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, 2024

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 120 **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 17, 2025 there were 98,119,804 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 $466.1 million as of June 28, 2024 (the last trading day of the registrant's most recently completed second quarter) based on the closing price of $8.51 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 2025 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, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

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:

- future economic conditions or performance, including *neffy* net product revenues and net product sales;
- research and development plans, including planned clinical trials, for our intranasal epinephrine technology product candidate;
- 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*;
- the size of the markets (including annual sales opportunities) for *neffy* and our intranasal epinephrine technology product candidates for its currently approved indications in the United States and the European Union ("EU"), the projected growth thereof, and our and our collaboration and marketing partners' ability to capture and grow those markets;
- the rate and degree of market acceptance of *neffy* or any future product candidate;
- our expected competitive position;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the likelihood of *neffy* attaining and maintaining favorable payer coverage;
- the expected intellectual property protection for *neffy*;
- 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 obtain, maintain and successfully enforce adequate patent and other intellectual property protection for *neffy* or any future product candidate;
- our expected use of the remaining net proceeds from the Silverback Therapeutics, Inc. ("Silverback") initial public offering; 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.

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* in the United States and in the EU for its currently approved indications in those jurisdictions. To the extent *neffy* is 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 *neffy* or our current or future intranasal epinephrine technology product candidates for additional indications, or experience significant delays in doing so, the commercial potential of *neffy* or our current or future intranasal epinephrine technology product candidates will be more limited.
- If the U.S. Food and Drug Administration ("FDA") does not conclude that our intranasal epinephrine technology product candidates for future indications satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for any such future indications under Section 505(b)(2) are not as we expect, the approval pathway for 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.
- 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 success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

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 is a trademark 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* (previously referred to as ARS-1 and currently identified in the EU by the trade name *EURneffy*) for the needle-free intranasal delivery of epinephrine for the 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 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, which, except for *neffy*, is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 20 million people are reported in the last 3 years of claims data to have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million were prescribed an epinephrine autoinjector. However (in 2023, for example), only 3.2 million filled their active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector with them due to the many drawbacks of these devices. 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 prescribed an epinephrine autoinjector in the United States represents an initial addressable market opportunity of approximately $3 billion in annual net sales with an additional 13.5 million diagnosed patients that have not been prescribed an epinephrine autoinjector.

The drawbacks of approved epinephrine devices, with the exception of *neffy* and our intranasal epinephrine technology product candidates, include the use of needles, which can result in patient and caregiver injury as well as hesitation and delays in administration due principally to apprehension and pain of needles, allowing the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events. In particular, intra-muscular injections also subject to dosing errors and risk of accidental blood vessel injections, which can cause a significant spike in the intravascular delivery of epinephrine potentially leading to serious cardiovascular complications or events. 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.

Data from our studies of *neffy* and our intranasal epinephrine technology product candidates demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products across single dosing, repeat dosing, self-administration or allergen challenge conditions, and produced clinically significant pharmacodynamic responses that were greater than or comparable to reference injection products. Pharmacodynamic response is a surrogate for efficacy and was observed approximately one minute after dosing with *neffy* and our intranasal epinephrine technology product candidates Pharmacodynamic response as a surrogate for efficacy was considered the primary basis for approval in the European Union with the EMA approval of *neffy* 2 mg.

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 commercial launch of *neffy* 2 mg in the United States, with product becoming available for shipment on September 23, 2024. This commercialization effort currently includes a direct sales force of 118 individuals targeting high-volume epinephrine prescribers that is supported by branded direct-to-consumer marketing, disease awareness campaigns with advocacy groups and non-personal promotion such as non-personal promotion including continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences.

On March 5, 2025, the FDA approved the supplemental NDA for *neffy* 1 mg dose 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.

neffy U.S. Commercial Launch Initiated on September 23, 2024

On August 22, 2024, the EC granted marketing authorization in the EU for *EURneffy* (the trade name for *neffy* 2 mg in the European Union and United Kingdom), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. Through our collaboration with ALK (discussed below), we anticipate that *EURneffy* will be made available to patients in certain EU member states in 2025. Regulatory review of *neffy* is ongoing in Canada, the United Kingdom, China, Japan, and Australia. ARS has filed in Canada in January 2025 and the United Kingdom in December 2024 on behalf of ALK, while Pediatrix, Alfresa and CSL have filed in China, Japan and Australia during the fourth quarter of 2024, respectively. Regulatory decisions are anticipated by mid-2025 in the U.K., the second-half of 2025 in Japan, year-end 2025 in Canada, and in the first-half of 2026 in China and Australia. *neffy* has already been approved or is under regulatory review in countries representing approximately 98% of the current global epinephrine autoinjector sales.

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, and anticipate initiating a Phase 2b randomized, placebo controlled outpatient clinical trial in chronic spontaneous urticaria patients on a chronic antihistamine treatment regimen who still experience flares or exacerbations. This Phase 2b study is anticipated to be initiated in the second quarter of 2025, with topline data anticipated in early 2026, followed by the potential initiation of a single pivotal efficacy study in 2026.

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:

- lack ease of portability with only 50% of patients filling prescriptions carrying the device;
- reluctance to use the device with approximately 25% to 60% of patients carrying 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, which occurred in approximately 14% of EpiPen subjects in our patient self-administration studies.

As a result, many of the approximately 40 million patients at risk of severe Type I allergic reactions do not receive or fill prescriptions for intra-muscular injectables. Of 3.2 million patients that do fill their prescriptions, approximately half do not carry the intra-muscular injectable products with them on a regular basis, while many of the other half delay or hesitate treatment during a severe Type I allergic reaction. This may contribute to treatment postponement, prolonging troublesome symptoms, reducing quality of life and increasing the risk of complications or even death. In addition to the 3.2 million patients who currently fill their prescriptions for an epinephrine injectable device, we estimate that approximately 3.3 million patients received a prescription, but either did not fill or renew it. We believe the advantages of *neffy,* will be attractive to this group and lead to an increase in the number of patients filling their prescription as further described below. These patients are additive to the 3.2 million patients that do fill a prescription per year, for an estimated total initial addressable market of 6.5 million, representing approximately $3 billion in annual net sales based on *neffy*'s current list price and target total gross-to-net yield to ARS Pharma. In addition, there are an estimated 13.5 million unique patients who are diagnosed, but never received an epinephrine prescription.

Our Approach

neffy 2 mg is approved by the FDA and EC 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 by the FDA 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. *neffy* and our intranasal epinephrine technology product candidates are a convenient "no needle, no injection," solution designed to be easier to carry, more reliable and easier to administer, without the aversion, safety concerns and fear and pain of needles associated with intra-muscular injectables. 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 from cumbersome, unreliable, intra-muscular injectable devices to an intranasal delivery method that makes patients more likely to administer epinephrine sooner, thus 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 it is pocket-sized, increasing the likelihood that the device is available for use in an emergency. Our registrational self-administration study (EPI-17) with 2.0 mg *neffy* demonstrated that adult patients had zero critical dosing errors, and 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. Unlike autoinjector delivery that has patients and caregivers hold an injection in place for three seconds, *neffy* and our intranasal epinephrine technology product candidates delivery requires no holding time with epinephrine being delivered nearly instantaneously into the systemic circulation via the nose after device activation. Dosing *neffy* and our intranasal epinephrine technology product candidates cannot be obstructed by common anaphylaxis co-morbidities such as vomiting or angioedema of the lips, face, mouth or tongue. No inhalation or breathing is needed during administration of *neffy* or our intranasal epinephrine technology product candidates.

- ***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 since the 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 United States 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 we have conducted, patients indicated a relief from fear of injection and an expectation to utilize *neffy* without delay in a manner more consistent with recommended guidelines due to *neffy* and our intranasal epinephrine technology product candidates being a nasal spray.

- ***Low potent dose of epinephrine.*** Delivery of higher exposures of epinephrine increases the risk of overexposure and potential adverse events including gastrointestinal (GI) symptoms due to swallowing of the excess epinephrine that is not absorbed. *neffy* and our intranasal epinephrine technology product candidates have high bioavailability matching the approved doses of injection at a low dose of 2.0 or 1.0 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. Due to its low dose of epinephrine and high bioavailability, *neffy* and our intranasal epinephrine technology product candidates have minimal to no GI symptoms. GI symptoms such as vomiting occur in approximately 20% of anaphylaxis events and the presence of such GI events due to administration of higher dose epinephrine products could confound the evaluation of anaphylaxis treatment response and monitoring.

- ***Increased stability over existing treatment options***. *neffy* 2 mg has a shelf-life of 30 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, and volume-weighted average shelf-life of between 22 and 23 months. Furthermore, *neffy* 2 mg 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.

- ***Combination of previously validated product components***. *neffy* consists of a unique combination of three validated products, which we believe will significantly reduce *neffy's* commercial development risks: epinephrine, which has been approved by regulators and accepted by the physician community as the only effective option to treat Type I allergic reactions; the intranasal device, which has been commercially proven with millions of sprayers sold to date across four FDA-approved products, including NARCAN for opioid overdose (marketed by Emergent BioSolutions); and Intravail, an innovative absorption enhancer that has been previously included in the formulations of FDA approved products, such as VALTOCO and TOSYMRA nasal spray. We believe the cost of goods for *neffy* will allow us to achieve gross profit margins similar to branded oral small molecule products at our current list price for *neffy* and our expected total gross-to-net yield.

- ***Potential for high demand and attractive product uptake conditions.*** We have conducted extensive market research with physicians, patients, parents and other caregivers that shows *neffy* clinical product profile that is highly desirable and addresses key unmet needs. We believe we can successfully commercialize *neffy* by targeting high-prescribing allergists, pediatricians and primary care physicians who we believe will prescribe *neffy* as it would be a very attractive treatment option within the patient community. In addition, our market research indicates that insurance plans (payors) perceive *neffy* as a differentiated product candidate, which has been validated by successful contracting with payers at a total gross-to-net yield which is in line with other innovator branded products. We anticipate approximately 52% of commercially insured patients will have unrestricted access to *neffy* as of April 1, 2025. We currently own or 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 2039 before consideration of any potential patent term adjustment.

Our Management Team, Financing History and Investors

We were created to innovate, develop and commercialize *neffy*, a novel, potentially 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 recently 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 R&D at Barr Laboratories, Somerset Pharmaceuticals and UDL Laboratories. 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, former Chairman of Synthorx (now part of Sanofi) and former Chief Executive Officer of Auspex Pharmaceuticals (now part of Teva Pharmaceuticals).

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 and Adapt Pharmaceutical (now part of Emergent BioSolutions).

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.

