
Officer compensation	2,491	-1.5%
Other	355	-0.2%
Changes in valuation allowance	33,276	-19.4%
Tax credits		
Federal R&D credit	(781)	0.5%
Changes in unrecognized tax benefits	339	-0.2%
Effective tax rate	$ (80)	0.0%

[(1)] State taxes in California comprise the majority (greater than 50 percent) of the tax effect in this category.

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate for the prior year not impacted by the adoption of ASU 2023-09 is as follows (in thousands):

	Year Ended December 31, 2024
Tax computed at federal statutory rate	$ 1,740
State income taxes, net of federal benefit	47
Officers compensation (Sec 162(m))	1,741
Equity compensation	(135)
FDII deduction	(161)
Research and development credits	(1,008)
Other	(66)
Valuation allowance	(1,870)
Income tax expense	$ 288

For the year ended December 31, 2025, the Company paid income taxes, net of refunds received totaling $0.2 million, including $0.2 million of federal income taxes and less than $0.1 million of other state income taxes.

Significant components of the Company's net deferred tax assets were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 32,250	$ 12,834
Research and development credits	4,882	4,364
Intangible assets	15,249	17,201
Equity compensation	3,317	2,283
Deferred revenue	16,165	—
Other	1,937	319
Total deferred tax assets	73,800	37,001
Deferred tax liabilities:		
ROU asset	(300)	(8)
Other	(94)	(130)
Total deferred tax liabilities	(394)	(138)
Gross deferred tax assets	73,406	36,863
Valuation allowance	(73,406)	(36,863)
Net deferred tax assets	$ —	$ —

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred assets. At such time as it is determined that it is more likely than not that the deferred tax asset will be realized, the valuation allowance will be reduced. The change in the valuation allowance for the year ended December 31, 2025 was an increase of $36.5 million.

At December 31, 2025, the Company had federal and state net operating loss carryforwards ("NOL") of $150.5 million and $16.7 million, respectively. Federal NOL carryforwards of $150.5 million, generated after 2017, may be carryforward indefinitely but can only be utilized to offset 80% of future taxable income. The state NOL carryforwards begin expiring in 2035. State NOLs totaling $3.3 million may be carried forward indefinitely. In addition, the Company has federal and state research and development credit carryforwards totaling $4.1 million and $1.0 million, respectively. The federal research and development credit carryforwards will begin to expire in 2039 unless previously utilized. Of the total state research credits, $0.4 million begin to expire in 2038 unless previously utilized, the remainder does not expire. The NOL and credit carryovers noted above do not include the pre-merger amounts attributable to Silverback as noted in the IRC Section 382 disclosure in the paragraph below.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the company's NOL and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has completed an ownership change analysis pursuant to IRC Section 382 through December 31, 2024, including the tax attributes acquired in the Silverback transaction. The Company experienced several ownership changes from inception. All tax attributes reported in the above table have been adjusted based on the result of this analysis. If ownership changes occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The following table summarizes the reconciliation of the unrecognized tax benefits activity (in thousands):

	Years Ended December 31,	
	2025	2024
Unrecognized tax benefits – beginning	$ 7,028	$ 2,946
Gross increases – current-period tax positions	685	583
Gross decreases – tax positions in prior period	(379)	—
Gross increases – tax positions in prior period	—	3,499
Unrecognized tax benefits – ending	$ 7,334	$ 7,028

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance.

The Company files income tax returns in the United States, various states, and Ireland. Due to the Company's losses incurred, the Company's income tax returns for all jurisdictions are subject to examination by tax authorities from inception. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. At December 31, 2025, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties. The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which enacts significant changes to U.S. tax and related laws. Some of the provisions of the new tax law affecting corporations include, but are not limited to, current deduction of domestic research expenses, increasing the limit of the deduction of interest expense deduction to thirty percent of earnings before interest, taxes, depreciation and amortization, and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. The Company has evaluated the impact the new tax law had on its financial condition and results of operations. The impact of the tax law changes from the OBBBA is included in the Company's financial statements.

15. Related-Party Transactions

In September 2015, the Company entered into a consulting agreement, superseded in July 2022, for regulatory and development services with Pacific-Link Regulatory Consulting, Inc., an entity owned by the President/Chief Executive Officer/director and his spouse, the Chief Medical Officer of the Company. The Company incurred consulting expenses related to this agreement totaling $2.4 million and $2.2 million for the years ended December 31, 2025 and 2024, respectively.