Since our inception, we have raised $518.9 million in proceeds, including equity financing from a syndicate of leading life sciences investors that include, among others, RA Capital, SR One and Deerfield, from our licensing and collaboration agreements and from our reverse merger with Silverback Therapeutics, Inc. We have entered into licensing and collaboration agreements for *neffy* with Alfresa Pharma for Japanese rights, Pediatrix Therapeutics (founded by F-Prime Capital, Eight Roads and Creacion Ventures) for Chinese rights and CSL Seqirus for Australia and New Zealand rights. We have also entered into a licensing and collaboration agreement with ALK for territories outside the United States and the territories covered by the Alfresa, Pediatrix and CSL agreements; these territories include Canada, the United Kingdom, European Union and other countries.

Our Strategy

Our strategy is focused on commercializing and developing *neffy* as the first and only approved intranasal treatment for the approximately 20 million patients in the United States under the active care of physicians between 2020-2022 who have been diagnosed with severe Type I allergic reactions and are at risk of anaphylaxis, for patients in geographic regions outside of the United States and for patients in other allergy indications. Key elements of our strategy include:

- ***Continue to educate healthcare providers about neffy:*** We began our commercialization efforts in the United States during the fourth quarter of 2024 by deploying a combination of direct promotion through a current sales force of 118 individuals comprising sales reps, virtual sales consultants and area sales managers, and non-personal promotion efforts, which are intended to reach, at a minimum, healthcare professionals that account for 40 to 45% of the current epinephrine prescriptions. Our promotion targets high-prescribing allergists, pediatricians and primary care physicians through both traditional and non-traditional professional channels. As of March 2025, approximately 2,500 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 challenge, and obtain direct clinical experience using *neffy*. We anticipate that our promotional reach will eventually exceed greater than 80% of the current epinephrine prescriptions in the United States through a combination of sales force expansion by early 2026 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 payer coverage and grow sales of neffy.*** Quickly attaining broad market access for severe allergy patients is a key element to ensuring a seamless patient experience to acquiring *neffy* and rapidly growing *neffy* sales. We have successfully contracted with key payers including Express Scripts, the second largest pharmacy benefit manager in the United States. We believe payers 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. We are on track to achieve access to commercial lives under contract of 60% or greater by the end of the first quarter of 2025, and 80% by the early part of the third quarter of 2025. With our payer contracting strategy, a $25 or less co-pay savings card, 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 similar to that of generic epinephrine autoinjectors, thereby minimizing cost barriers to acquiring *neffy*.

- ***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 quickly and efficiently 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 either 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 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 2020-2022.

- ***Commercialize neffy outside of the United States with our partners***. We believe that there is significant commercial potential for *neffy* in markets outside of the United States. The EC granted marketing authorization in the EU for *EURneffy* (the trade name for *neffy* 2 mg in the EU), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. Through our collaboration with ALK, we anticipate that *neffy* will be made available to patients in certain EU member states, the United Kingdom and Canada. ALK anticipates peak sales for *neffy* of approximately $425 million USD in Canada, the United Kingdom and European Union. Regulatory review of *neffy* is ongoing in Canada, the United Kingdom, China, Japan, and Australia with filings for marketing approval submitted in the fourth quarter of 2024 or January 2025. Regulatory decisions are anticipated by mid-2025 in the U.K., the second-half of 2025 in Japan, year-end 2025 in Canada, and in the first-half of 2026 in China and Australia.

- ***Conduct additional studies of neffy and our intranasal epinephrine technology product candidates to address additional Type I allergic reactions***. There remains a significant unmet need for treatments for allergies that can produce Type I reactions. 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, and anticipate initiating a Phase 2b randomized placebo-controlled outpatient clinical trial in chronic spontaneous urticaria patients who are on a chronic antihistamine regimen, but still experience flares, in the second quarter of 2025, with topline data anticipated in early 2026.

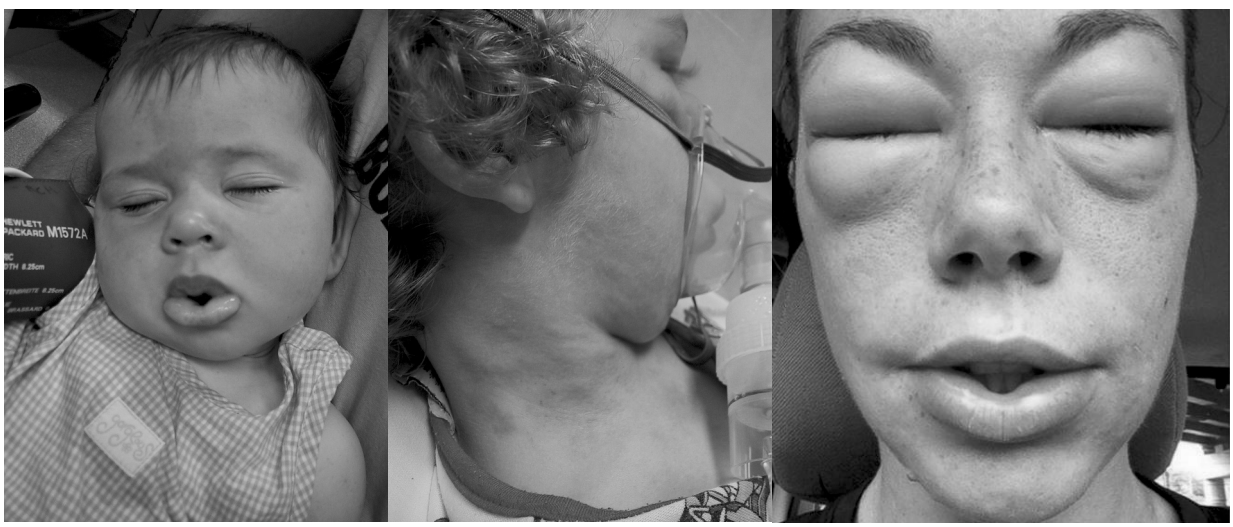
Overview of Type I Allergic Reactions and Current Challenges

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 results 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 foods (most commonly, nuts, eggs, shellfish), drugs and venoms 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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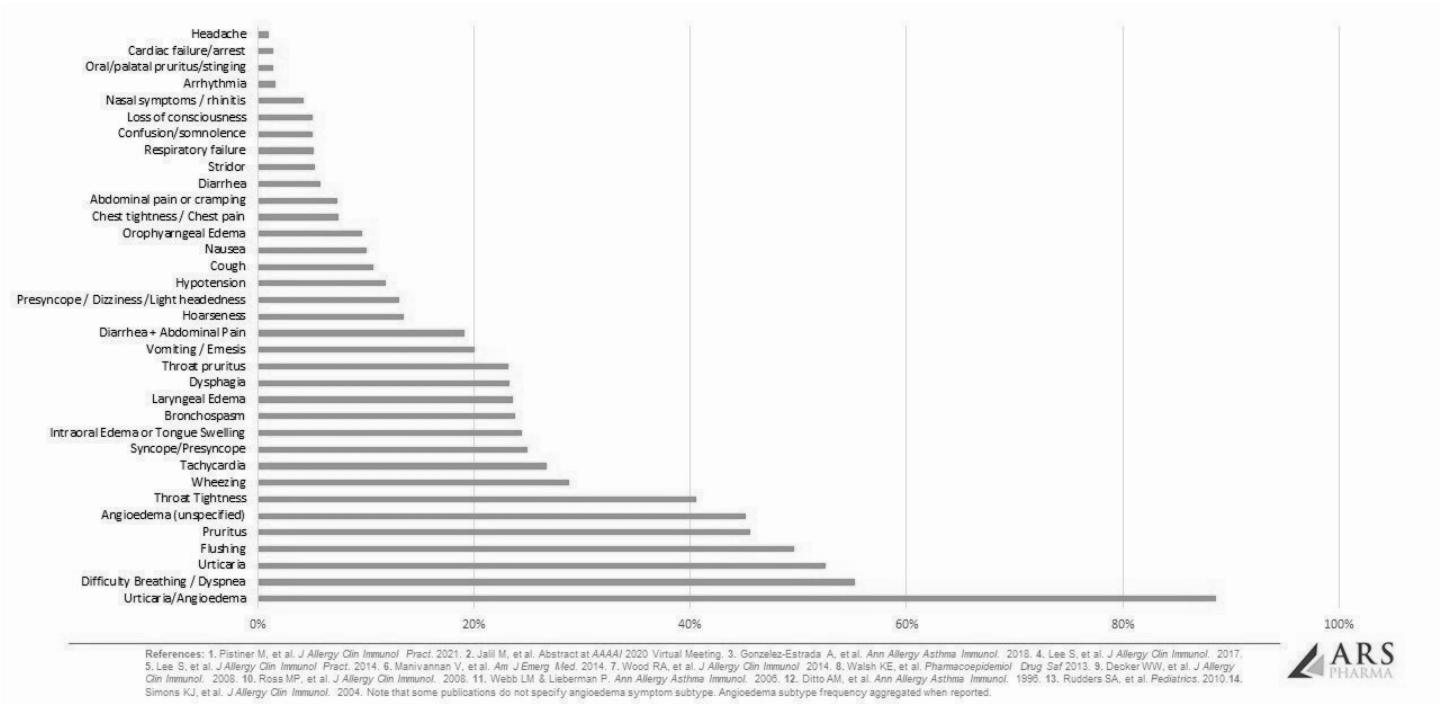
Analysis of symptom frequency during anaphylaxis in the United States (n = 4,805 events)

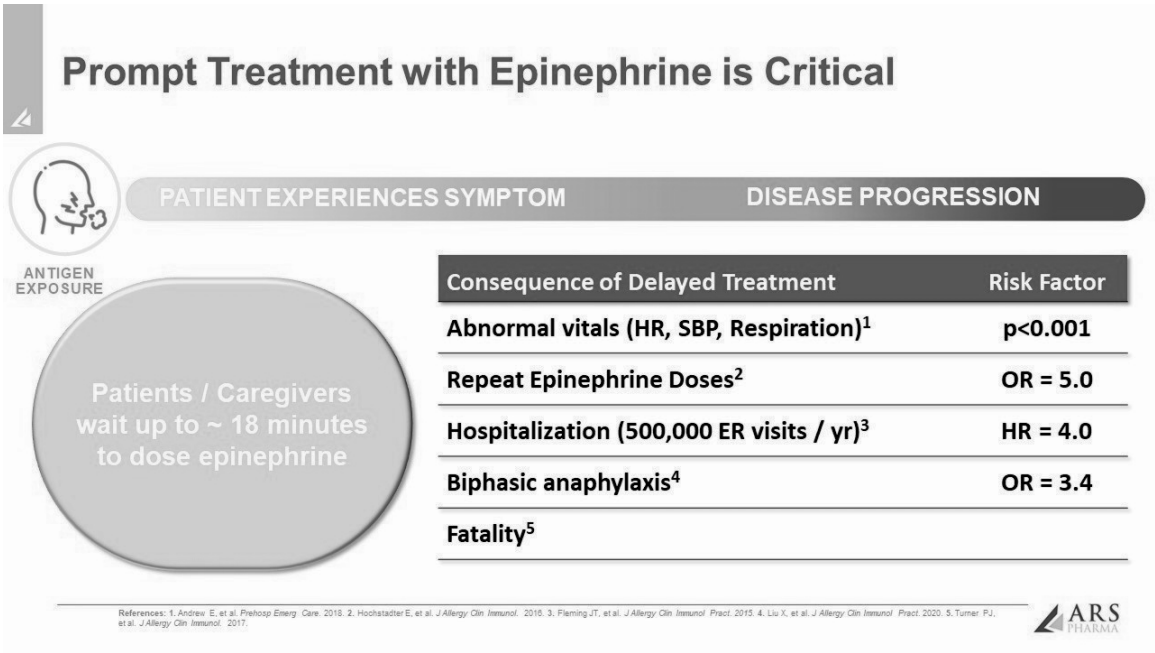


Role of Epinephrine in Treating Type I Allergic Reactions

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. Even a few minutes delay in the administration of epinephrine can lead to the need for emergency services and/or hospitalizations, comorbidities and life-threatening symptoms or events, while also prolonging the significant negative impact on patient quality of life by delaying symptom relief.

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 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.

Epinephrine works due to its agonistic effects on the body's adrenergic receptors (alpha and beta receptors). By activating alpha-1 receptors, epinephrine prevents and relieves airway edema, hypotension and shock. By activating beta-1 receptors, epinephrine increases the rate and force of cardiac contractions. Lastly, epinephrine's effect on beta-2 receptors leads to bronchodilation and decreased allergy causing mediator release by mast cells. Alpha-1 receptors responsible for systolic blood pressure increases are the least sensitive to epinephrine, followed by beta-1 receptors that are responsible for heart rate increases, while beta-2 receptors responsible for stopping mast cell degranulation and the allergic reactions are the most sensitive to epinephrine.



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. 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.

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 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 United States in 2023 for outpatient use are 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 to 30 kg and 1% contain 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, and work as intended, 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 has been limited among eligible patients with severe Type I allergic reactions at risk of anaphylaxis. Of the approximately 20 million people in the United States under the active care of physicians between 2020-2022 who have been diagnosed with Type I severe allergic reactions, only 3.2 million had an active and filled epinephrine autoinjector prescription in 2022, and 3.3 million received, but did not fill an epinephrine autoinjector prescription during 2020-2022. The remaining 13.5 million patients that have been diagnosed with a Type I severe allergic reaction between 2020-2022 did not receive an epinephrine prescription from their physician, and are managed almost entirely by non-allergist physicians who we believe are not well-educated about the management of Type I severe allergic reactions.

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 in 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. In our clinical studies, we observed instances of potential accidental blood vessel injection in approximately 14% of patients dosing themselves with EpiPen.

In comparison, *neffy* is perceived by patients and parents as a potentially "game changing" device that 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

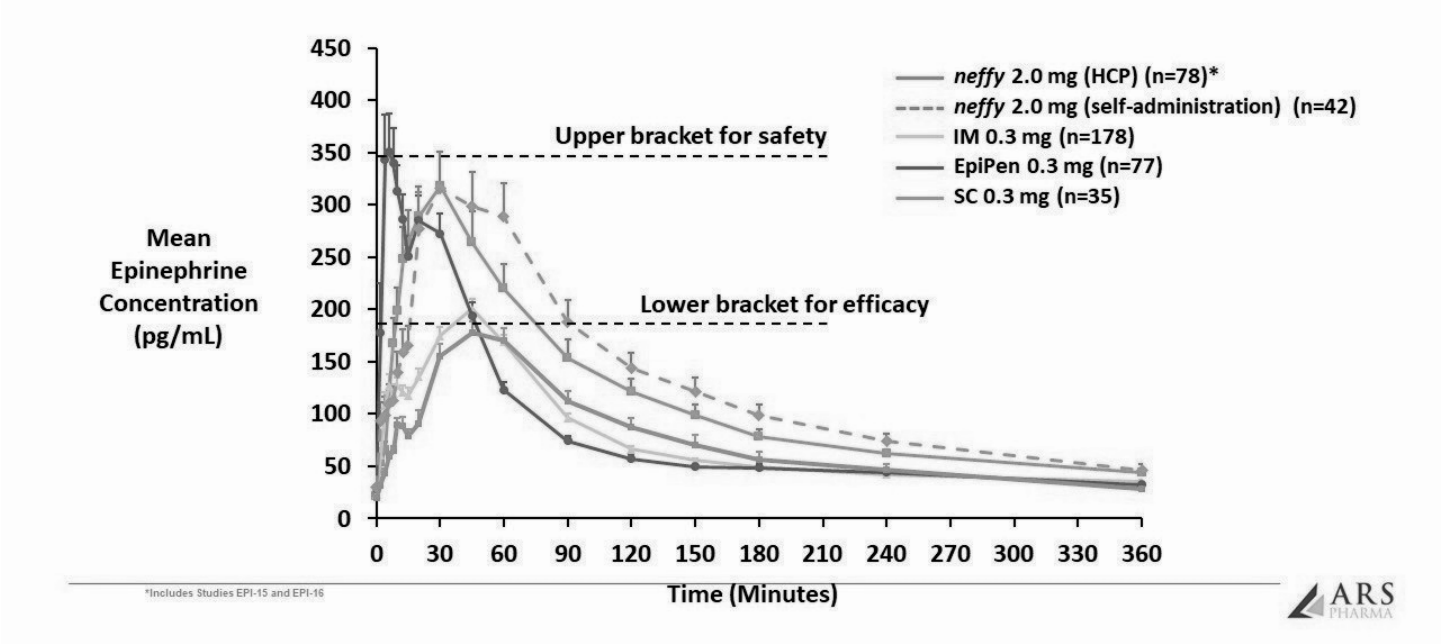
Our intranasal technology, including *neffy*, is designed to provide injection-like absorption of epinephrine at a 2.0 or 1.0 mg dose comparable to 0.3 mg or 0.15 mg injection, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray. On August 9, 2024, the FDA approved *neffy* 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 for shipment on September 23, 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.

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.

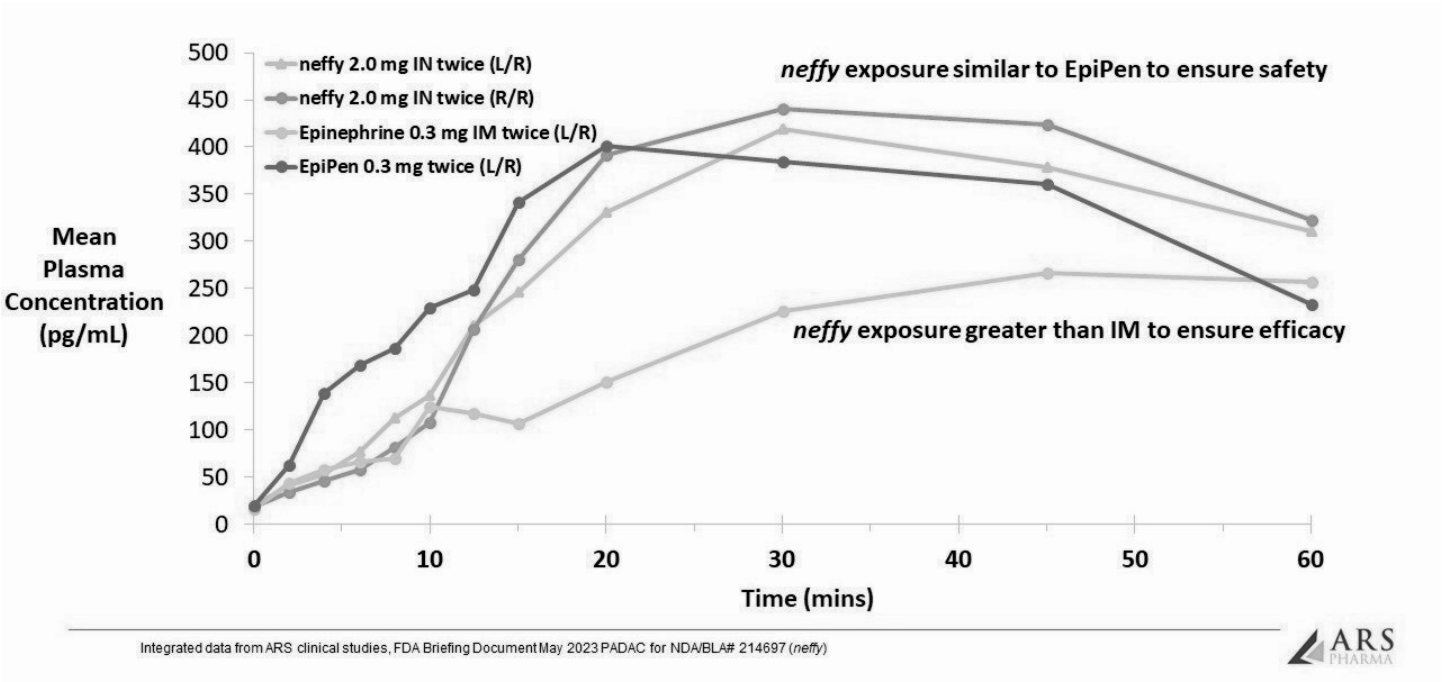
2.0 mg *neffy* is intended to be the dose that is comparable to approved 0.3 mg epinephrine intra-muscular injection products for persons 30 kg or greater in weight, which represents approximately 80% of the prescriptions in the United States. 1.0 mg *neffy* is intended to be the dose for persons 15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

In contrast, for patients self-administering devices, which involved 132 subjects dosed with EpiPen, approximately 14% of subjects dosed with EpiPen (auto-injector) experienced a potential blood vessel injection leading to a rapid bolus dose of epinephrine, which could lead to serious side effects including cardiovascular events and cerebral hemorrhage according to the FDA EpiPen label. No subjects dosed with *neffy* experienced a blood vessel injection since it is not possible via the nasal route of administration.

Furthermore, our registrational self-administration study of 2.0 mg *neffy* by adults with severe Type I allergies (EPI-17) 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.

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 PDs 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.