As described in Note 9 – Term Loans, in September 2025, the Company entered into the Credit Agreement with a Lender whom is an affiliate of RA Capital. The general partner of RA Capital is RA Capital Management GP, LLC, of which a member of the Board of Directors of the Company is a controlling person. RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P. collectively hold in excess of 10% of the Company's outstanding common stock and are currently the Company's largest stockholder. RA Capital serves as the investment adviser for each of RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P.

As described in Note 11 – In-Licensing and Supply, the Company is required to make milestone payments to OrbiMed upon achievement of certain regulatory and commercial milestones, and royalty payments based on net product sales of *neffy*. A member of the Company's Board of Directors is a General Partner at OrbiMed. The Company incurred $4.8 million and $0.2 million in royalty expense payable to an affiliate of OrbiMed during the years ended December 31, 2025 and 2024, respectively, and $2.0 million in sales-based milestone payments to an affiliate of OrbiMed during the year ended December 31, 2025.

16. Segment Information

The Company reports segment information using the management approach and views its operations and manages its business as a single operating segment. The Company's Chief Operating Decision Maker ("CODM"), who is the Chief Executive Officer, allocates resources and evaluates the performance of the operating segment based on historical and projected product sales, segment operating expenses, and consolidated net (loss) income, as reflected in the accompanying consolidated statements of operations and comprehensive (loss) income, which is the segment measure of (loss) income.

The segment reports that are provided to the CODM are tracked against the Company's internally budgeted expenses. The segment operating expense categories consist primarily of the Company's functional departments: clinical, development, medical affairs, sales and marketing, and general and administrative. The CODM does not review assets when evaluating the operating segment's performance; therefore, this information is not presented.

Segment reporting for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Total revenue	$ 84,278	$ 89,149
Less segment operating expenses:		
Cost of goods sold	20,423	977
Clinical	5,342	6,113
Development	5,315	8,485
Medical affairs	4,334	2,462
Sales and marketing	176,087	36,679
General and administrative	29,352	22,849
Stock-based compensation	22,095	14,534
Other segment operating expenses	778	133
Other segment (income) expense:		
Interest income	(10,669)	(11,369)
Interest expense	2,599	—
Income tax (benefit) expense	(80)	288
Segment net (loss) income	$ (171,298)	$ 7,998

The following table summarizes revenue by geographic area based on the customers' location (in thousands):

	Years Ended December 31,	
	2025	2024
United States	$ 72,192	$ 7,255
Rest of world	12,086	81,894
Total revenue	$ 84,278	$ 89,149

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Arrangements

During the quarter ended December 31, 2025, our executive officers adopted, modified or terminated trading plans for the orderly disposition of the Company's securities as set forth in the table below.

Name and Position	Action	Adoption / Termination Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1[1]	Non-Rule 10b5-1[2]		
Laura Shawver *Director*	Adoption	November 13, 2025	X		128,562	December 31, 2026
Alexander Fitzpatrick *Chief Legal Officer*	Termination[3]	November 20, 2025	X		100,000	January 30, 2026
Brian Dorsey *Chief Operating Officer*	Adoption	November 25, 2025	X		296,065	April 1, 2027
Alexander Fitzpatrick *Chief Legal Officer*	Adoption	December 5, 2025	X		103,355	December 31, 2026
Eric Karas *Chief Commercial Officer*	Adoption	December 11, 2025	X		100,000	January 29, 2027

[1] Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

[2] "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

[3] Represents the termination of a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) that was adopted on May 29, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in the proposal headed *Election of Directors* and section headed *Executive Officers* contained in our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the Securities and Exchange Commission on or before April 30, 2026 (the "Proxy Statement") pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at *ir.ars-pharma.com*. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the sections headed *Executive Compensation* and *Non-Employee Director Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners and Management* and *Executive Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in the sections headed *Certain Related-Person Transactions* and *Information Regarding the Board of Directors and Corporate Governance* contained in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in the proposal headed *Ratification of Selection of Independent Registered Public Accounting Firm* contained in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) *Documents filed as part of this report.*

(1) *Financial Statements.* The following financial statements of ARS Pharmaceuticals, Inc., together with the report of Ernst & Young LLP, an independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

(2) *Financial Statement Schedules.* None.

(3) *List of exhibits required by Item 601 of Regulation S-K*. See part (b) below.

(b) Exhibits.

Exhibit Number	Description
2.1‡	Agreement and Plan of Merger and Reorganization, dated as of July 21, 2022, by and among Silverback Therapeutics, Inc., Sabre Merger Sub, Inc. and ARS Pharmaceuticals, Inc., as amended by the First Amendment, dated August 11, 2022 and the Second Amendment, dated October 25, 2022 (incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K, as amended, filed with the SEC on November 8, 2022).
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2020).
4.1	Reference is made to Exhibit 3.1 and 3.2.
4.2	Description of Registrant's Common Stock (incorporated by reference to Exhibit 4.3 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
4.3	Warrant to purchase stock issued to Silicon Valley Bank, dated as of September 30, 2019, as amended on December 7, 2020 (incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.1+	Form of Indemnity Agreement, by and between the registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.2+	ARS Pharmaceuticals, Inc. 2016 Equity Incentive Plan, as amended, and Forms of Option Agreement, Notice of Exercise, Notice of Early Exercise, Restricted Stock Grant Notice and Restricted Stock Award Agreement thereunder (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
10.3+	ARS Pharmaceuticals, Inc. 2020 Equity Incentive Plan, and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1/A (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.4+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the ARS Pharmaceuticals, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 31, 2022).
10.5+	ARS Pharmaceuticals, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 30, 2020).
10.6+	ARS Pharmaceuticals, Inc. 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the registrant's Registration Statement on Form S-8 (File No. 333-269262) filed with the SEC on January 17, 2023).

Exhibit Number	Description
10.7+	Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise and Early Exercise Stock Purchase Agreement under the ARS Pharmaceuticals, Inc. 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the registrant's Registration Statement on Form S-8 (File No. 333-269262) filed with the SEC on January 17, 2023).
10.8+	ARS Pharmaceuticals Inc. Change in Control and Severance Benefit Plan (incorporated by reference to Exhibit 10.8 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
10.9+	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2025).
10.10‡*	License Agreement, dated as of June 18, 2018, by and between ARS Pharmaceuticals, Inc. and Aegis Therapeutics, LLC, as amended by the First Amendment to License Agreement, dated as of July 15, 2020, and the Second Amendment to License Agreement, dated as of January 6, 2021 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.11‡*	Collaboration and Distribution Agreement, dated as of March 1, 2021, by and between ARS Pharmaceuticals, Inc. and Pediatrix Therapeutics (incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.12‡*	Manufacturing Agreement, dated as September 9, 2020, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC (incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.13+	Executive Employment Agreement, dated as of September 14, 2018, by and between ARS Pharmaceuticals, Inc. and Richard E. Lowenthal (incorporated by reference to Exhibit 10.6 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.14+	Executive Employment Agreement, dated as of September 14, 2018, by and between ARS Pharmaceuticals, Inc. and Dr. Sarina Tanimoto, as amended by Amendment No. 1 to Executive Employment Agreement, dated as of September 1, 2021 (incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.15+	Executive Employment Agreement, dated as of June 1, 2019, by and between ARS Pharmaceuticals, Inc. and Justin Chakma (incorporated by reference to Exhibit 10.10 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.16+	Consulting Agreement, dated as of April 26, 2021, by and between ARS Pharmaceuticals, Inc. and Brenton L. Saunders, as amended on April 25, 2022 (incorporated by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.17+	Consulting Agreement, by and between ARS Pharmaceuticals, Inc. and Marlinspike Group, LLC, dated September 14, 2018 (incorporated by reference to Exhibit 10.12 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.18+	Consulting Agreement, by and between ARS Pharmaceuticals, Inc. and Pacific-Link Regulatory Consulting, Inc., dated July 1, 2022 (incorporated by reference to Exhibit 10.13 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.19‡*	First Amendment, dated July 26, 2023, to Manufacturing Agreement, dated as September 9, 2020, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC. (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023)
10.20‡*	Second Amendment, dated September 17, 2024, to Manufacturing Agreement, dated as September 9, 2020 and first amended July 26, 2023, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC. (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2024).
10.21‡*	Collaboration, License and Distribution Agreement, dated November 9, 2024, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló A/S. (incorporated by reference to Exhibit 10.27 to the registrant's Annual Report on Form 10-K filed with the SEC on March 20, 2025).
10.22‡*	Supply Agreement, dated November 9, 2024, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló A/S. (incorporated by reference to Exhibit 10.28 to the registrant's Annual Report on Form 10-K filed with the SEC on March 20, 2025).
10.23*	Letter Agreement, dated December 6, 2024, to Manufacturing Agreement, dated as September 9, 2020, and as amended July 25, 2023 and September 17, 2024, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC., amend (incorporated by reference to Exhibit 10.30 to the registrant's Annual Report on Form 10-K filed with the SEC on March 20, 2025).
10.24‡*	Co-Promotion Agreement dated May 2, 2025, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló Inc. (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2025).