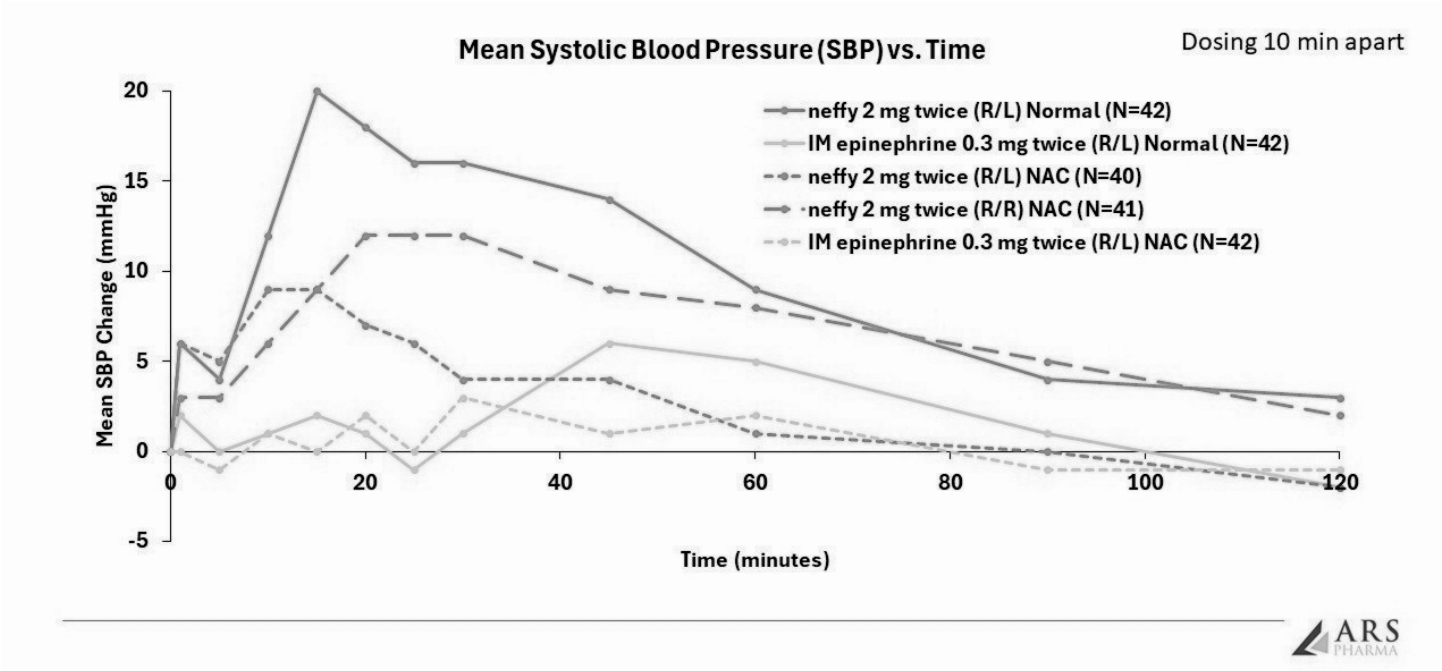
Easy to use	No critical dosing errors during self-administration with 2.0 mg *neffy* by Type I allergy adult subjects (EPI-17). Zero percent error rate in human factor validation studies with intended commercial instructions for use and quick reference guide, when used by untrained adults or untrained 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.

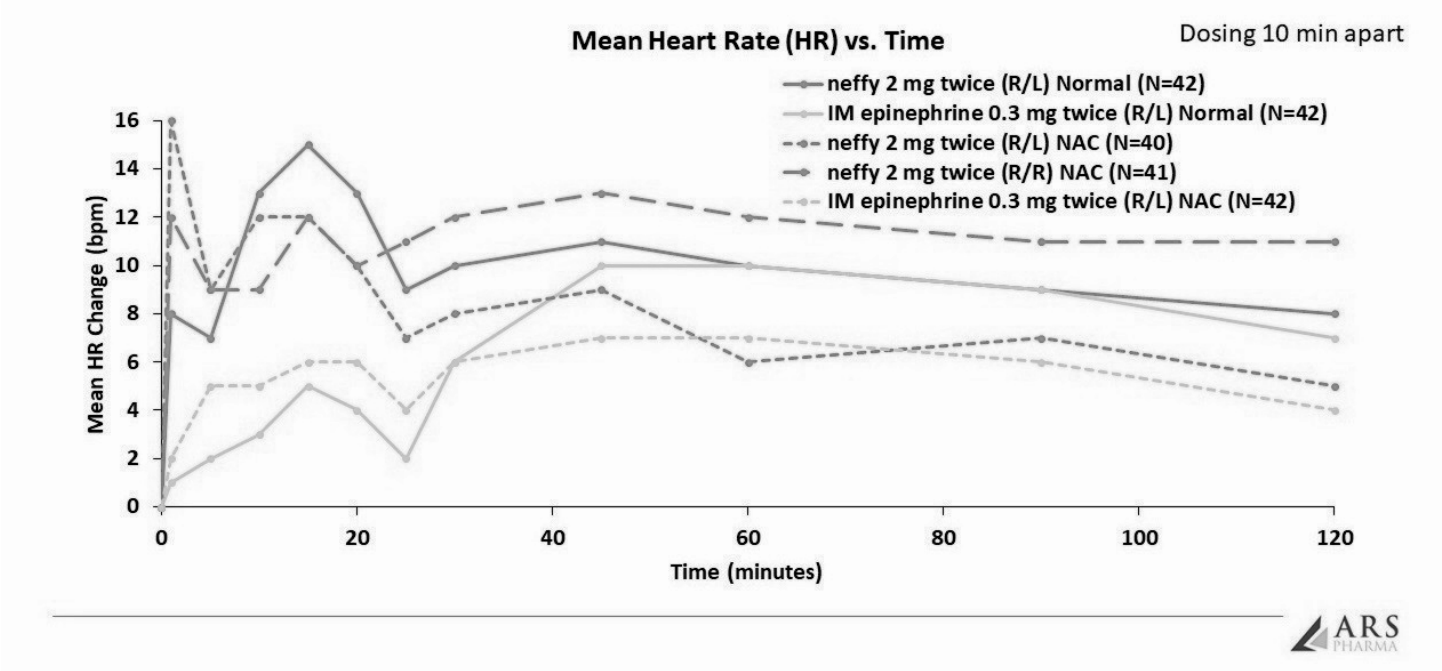
Regulatory Review of neffy by the FDA

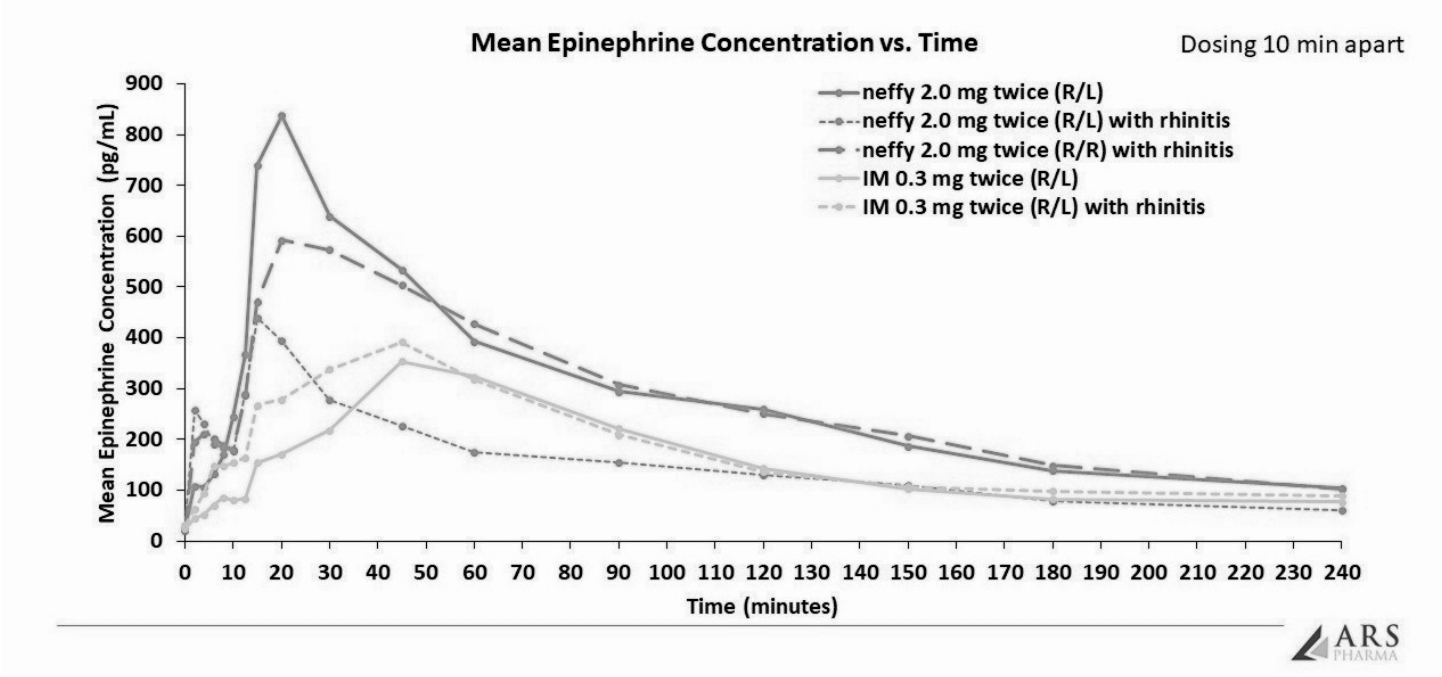
Following the acceptance of our new drug application ("NDA") in October 2022 for review by the FDA, on May 11, 2023, the FDA held a virtual meeting of the PADAC. At that meeting, on the question of whether the data from our *neffy* PK/PD results support a favorable benefit-risk assessment in adults for the emergency treatment of Type I allergic reactions including anaphylaxis, the PADAC voted 16 (yes) and 6 (no). On the question of whether the *neffy* PK/PD results support a favorable benefit-risk assessment in children weighing 30 kg or greater for the emergency treatment of Type I allergic reactions including anaphylaxis, the PADAC voted 17 (yes) and 5 (no).

On September 19, 2023, the FDA issued a complete response letter ("CRL") for our NDA requesting completion of a PK/PD study assessing repeat doses of *neffy* compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis. This request came after the favorable benefit-risk assessment of the PADAC to approve *neffy* without need for additional studies. In addition, the FDA and ARS Pharma had previously aligned in August 2023 on final physician's labeling and a post-marketing requirement to conduct this study as informative for labeling.

We reported topline results in February 2024 from this additional repeat dose study requested by the FDA. In this study, repeat doses of *neffy* under allergen-induced allergic rhinitis conditions demonstrated a PK and PD profile comparable to or better than repeat doses of intra-muscular injection. The results are shown below:


Mean Systolic Blood Pressure (SBP) vs. Time
Dosing 10 min apart
neffy 2 mg twice (R/L) Normal (N=42)
IM epinephrine 0.3 mg twice (R/L) Normal (N=42)
neffy 2 mg twice (R/L) NAC (N=40)
neffy 2 mg twice (R/R) NAC (N=41)
IM epinephrine 0.3 mg twice (R/L) NAC (N=42)
Mean SBP Change (mmHg)
Time (minutes)
20
15
10
5
0
-5
0
20
40
60
80
100
120
ARS PHARMA


Mean Heart Rate (HR) vs. Time
Dosing 10 min apart
neffy 2 mg twice (R/L) Normal (N=42)
IM epinephrine 0.3 mg twice (R/L) Normal (N=42)
neffy 2 mg twice (R/L) NAC (N=40)
neffy 2 mg twice (R/R) NAC (N=41)
IM epinephrine 0.3 mg twice (R/L) NAC (N=42)
Mean HR Change (bpm)
Time (minutes)
16
14
12
10
8
6
4
2
0
0
20
40
60
80
100
120
ARS PHARMA



As part of the CRL, the FDA also requested additional information on nitrosamine impurities to be tested for based on new draft guidance issued in August 2023 after the *neffy* NDA submission. We completed this updated testing, and no measurable levels of nitrosamine impurities were detectable. We submitted our response to the FDA CRL in April 2024.

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 commercial launch of *neffy* 2 mg in the United States, with product becoming available for shipment on September 23, 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.

Planned Clinical Trials in Additional Indications

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. We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients, and anticipate initiating a Phase 2b randomized placebo-controlled clinical trial in the outpatient urticaria setting in the second quarter of 2025, with topline data anticipated in early 2026, followed potentially by a single pivotal registration study in 2026.

Development outside the United States

On August 22, 2024, the EC granted marketing authorization in the EU for *EURneffy* (the trade name for *neffy* 2 mg in the EU), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. Through our collaboration with ALK, we anticipate that *EURneffy* will be made available to patients in certain EU member states in 2025.

In the first quarter of 2025 we submitted a post-approval variation to EMA for the 1.0 mg *neffy* for patients who weigh 15 kg to less than 30 kg in the first quarter of 2025.

Using the same clinical studies that supported *neffy* approval by FDA and EC, we have also filed for regulatory approval of *neffy* in Canada and the United Kingdom on behalf of our partner ALK.

Our partners in Japan, China and Australia filed for regulatory approval of *neffy* in their respective regions in the fourth quarter of 2024. Regulatory decisions are expected in UK by mid-2025, Canada and Japan by year-end 2025, and China and Australia in the first half of 2026.

Commercialization Opportunity and Commercialization Plan

Type I Allergy Market Overview

neffy is a needle-free, low-dose intranasal epinephrine nasal spray approved for use as a rescue medication for people with Type I severe allergic reactions including anaphylaxis. *neffy* was designed to provide injection-like absorption of epinephrine, in a small, easy-to-carry, easy-to-use, rapidly administered, and reliable nasal spray device.

All systemic allergic reactions have the potential of progressing to anaphylaxis and becoming life-threatening. These reactions can be unpredictable and progress quickly to develop severe symptoms within a few minutes after exposure and can progress to a life-threatening event if not treated immediately. Patient and caregiver preparedness to act quickly and confidently during a severe allergic reaction is imperative. Hesitation can lead to worse clinical outcomes and can be fatal.

Epinephrine is the first-line treatment for the emergency treatment of Type I allergic reactions including anaphylaxis. Epinephrine needs to be given as soon as symptoms occur because it is the only medication proven to stop a potentially life-threatening allergic reaction.

Needle-free and easy-to-use *neffy* may allow for improved patient and caregiver preparedness to give epinephrine quickly, confidently, and without hesitation that is caused by fear of the needle. Intended for use at the first signs of an allergic response, *neffy* is designed to provide patients and their families with a new option to rapidly resolve symptoms and prevent progression to severe anaphylaxis.

We believe our first-in-class nasal spray may transform the way we think about and use life-saving epinephrine.

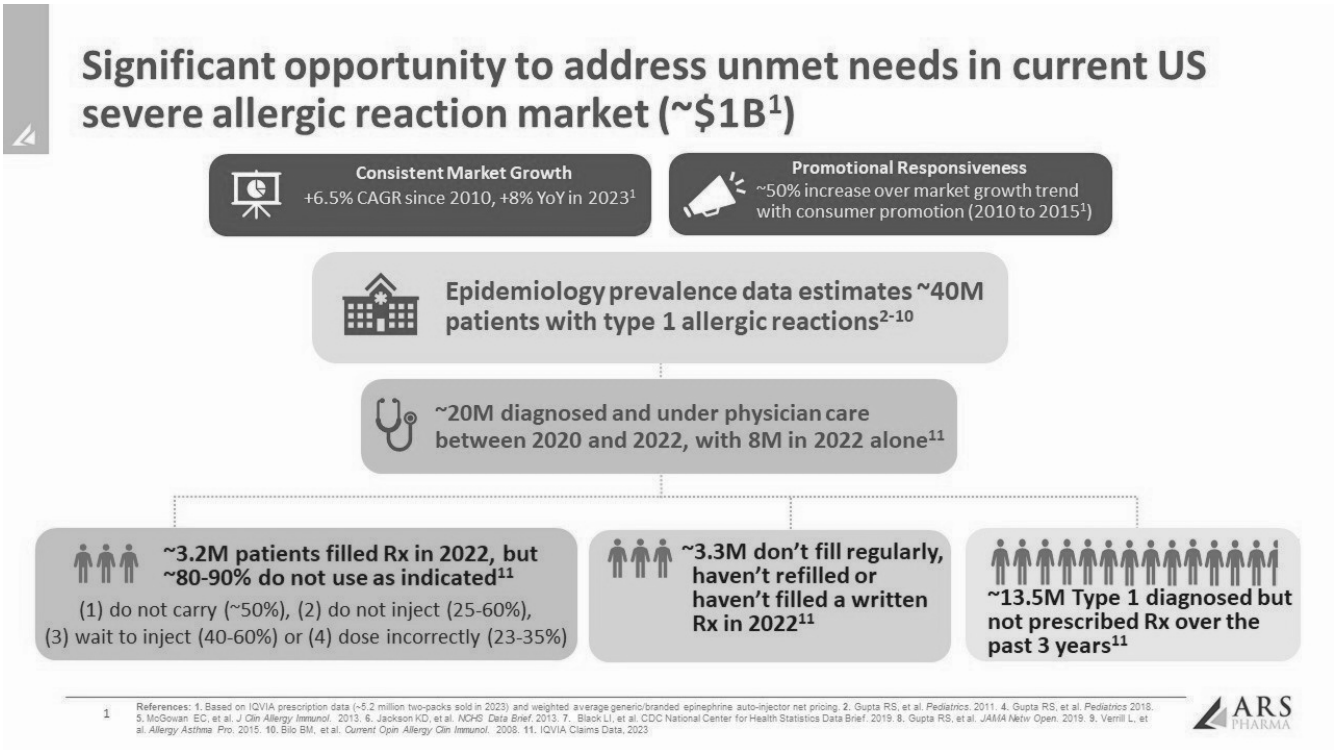
Existing U.S. Market Opportunity

We estimate approximately 40 million people in the United States have experienced Type I allergic reactions. Of this group, approximately 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only about 3.2 million of them filled a prescription in 2022 for an epinephrine intra-muscular injectable device, including auto-injectors, equating to approximately 5 million two-pack units.

Of those 3.2 million people, roughly half don't carry these devices due to many drawbacks that can result in patient and caregiver injury, hesitation, and delays in administration principally because of apprehension and pain of needles. In turn, the failure or delay of epinephrine delivery can allow the allergic reaction to progress in severity causing life-threatening symptoms or events that potentially require emergency services and/or hospitalization.

We believe *neffy* could address the needs of the approximately 3.2 million patients in the United States who currently fill intra-muscular injectable prescriptions, the approximately 3.3 million former injectable patients in the United States 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 market opportunity of 6.5 million patients who have been prescribed epinephrine during 2020-2022 is approximately $3 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 billion in annual net sales for *neffy*.



We have conducted multiple market research studies with caregivers, generally parents, and patients with severe Type I allergic reactions in the United States to evaluate potential market perceptions of *neffy* and currently available epinephrine delivery devices. Based on quantitative market research studies including a total of 480 patients and 185 allergists, pediatricians and primary care physicians, approximately 88% of patients with a current epinephrine auto-injector prescription stated that they would prefer *neffy*. Furthermore, 99% of the physicians surveyed stated they would prescribe if their patient asked for *neffy*, indicating that *neffy* prescriptions would likely be highly driven by patient preference and awareness of *neffy*.

In our market research, parents and people with current or prior epinephrine auto-injector prescriptions were asked if and when they would adopt a new nasal spray device product such as *neffy*.

- 75% of patients indicated they would adopt *neffy* within one year of approval
- 81% of patients indicated they would use *neffy* sooner than their current auto-injector device,
- 72% of patients indicated that they would use *neffy* first instead of an over-the-counter antihistamine
- 88% reported they would be more willing to use *neffy* in public.

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 United States 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, and our market research has indicated that *neffy*'s user-friendly product profile has the potential to resonate significantly with consumers. We estimate that branded marketing of EpiPen prior to generic entry contributed a promotional lift of 31% over base epinephrine intra-muscular injectable market trends. We plan to reach and support patients directly through efficient direct-to-consumer advertising after educating professional physician practices and securing appropriate payor coverage for *neffy*.

- **Targeting the approximately 3.3 million former patients that either do not fill their epinephrine intra-muscular injectables prescriptions or whose prescriptions have recently lapsed**. The exodus of patients who have received prescriptions from the market has 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). In our market research of 88 former patients who refused to fill or renew a prescription, approximately 89% indicated a willingness to return to the market and request *neffy*. We hope to engage with these patients through programs to encourage appropriate epinephrine use with *neffy* and increase consistency of epinephrine acquisition to help manage their condition.

- **Increased per patient device acquisition by patients and parents.** In our market research of 350 patients with an active intra-muscular injectable prescription, approximately 70% to 80% of patients reported an intention to acquire additional devices compared to their current injectable device if *neffy* is approved by the FDA. Currently, we estimate only between 20% to 30% of patients obtain more than one pack (containing two devices) per year today.

US 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. Outside of the 6.5 million patients who were recently prescribed an epinephrine injectable device, there are approximately 13.5 million patients who are under the care of physicians per IQVIA claims data, but have not been prescribed an epinephrine intra-muscular injectable device, as well as another approximately 20 million patients not currently under the care of physicians.