Exhibit Number	Description
10.25‡	Third Amendment, dated July 10, 2025, to Manufacturing Agreement, dated as September 9, 2020, and as amended July 26, 2023 and September 17, 2024, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC. (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2025).
10.26‡*	Credit Agreement, dated September 29, 2025, by and between ARS Pharmaceuticals Operations, Inc., as the borrower, ARS Pharmaceuticals, Inc. and certain of its subsidiaries from time to time party thereto as guarantors, the lenders from time to time party thereto, and RA Capital Agency Services, LLC, as administrative agent and collateral agent for the lenders (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on September 29, 2025).
10.27*	First Amendment, dated October 23, 2025, to Co-Promotion Agreement, dated May 2, 2025, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló Inc. (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025).
19.1	Insider Trading Policy.
21.1	Subsidiaries of the registrant (incorporated by reference to Exhibit 21.1 to the registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive and Financial Officers Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 to the registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

+ Indicates management contract or compensatory plan.

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

* Certain information in this exhibit is omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type that the registrant treats as private or confidential.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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, thereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: March 9, 2026

By: /s/ Richard Lowenthal
Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard Lowenthal and Kathleen Scott, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Richard Lowenthal Richard Lowenthal, M.S., MSEL	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	March 9, 2026
/s/ Kathleen D. Scott Kathleen D. Scott	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 9, 2026
/s/ Pratik Shah Pratik Shah, Ph.D.	Chairman of the Board of Directors	March 9, 2026
/s/ Peter Kolchinsky Peter Kolchinsky, Ph.D.	Director	March 9, 2026
/s/ Rajeev Dadoo Rajeev Dadoo, Ph.D.	Director	March 9, 2026
/s/ Brenton L. Saunders Brenton L. Saunders	Director	March 9, 2026
/s/ Phillip Schneider Phillip Schneider	Director	March 9, 2026
/s/ Michael Kelly Michael Kelly	Director	March 9, 2026
/s/ Laura Shawver Laura Shawver, Ph.D.	Director	March 9, 2026
/s/ Peter A. Thompson Peter A. Thompson, M.D.	Director	March 9, 2026
/s/ Saqib Islam Saqib Islam, J.D.	Director	March 9, 2026

EXHIBIT 19.1

ARS PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

Persons Covered

This Insider Trading Policy (this "***Policy***") of ARS Pharmaceuticals, Inc. (the "***Company***") applies to all directors, officers, other employees and consultants of the Company and any subsidiaries. It also applies to their family members who reside with them, anyone else who lives in their households and any family members who do not live in their households but whose transactions in the Company's securities are directed by, or subject to, the influence or control of a director, officer, other employee or consultant of the Company, and any other individuals or entities whose transactions in securities they influence, direct or control. To the extent the Company engages in market repurchase transactions of its securities, the Company intends to comply with applicable laws and regulations relating to insider trading.

Purpose and Policy

The purpose of this Policy is to clarify the circumstances under which trading in the securities of the Company or another publicly traded company with which the Company has business dealings or which shares a close market connection with the Company (such as a competitor) (each, a "***Third Party***") by the Company's directors, officers, other employees and consultants will result in civil liability and criminal penalties, as well as disciplinary action by the Company.

During the course of your employment or service with the Company, you may receive important information that is not yet publicly available, *i.e.*, not disclosed to the public in a press release or filing with the Securities and Exchange Commission ("***Inside Information***"), about the Company or a Third Party. Because of your access to this information, you may be in a position to profit financially by buying or selling or in some other way dealing in the Company's or a Third Party's stock, or to disclose such information to a third party who does so (known as a "***Tippee***").