- **Over time, targeting the approximately 13.5 million identified and diagnosed in-office patients in IQVIA claims data with Type I allergic reactions that are eligible but have not been prescribed epinephrine device between 2020-2022.** In our market research, physicians indicated they would prescribe *neffy* to 75 to 85% of the patients who were eligible, but do not currently receive an intra-muscular injectable prescription.

- **Development in new allergy indications.** There are approximately 1 million patients in the United States 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 may be as meaningful 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, 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 payers 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 February 2024, and anticipate initiating a Phase 2b randomized placebo-controlled outpatient clinical trial in chronic spontaneous urticaria patients on a chronic antihistamine regimen, but who still experience flares, in the second quarter of 2025, with topline data anticipated in early 2026.

Ex-US Market Opportunity

- Outside of the United States, we estimate that there are an additional 15 million patients in Europe, and over 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.

- Market research conducted in Europe with 120 patients who have an epinephrine auto-injector prescription indicated that 98% would prefer *neffy*, and that they would acquire approximately twice as many *neffy* devices compared to their current injectable device.

- To target these opportunities outside of the United States, we have entered into licensing, collaboration and partnership agreements, including with Alfresa Pharma for Japanese rights to *neffy* and Pediatrix Therapeutics (founded by F-Prime Capital, Eight Roads and Creacion Ventures) for Chinese rights to *neffy*, CSL for Australian and New Zealand rights to *neffy*, and ALK for, among other things, rights to *neffy* in all other territories outside of the United States.

- ALK anticipates peak sales in excess of $425 million for its licensed regions alone, principally comprising Canada, the United Kingdom and the European Union.

Commercial Strategy

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*. 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.

Our go-to-market strategy for *neffy* includes the following key elements:

We have initiated the commercialization of *neffy* in the United States with a combination of direct promotion, virtual sales consultants, and non-personal promotion intended to reach, at a minimum, the healthcare professionals that account for 40 to 45% of the current epinephrine prescriptions. Our launch has focused on the highest potential practicing allergists, pediatricians, and primary care physicians. In our market research, approximately 80% of patients see their treating physicians at least every six months, and 98% at least once a year. We have optimized our field representatives based on research on current market dynamics, geo-targeting and assessment of current professional-industry interaction preferences initially to reach these professionals. As of January 2025, about three months after launch, approximately 50% of the prioritized 4,000 top decile healthcare providers (deciles 8 to 10) have already prescribed *neffy*. Our current sales force of 118 individuals includes sales reps, virtual sales consultants and area sales managers, and we anticipate potentially expanding our sales force to over 200 individuals by early 2026. We expect significant reach of approximately 80% of epinephrine prescriptions to be achieved based on expanded use of non-personal promotional tactics to reach healthcare professionals and focus on the sequential activation of patient demand through direct-to-consumer tactics that will help also drive physician awareness due to overlapping exposure. As of March 2025, approximately 2,500 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 challenge.

We intend to secure affordable market access for all consumers by optimizing contracting, co-pay support and distribution of *neffy*. To ensure access and affordability for *neffy*, we have engaged and successfully contracted with insurers and payers to convey the clinical rationale and value proposition of *neffy*. We are on track to achieve commercial coverage of 60% or greater by the end of the first quarter of 2025, and commercial coverage of 80% or greater by the early part of the third quarter of 2025. The second largest pharmacy benefit manager in the United States, ExpressScripts, added *neffy* to its national commercial formularies at Tier 2 preferred, which is the lowest possible tier for a branded innovator product, only 9 weeks after product availability on September 23, 2024. With our contracting strategy, a $25 or less co-pay savings card, a $199 cash price, and patient assistance programs, we anticipate that the out-of-pocket cost to patients for acquiring *neffy* may be less than or similar to that of generic epinephrine autoinjectors. Prior to our anticipated inclusion on formularies by a vast majority of payers later in 2025, our *neffyconnect* program provides patients, caregivers, and healthcare professionals (HCPs) with information about patient support programs, such as medication fulfillment services and financial support to guide their treatment journey, including navigating insurance requirements and potential barriers to access. In particular, the program has been facilitating prior authorization formwork required by payers today that do not currently include *neffy* in their formulary, with a majority of prior authorizations submitted by healthcare providers currently being approved on the first pass. We believe our comprehensive market access strategy can ensure access and affordability for all patients that may be interested in *neffy*.

We intend to leverage an omnichannel strategy including direct-to-patient and parent tactics, social and traditional media, digital presence, and additional public relations including partnerships with patient advocacy organizations as well as influencers to drive awareness, for patients to ask for *neffy*, and communicate our value proposition. The pent-up patient demand that we believe is ready to be activated by *neffy* is reflected in our market research where 87% of patients indicated a high likelihood to proactively visit their physician in-person and ask about getting a new prescription for *neffy* (43% of patients indicating a 10 out of 10 likelihood, and 44% of patients indicating a 7-9 out of 10 likelihood). Our research also showed that physicians would recommend *neffy* to approximately 70% of their patients. In addition, the severe Type I allergy market has historically been highly promotionally sensitive, and in recent years, there has been limited investment in education or promotion, which we believe provides an opportunity for significant promotional lift from our planned marketing efforts. To activate this pent-up patient demand for *neffy*, we intend to launch an extensive branded direct-to-consumer marketing campaign to raise awareness of *neffy*, and motivate action, including television, radio, print, digital and social media in the second quarter of 2025 following attainment of our commercial payer coverage goals in mid-2025 and availability of the 1 mg *neffy* dose, for patients who are four years of age and older and weigh 15 kg to less than 30 kg, in the second quarter of 2025. This *neffy* direct-to-consumer marketing campaign will also coincide with the "back to school" increased seasonal volume of epinephrine prescriptions during the summer that is driven by the pediatric population, which is approximately half of the epinephrine injection market today.

We intend to establish *neffy* as the dominant and most recognized brand in the category. We believe *neffy*'s potential brand recognition and user-friendly profile can be an important driver of growth and source of competitive differentiation, especially as the first "no needle, no injection" solution for severe Type I allergic reactions. We have designed *neffy* to offer healthcare professionals, patients and caregivers a simple, injection-free, portable, highly reliable and user-friendly alternative that facilitates early administration of epinephrine to provide rapid symptom relief and to stop the allergic reaction from progressing to more serious events. We believe the attractiveness and meaningful differentiation of *neffy* across both physicians and payors will stimulate a high patient and parent desire to switch to or return to managing their condition with *neffy*.

We intend to expand the market beyond the 3.2 million patients currently filling epinephrine injection device prescriptions. We believe that the severe Type I allergy market is currently significantly underpenetrated due to the lack of, and limitations in, current treatment options. We believe the availability of *neffy* could drive increased device uptake among the existing 3.2 million patients currently filling epinephrine injection device prescriptions, adoption by the approximately 3.3 million patients that receive, but do not fill their prescription, and the 13.5 million patients diagnosed and managed by physicians who do not currently have an epinephrine auto-injector, especially those incorrectly using antihistamines as a substitute. Other launches of intranasal products for emergency use into previously injection-only markets such as NARCAN (marketed by Emergent BioSolutions), VALTOCO (marketed by Neurelis), NAYZILAM (marketed by UCB) and BAQSIMI (marketed by Eli Lilly) have rapidly captured a significant percentage of the existing market, and also expanded their respective markets. Both products use the same device that we have chosen for *neffy*. We believe that NARCAN's widespread use clearly demonstrates market uptake in response to the advantages of an intranasal product via proven device over injection, considering in particular that NARCAN is used in life threatening rescue situations where reliable administration is required for confident administration, similar to severe Type I allergic reactions. Beyond just reliability, we believe that an intranasal product has unique advantages for treating a severe Type I allergic reaction due to patient and parent fear and avoidance of injection and because time is of the essence. This perspective is distinct from other diseases with chronic use of injection products, administration by a trained professional is required, or where the injection is more manageable and tolerated. In our market research, respondents have described *neffy* as "game-changing" and we believe *neffy* can make a significant difference in patient lives and outcomes.

We have established a distribution channel in the United States for the commercialization of *neffy*. We are selling *neffy* to wholesalers, who, in turn, sell *neffy* to retailers and other customers. We are using a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration, order management and chargeback processing and accounts receivable management. *neffy* is also available through telemedicine.

To target markets outside of the United States, we have entered into strategic partnerships with several pharmaceutical companies to obtain regulatory approval and market *neffy*. These include Alfresa Pharma for Japan, Pediatrix Therapeutics for China, CSL for Australia and New Zealand, and ALK for all other regions outside of the United States including Canada, the United Kingdom and the European Union. The EC has granted marketing authorization for *EURneffy* (the trade name for *neffy* 2 mg in the European Union), and regulatory filings are actively under review in Canada, the United Kingdom, Japan, China and Australia and New Zealand, with additional filings anticipated in other countries. Regulatory decisions are expected in UK by mid-2025, Canada and Japan by year-end 2025, and China and Australia in the first half of 2026.

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, Orexo AB, Insignis Therapeutics and Belhaven BioPharma. Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine.

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 intend to 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 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 United States, 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 Pharmaceuticals, Inc. ("Renaissance Pharma"), which has been actively involved in supporting the manufacture of *neffy* and our intranasal epinephrine technology product candidates. We intend to 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 Pharma, and believe they have sufficient capacity to satisfy our long-term requirements, although we are evaluating alternating 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 2.0 mg dose of *neffy* for 30 months and the 1.0 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* 2.0 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.

Intellectual Property

We strive to protect our intranasal epinephrine product candidates by seeking, maintaining, and defending our patent rights in the United States 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 co-own or exclusively license the patents and patent applications relating to our intranasal epinephrine product candidates. As of December 31, 2024, our patent portfolio consisted of issued patents and pending patent applications that we co-own or exclusively license from Aegis Therapeutics LLC in the United States and other countries throughout the world. In total, as of that date, our patent portfolio consisted of seven issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, Europe, the United Kingdom, two pending U.S. non-provisional patent applications, a pending U.S. provisional patent application, and over fifteen pending foreign patent applications 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 United States 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 United States as well as in certain 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 United States 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, 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 with Aegis Therapeutics, LLC ("Aegis"), which was amended in July 2020 and January 2021. Pursuant to the 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 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, and Aegis may not directly or indirectly exploit an Aegis Licensed Product or Aegis Licensed Compound or derivatives thereof without our consent.

Under the agreement, Aegis received an upfront license fee of $50,000 and is entitled to receive development milestone payments of up to $3.95 million in 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 during 2019, a $1.0 million payment to Aegis upon the FDA's acceptance of our U.S. NDA filing, which occurred in the third quarter of 2022, a $2.5 million milestone payment to Aegis for achieving FDA approval of *neffy* 2.0 mg in September 2024, and a $5.0 million milestone payment to Aegis for the first commercial sale of *neffy* 2.0 mg in October 2024. 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 agreement will continue until the expiration of the last-to-expire Aegis Royalty Term, unless sooner terminated. We have the right to terminate the agreement at any time after a specified notice period to Aegis. Either party may terminate the 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 with Alfresa Pharma Corporation ("Alfresa"). Pursuant to the 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 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 agreement, we received a one-time upfront payment of $2.0 million, earned $5.0 million upon the achievement of a clinical milestone during 2021, and earned $6.0 million upon the completion of a regulatory milestone in Japan. We are eligible to receive a final regulatory milestone of $2.0 million. Further, we are eligible to receive a negotiable transfer price expected to be in the low-double-digit percentage on net sales subject to the regulatory approval to commercialize *neffy* in Japan. We share the cost of any additional clinical studies required for approval of *neffy* in Japan. Additionally, Alfresa is obligated to either (i) enter into a commercial supply agreement with us pursuant to which we will supply drug product for commercial sale at an agreed upon transfer price, or (ii) if Alfresa elects to manufacture its own supply of drug product, 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.

The 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 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 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 Distribution Agreement with Pediatrix

In March 2021, we entered into a collaboration and distribution agreement with Pediatrix Therapeutics ("Pediatrix"). Pursuant to the 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 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 agreement, we received a one-time upfront payment of $3.0 million and are eligible to receive a regulatory milestone payment of $4.0 million and 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 agreement will continue until the expiration of the last-to-expire Pediatrix Royalty Term. Pediatrix has the right to terminate the agreement at any time after a specified notice period to us. Either party may terminate the 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.

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 and September 2024 (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 (a) for Renaissance Product designated for commercial sale in the U.S., on December 31 immediately following the fifth anniversary of the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the EU, on December 31 immediately following the fifth anniversary of the initial EU launch date ("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.

Supply Agreement with Ompi

In October 2024, we entered into a supply agreement (the "Ompi Agreement") with Nuova Ompi S.r.l. (the "Ompi"), pursuant to which Ompi has agreed to supply glass microvials to support our manufacture and commercialization of *neffy*. Under the Ompi Agreement, we have committed to purchase, and Ompi has committed to supply, specified annual minimum quantities of glass microvials, which may be increased with prior notice by us or through the rolling forecast process, subject to a specified annual cap. Ompi is obligated to establish the relevant manufacturing force, assets and capabilities needed to comply with its supply obligations.

In December 2024, as partial consideration for the supply arrangement, we made an upfront payment of €3.0 million (approximately $3.2 million in U.S. dollars) to Ompi. The supply price for the glass microvials is specified in the Ompi Agreement, subject to an annual adjustment that is capped at a specified percentage except in the case of material and extraordinary increase in Ompi's cost of manufacturing the glass microvials.

The Ompi Agreement will expire on December 31, 2035, and may be terminated (i) upon the parties' mutual written consent, (ii) by the Company for any reasonable business reasons (in which case the termination will become effective at the end of the following calendar year), or (iii) by the non-breaching party if the other party is in material breach of the Ompi Agreement and fails to cure such breach within 90 days after receipt of notice thereof from the non-breaching party.

Collaboration, License and Distribution Agreement with ALK

ALK Agreement

In November 2024, we entered into a collaboration, license and distribution agreement (the "ALK Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the ALK 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 Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Agreement, we are obligated to transfer to ALK the existing marketing authorizations for the Products in ALK's territory. We are also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in ALK's 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 ALK's territory. Following such approval for a Product in each indication within specified countries within ALK's 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 Agreement.

Under the ALK Agreement, ALK made an upfront payment to us of $145.0 million in November 2024. We are eligible to receive regulatory and development milestones of up to $20.0 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 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 Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Agreement for convenience upon prior written notice or for a safety or regulatory concern. We may terminate the ALK 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 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 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 "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 Supply Agreement in the event of an uncured material breach of the other party.

Government Regulation and Product Approval

As a pharmaceutical company that operates in the United States, 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 such as those we are developing. Product candidates that we develop must be approved by the FDA, before they may be legally marketed in the United States 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 United States, 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. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for 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 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 cGMP requirements applicable to both drugs and devices, including the Quality 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. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some preclinical testing may continue even after the IND is submitted. 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. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. 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. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. 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. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. 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. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted 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. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. 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.

Fast Track Designation

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, the FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority. 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 will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

Fast track designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, such designations or shortened review periods may not provide a material commercial advantage.

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 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. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been amendments and judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges and the healthcare reform measures of the second Trump administration will impact the ACA.

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 IRA, among other things, (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare (the "Medicare Drug Price Negotiation Program"), and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs under the law, and (ii) imposes rebates with respect to certain drugs covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. In addition, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program ("MDRP"), which is currently capped at 100% of the AMP for a covered outpatient drug.

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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. 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 EMA's Committee for Medicinal Products for Human Use("CHMP"), 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.

Corporate Information

We incorporated in Delaware in January 2016. Our corporate headquarters are located at 11682 El Camino Real, Suite 120, San Diego, California 92130, and our telephone number is (858) 771-9307. Our corporate website address is www.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.

Employees

As of December 31, 2024, we had 155 full-time employees and 5 part-time employees. Of these employees, three 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.

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 in the United States and in the EU for its currently approved indications in those jurisdictions. To the extent neffy is 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 and it has only been approved in the United States 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 (in the case of *neffy* 1 mg), and in adults and children who weigh 30 kg or greater (in the case of *neffy* 2 mg), and in the EU (under the trade name *EURneffy*, and only in the 2 mg form) for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis, for adults and children with a body weight 30 kg or greater. 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 the EU (under the trade name *EURneffy)*. 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 to commercialize *neffy* in the United States. In order to successfully commercialize *neffy*, we must 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;
- 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.

If we are unable to maintain an effective sales force 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 to be credible in educating physicians and pharmacists on the benefits of *neffy*. In addition, we must continually train our sales force 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 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; CSL 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 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. 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. We 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 indication 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. 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. Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs in the United States. 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.

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 for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the listed drug is invalid, unenforceable or will not be infringed by the generic product. In that case, the applicant may submit its application four years following approval of the listed drug and seek to launch its generic product even if we still have patent protection for our product unless an infringement suit is timely filed by the NDA or patent holder in which case the FDA cannot approve the ANDA or a Section 505(b)(2) NDA for 30 months unless a court decision in favor of the generic manufacturer is issued earlier.

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 and the EU, 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 neffy or our current or future intranasal epinephrine technology product candidates for additional indications, or experience significant delays in doing so, the commercial potential of neffy or our current or future intranasal epinephrine technology product candidates will be more limited.

Successful continued development and ultimate regulatory approval of *neffy* and our current or future intranasal epinephrine technology product candidates s important to the future success of our business. The future regulatory and commercial success of *neffy* and our current or future intranasal epinephrine technology product candidates 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 intranasal epinephrine technology product candidates for future indications satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for any such future indications under Section 505(b)(2) are not as we expect, the approval pathway for 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 any 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 potential additional indications, including urticaria, for our current and future intranasal epinephrine technology product candidates, 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 *neffy* or our current or future intranasal epinephrine technology product candidates 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 potential additional indications, including urticaria, for our intranasal epinephrine technology, 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 candidate, including 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 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 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 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 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 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 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 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 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 in the United States 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 (in the case of *neffy* 1 mg), and in adults and children who weigh 30 kg or greater (in the case of *neffy* 2 mg), and in the EU (under the trade name *EURneffy*, and only in the 2 mg form) for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis, for adults and children with a body weight 30 kg or greater, 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 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 indication and labeling, or the future approvability or labeling of our current or future intranasal epinephrine technology product candidates, including 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 received Fast Track designation for neffy in the United States and may in the future pursue Fast Track designation for other product candidates that we may develop, but we might not receive such future designations, and Fast Track designations may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the FDA may grant a product candidate Fast Track designation. Fast Track designation is intended to expedite or facilitate the process for reviewing new drug products meeting the specified criteria and gives the sponsor of a Fast Track product opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. We were granted Fast Track designation for *neffy* for the emergency treatment of Type I allergic reactions and may in the future request Fast Track designation for additional indications for our current or future intranasal epinephrine technology product candidates, however, we cannot assume that any such applications will meet the criteria for that designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development activities.

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 indication 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.

Remote work has become more common and 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 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers 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 could cause a security incident or other interruption that could 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. 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 may not, 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 may 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. 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.

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 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 have generated only limited revenue from product sales to date, 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 income was $8.0 million for the year ended December 31, 2024 and our net loss $54.4 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $123.3 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 indications for which we may obtain regulatory approval;
- continue to develop and conduct nonclinical studies and clinical trials for *neffy* on a post-approval basis and our current or future intranasal epinephrine technology product candidates;
- seek regulatory approvals in the United States and in the EU for our current or future intranasal epinephrine technology product candidates, 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 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;
- 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.

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 indication in the United States, or for our current or future intranasal epinephrine technology product candidates which receives 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 indication 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 indication and our current or future intranasal epinephrine technology product candidates, and the similar costs of any other product candidate 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* for its approved indication and our current or future intranasal epinephrine technology product candidates;
- 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;
- 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;
- 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, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, bank failures, trade wars and uncertainty about economic stability. If the equity and credit markets 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 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℠ 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. 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.

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. 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.

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. The ACA and subsequent regulations increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and revised the definition of "average manufacturer price" for reporting purposes, which could further increase the amount of Medicaid drug rebates to states. However, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, effective January 1, 2024. Further, the ACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products, increased the number of entities eligible for discounts under the 340B program and included a discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or "donut hole." Substantial provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners.

Since its enactment, there have been amendments and judicial, executive and Congressional challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the second Trump 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. These 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. At the federal level, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare (the "Medicare Drug Price Negotiation Program"), and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs under the law, and (ii) imposes rebates with respect to certain drugs covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have become increasingly aggressive in passing legislation and 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, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or EU, or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

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 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 and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our current or future intranasal epinephrine technology product candidates in the EU and 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 provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still uncertainties. 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. 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, particularly in light of the upcoming U.S. presidential and Congressional elections, 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.

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 foresees a three-year transitional period and 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;

- 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 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.

In the past few years, 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 (the "CCPA"), applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. 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 addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. 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 similarly stringent interpretations of their 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 and UK's 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. Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and have proposed and may enact data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

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, whitepapers, 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. Additionally, we publish privacy policies, marketing materials, and other statements 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 by regulators or experience other adverse consequences.

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 and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data or sensitive data on our behalf.