It is illegal for anyone to use Inside Information to gain personal benefit, or to pass on, or "tip," the information to someone who does so. There is no *de minimis* exception to this rule. Use of Inside Information to gain personal benefit and tipping are as illegal with respect to a few shares of stock as they are with respect to a large number of shares. You can be held liable both for your own transactions and for transactions effected by a Tippee, or even a Tippee of a Tippee. Furthermore, it is important that the appearance as well as the act of insider trading in stock be avoided.

Exceptions

Please note that, generally, transactions directly with the Company, i.e., option exercises or purchases under the Company's employee stock purchase plan, will not create problems. However, the subsequent sale or other disposition of such stock is fully subject to these restrictions. This Policy also does not apply to the acquisition or disposition of the Company's securities pursuant to a domestic relations order, as defined in the Internal Revenue Code of 1986, as amended, or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder. For the avoidance of doubt, this exception applies only to a transfer of the Company's securities to a former spouse pursuant to such a "domestic relations order" and does not apply to any sale of the Company's securities in order to provide cash proceeds that may be used to satisfy cash payment obligations under a "domestic relations order" or otherwise. In addition, purchases, or sales pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, may be made without restriction provided that the plan was adopted in accordance with Company policies.

Inside Information

As a practical matter, it is sometimes difficult to determine whether you possess Inside Information. The key to determining whether nonpublic information you possess about a public company is Inside Information is whether dissemination of the information would be likely to affect the market price of the company's stock or would be likely to be considered important by investors who are considering trading in that company's stock. Certainly, if the information makes you want to trade, it would probably have the same effect on others. Both positive and negative information can be material. If you possess Inside Information about a company, you must refrain from trading in that company's securities, advising anyone else to do so or communicating the information to anyone else until you know that the information has been disseminated to the public. This means that in some circumstances, you may have to forego a proposed transaction in a company's securities even if you planned to execute the transaction prior to learning of the inside information and even though you believe you will suffer an economic loss or sacrifice an anticipated profit by waiting. "Trading" includes engaging in short sales, transactions in put or call options, hedging transactions and other inherently speculative transactions. It may also include gifts, in certain circumstances.

Additionally, you may not discuss material nonpublic information about the Company with anyone outside the Company. This prohibition covers spouses, family members, friends, business associates, or persons with whom we are doing business (except to the extent that such persons are covered by a non-disclosure agreement and the discussion is necessary to accomplish a business purpose of the Company). You may not participate in Internet forums, message boards, social media sites, "chat rooms" or other Internet discussion forums concerning the activities of the Company or other companies with which the Company does business, even if you do so anonymously.

Although this is by no means an exhaustive list, information about the following items may be considered to be Inside Information until it is publicly disseminated:

- clinical developments;
- financial results or forecasts;
- changes to previously announced earnings guidance or the decision to suspend earnings guidance;
- regulatory developments, including developments with the United States Food and Drug Administration and similar foreign agencies;
- major new products or product candidates;
- establishment of, or developments in, strategic partnerships, joint ventures or similar collaborations;
- communications with government agencies;
- strategic plans;
- potential mergers, acquisitions, tender offers or the sale of assets of the Company or a subsidiary thereof;
- significant write-offs;
- potential acquisitions of additional product candidates or technology;
- notice of issuance of patents, the acquisition of other material intellectual property rights or other significant intellectual property developments;
- significant changes or developments in the biopharmaceutical industry or technological innovations;
- new major contracts, orders, suppliers, or finance sources, or the loss thereof;
- significant changes or developments in supplies;
- significant marketing changes;
- significant pricing changes;
- events regarding the Company's securities (e.g., defaults on senior securities, calls of securities for redemption, repurchase plans, stock splits, public or private equity/debt offerings, the imposition of a ban on trading in the Company's securities or changes in Company dividend policies or amounts);
- significant changes in control or senior management;
- significant changes in compensation policy;
- bankruptcies or receiverships;
- actual or threatened major litigation, or a major development in or the resolution of such litigation; and
- change in auditors or a notification that the Company can no longer rely on an auditor's report.

For information to be considered publicly disseminated, it must be widely disclosed through a press release, SEC filing or other means of wide dissemination (such as an earnings call), and a sufficient amount of time must have passed to allow the information to be fully disclosed. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this Policy after one full trading day has elapsed since the information was publicly disclosed. For example, if the Company announces Inside Information before trading begins on Thursday, then you may execute a transaction in the Company's securities on Friday; and if the Company announces Inside Information after trading ends on Thursday, then you may execute a transaction in the Company's securities on Monday. Depending on the particular circumstances, the Company may determine that a longer or shorter waiting period should apply to the release of specific Inside Information.

Prohibition of Speculative Trading

No officer, director, other employee or consultant of the Company may engage in short sales, transactions in put or call options, hedging or monetization transactions, or other inherently speculative transactions with respect to the Company's stock at any time. In addition, no officer, director, other employee or consultant of the Company may margin, or make any offer to margin, or otherwise pledge as security, any of the Company's stock, including without limitation, borrowing against such stock, at any time.

Window Period Policy

Because the officers, directors and certain other designated employees of the Company are the most visible to the public and are most likely, in the view of the public, to possess Inside Information about the Company, we ask them to do more than refrain from insider trading. Under a separate policy applicable to this group of individuals known as the Company's Window Period Policy, the Company's directors, officers and certain other designated employees are required to limit their transactions in the Company's stock to defined time periods following public dissemination of quarterly and annual financial results, notify one or more designated pre-clearance individuals prior to engaging in transactions in the Company's stock and observe other restrictions designed to minimize the risk of apparent or actual insider trading. Other employees of the Company may also be subject to the Window Period Policy from time to time as determined by the Company's Board of Directors.

Application

Anyone who effects transactions in the Company's or a Third Party's securities (or provides information to enable others to do so) on the basis of Inside Information is subject to both civil liability and criminal penalties, including imprisonment, as well as disciplinary action by the Company, up to and including termination for cause.

This Policy will continue to apply to your transactions in the Company's or a Third Party's stock even after your employment or service with the Company has terminated. If you are in possession of Inside Information when your employment or service terminates, you may not trade in the Company's securities or a Third Party's securities until the Inside Information has become public or is no longer material.

A director, officer, other employee, or consultant who has questions about these matters should speak with his or her own attorney or to the Company's Chief Financial Officer or Chief Legal Officer.

Any director, officer, other employee, or consultant of the Company who knows of or suspects a violation of this Insider Trading Policy should report the violation immediately to the Company's Chief Financial Officer or Chief Legal Officer or through the procedures for anonymous reporting outlined in the Company's Code of Business Conduct and Ethics. The Company and its subsidiaries will comply with all requests from the U.S. Securities and Exchange Commission, the Nasdaq Stock Market, Inc., and other agencies for information related to insider trading investigations.

AMENDMENTS

The Company is committed to continuously reviewing and updating its policies and procedures. The Company therefore reserves the right to amend, alter or terminate this Policy at any time and for any reason. A current copy of the Company's policies regarding insider trading may be obtained by contacting the legal department.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-271359) of ARS Pharmaceuticals, Inc.;

(2) Registration Statement (Form S-8 No. 333-269262) pertaining to the 2018 Equity Incentive Plan, the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc.;

(3) Registration Statement (Form S-8 No. 333-261980) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.);

(4) Registration Statement (Form S-8 No. 333-254827) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.);

(5) Registration Statement (Form S-8 No. 333-251143) pertaining to the 2016 Equity Incentive Plan, the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.);

(6) Registration Statement (Form S-3ASR No. 333-284650) of ARS Pharmaceuticals, Inc.;

(7) Registration Statement (Form S-8 No. 333-278150) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.); and

(8) Registration Statement (Form S-8 No. 333-285955) pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.),

of our report dated March 9, 2026, with respect to the consolidated financial statements of ARS Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of ARS Pharmaceuticals, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

San Diego, California
March 9, 2026

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Lowenthal, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of ARS Pharmaceuticals, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2026

By: /s/ Richard Lowenthal
Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kathleen Scott, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of ARS Pharmaceuticals, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2026

By: /s/ Kathleen D. Scott
Kathleen D. Scott
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSURANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ARS Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025, to which this Certification is attached, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 9, 2026

By: /s/ Richard Lowenthal
Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 9, 2026

By: /s/ Kathleen D. Scott
Kathleen D. Scott
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.