Obligations related to data privacy and security 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 data on our behalf. 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 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, active pharmaceutical ingredient ("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. We have also entered into a supply agreement with Nuova Ompi S.r.l. ("Ompi") pursuant to which Ompi has agreed to supply glass microvials to support the Company's manufacture and commercialization of *neffy*. We will rely on Ompi as the primary source of glass microvials. Unless and until we can secure alternative sources for microvials, drug product manufacturing and final packaging, our dependence on Renaissance and Ompi 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 any 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. For example, in February 2023, we terminated the Recordati License and Supply Agreement, which eliminated the potential for us to receive milestone and royalty payments from Recordati under the Recordati License and Supply Agreement. Although we found a partner for the regions previously licensed to Recordati, under the Recordati Termination Agreement, we are obligated to pay certain milestone and royalty payments to Recordati.

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 performs 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.

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. For example, we are currently a party to an appeal from a Final Written Decision in an Inter Partes Review of U.S. Patent No. 10,682,414 B2 and to an opposition proceeding at the European Patent Office with respect to EP 3678649, and we may be subject to new or additional 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, 2024 we co-own or exclusively license seven issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, and member states of the European Patent Organization, including the United Kingdom, directed to *neffy* and its uses, among other things, two pending U.S. non-provisional patent applications, one pending U.S. provisional patent application and over fifteen pending foreign patent applications directed to *neffy* and its uses, 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. 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 (such as the Russia and Ukraine conflict) 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. 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 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 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. 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.

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. 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.

We are currently a party to an appeal from a Final Written Decision in an Inter Partes Review of U.S. Patent No. 10,682,414 B2 and to an opposition proceeding at the European Patent Office with respect to EP 3678649. 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 or have 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 inhalable 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* as early as our approval by the FDA. Upon approval of *neffy* by the FDA, we listed 7 patents with claims covering *neffy* in the Orange Book. Any subsequent 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. 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 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 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. 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 may 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 may 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 recently expanded our organization following FDA approval of *neffy* in August 2024. Specifically, we added 108 people to 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 155 full-time employees and 5 part-time employees as of December 31, 2024. 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 potential for trade wars;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- 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.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined under the Jumpstart Our Business Startups Act (the "JOBS Act"). For so long as we are an "emerging growth company," we plan to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive, or us less comparable to certain other public companies because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period under the JOBS Act.

General Risk Factors

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 4,047 square feet of office space. On January 24, 2025, we entered into a lease amendment ("Headquarters Amendment") for our corporate headquarters, pursuant to which we will relocate to a new premises located in the same building which consists of 9,254 rentable square feet of office space. We will take possession of the new office space when the landlord's work is substantially complete, which is estimated to be July 1, 2025. We must vacate our current corporate headquarters within 15 days of taking possession of the new premises. Under the Headquarters Amendment, the term of the lease will be extended to 36 full calendar months following the date we take possession of the new office space. We believe that our existing facilities and those to be leased under the Headquarters Amendment 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 17, 2025, there were 16 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

On December 3, 2020, Silverback Therapeutics, Inc. ("Silverback") commenced its initial public offering ("IPO") pursuant to a registration statement on Form S-1 (File No. 333-250009) that was declared effective by the SEC on December 3, 2020, for 11,500,000 shares of its common stock for sale to the public at a price of $21.00 per share. In addition, in December 2020, the underwriters exercised their over-allotment option to purchase 1,725,000 additional shares of Silverback common stock in the initial public offering at the public offering price of $21.00 per share, such that the aggregate offering price of the IPO was $277.7 million. The net offering proceeds to Silverback, after deducting underwriting discounts and commissions and offering costs, were $255.3 million. No offering expenses were paid directly or indirectly to any of the Silverback directors or officers (or their associates) or persons owning 10% or more of any class of Silverback's equity securities or to any other affiliates. The underwriters for the Silverback initial public offering were Goldman Sachs & Co. LLC, SVB Leerink LLC, Stifel, Nicolaus & Company, Incorporated, and H.C. Wainwright & Co., LLC.

On November 8, 2022, Silverback completed its reverse merger with privately-held ARS Pharmaceuticals, Inc. On November 9, 2022, the combined company changed its name to ARS Pharmaceuticals, Inc.

The net proceeds from the IPO are held in cash and cash equivalents, primarily in treasury money market accounts, and investments, primarily in U.S. Treasury securities. Through December 31, 2024, approximately $243.0 million of the net proceeds from the IPO have been used, of which, (i) an estimated $51.7 million was used toward development of Silverback's product candidates, (ii) $0.8 million was used to repay outstanding indebtedness, (iii) $16.0 million was used for transaction costs related to the Merger, including $7.0 million in severance and change in control benefit payments made to Silverback's former officers, (iv) an estimated $65.4 million was used for development and pre-commercial launch activities related to *neffy*, (v) an estimated $78.1 million was used for working capital and general corporate purposes, and (vi) an estimated $31.0 million was used for commercial-related activities.

There have been no updates to the planned use of proceeds information from the IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on December 4, 2020, except as otherwise disclosed in our Annual Report on Form 10-K, filed with the SEC on March 31, 2022, and our Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2022. We intend to use the remaining net proceeds from the IPO, together with our existing cash and cash equivalents, to fund the manufacture and commercialization of *neffy* for the emergency treatment of Type I allergic reactions and other indications, if approved, as well as for working capital and other general corporate purposes. We may also use a portion of the net proceeds from the IPO to license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

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* (previously referred to as ARS-1 and, in the case of the 2 mg form, currently identified in the EU by the tradename *EURneffy*) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only FDA and EC-approved needle-free epinephrine product, and 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, which, except for *neffy*, is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million were prescribed an epinephrine autoinjector. However (in 2023, for example), only 3.2 million filled their active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector with them due to the many drawbacks of these devices. In aggregate, we estimate that up to 90% of patients prescribed an epinephrine device are not achieving an optimal treatment outcome today. We believe the market opportunity for *neffy* in the United States alone is significant. At the current list price for a two-pack of *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 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 billion in annual net sales.

These drawbacks include the use of needles, which can result in patient and caregiver injury as well as hesitation and delays in administration due principally to apprehension and pain of needles, allowing the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events. In particular, intra-muscular injections are subject to dosing errors and risk of accidental blood vessel injections, which can cause a significant spike in the intravascular delivery of epinephrine potentially leading to serious cardiovascular complications or events. 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.

Data from our studies of *neffy* and our intranasal epinephrine technology product candidates demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products across single dosing, repeat dosing, self-administration or allergen challenge conditions, and produced statistically significant responses compared to injection on pharmacodynamic surrogates for efficacy even one minute after dosing with *neffy* and our intranasal epinephrine technology product candidates.

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 commercial launch of *neffy* 2 mg in the United States, with product becoming available for shipment on September 23, 2024. This commercialization effort currently includes a direct sales force of 118 individuals targeting high-volume epinephrine prescribers that is supported by branded direct-to-consumer marketing, disease awareness campaigns with advocacy groups and non-personal promotion such as non-personal promotion including continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences. 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.

neffy U.S. Commercial Launch Initiated in September 2024

Our launch strategy for *neffy* in the United States involves an initial direct sales force outreach to high-volume prescribers of epinephrine accounting for 40% to 45% of prescriptions in the last year through an efficient sales force comprised of 118 individuals serving as sales reps, virtual reps and areas sales managers that began field operations in early October 2024; active participation since November 2024 of approximately 2,500 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; extensive non-personal promotion including continuing 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 payers 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; a telemedicine service to conveniently obtain a prescription online; partnerships with patient advocacy organizations including disease awareness campaigns in 2025; and branded direct to consumer advertising including a celebrity that is expected to commence in the second quarter of 2025.

On August 22, 2024, the EC granted marketing authorization in the EU for *EURneffy* (the trade name for *neffy* 2 mg in the EU), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. Through our collaboration with ALK (discussed below), we anticipate that *EURneffy* will be made available to patients in certain EU member states in 2025. Regulatory review of *neffy* is ongoing in Canada, the United Kingdom, China, Japan, and Australia with filings submitted by the partners, or by ARS Pharma on behalf of our partners, during the fourth quarter of 2024. *neffy* has already been approved or is under regulatory review in countries representing approximately 98% of the current global epinephrine autoinjector sales. Regulatory decisions are anticipated by mid-2025 in the U.K., the second-half of 2025 in Japan, year-end 2025 in Canada, and in the first-half of 2026 in China and Australia.

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, and anticipate initiating a Phase 2b randomized, placebo controlled outpatient clinical trial in chronic spontaneous urticaria patients on a chronic antihistamine treatment regimen who still experience flares or exacerbations. This Phase 2b study is anticipated to initiate in the second quarter of 2025, with topline data anticipated in early 2026, followed by the potential initiation of a single pivotal efficacy study in 2026.

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 began commercial operations in September 2024 and therefore have had limited net product sales. We have funded our operations primarily with proceeds from the Merger (see Note 1 - Nature of Business to the notes to the consolidated financial statements included in this report), private placement of convertible preferred stock, licensing, supply and distribution arrangements with our commercialization partners, bank debt, and limited net product sales. From inception to December 31, 2024, we have raised $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs, from the Merger; net proceeds of $76.3 million from the issuance of convertible preferred and common stock; $181.0 million from our collaboration, licensing, supply and distribution arrangements; $10.0 million from bank debt, $7.3 million from net product sales and $0.4 million in revenue under supply agreements. As of December 31, 2024, we had cash, cash equivalents, and short-term investments of $314.0 million.

We have incurred net losses from operations in most years since our inception. Our net income was $8.0 million for the year ended December 31, 2024 and our net loss was $54.4 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $123.3 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 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. 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.

ALK Agreement

In November 2024, the Company entered into a collaboration, license and distribution agreement (the "ALK Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the ALK 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 tradename for *neffy* 2 mg in the European Union) ("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 Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Agreement, we are obligated to transfer to ALK the existing marketing authorizations for the Products in ALK's territory. We are also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in ALK's 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 ALK's territory. Following such approval for a Product in each indication within specified countries within ALK's 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 Agreement.

Under the ALK Agreement, ALK made an upfront payment to us of $145.0 million in November 2024. We are eligible to receive regulatory and commercialization milestones of up to $20.0 million and sales-based milestones of up to $300.0 million, provided that $55.0 million of such sales-based milestones are contingent upon 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 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 Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Agreement for convenience upon 12 months' prior written notice or for a safety or regulatory concern. We may terminate the ALK 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 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 Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

ALK Supply Agreement

In November 2024, in connection with the ALK Collaboration Agreement, ARS and ALK also entered into a commercial supply agreement (the "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 the Company or ALK may terminate the Supply Agreement in the event of an uncured material breach of the other party.

Financial Overview

Revenues

We have recognized limited 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, up-front 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 related to the manufacture of *neffy* for commercial sale, including third-party manufacturing costs, raw material and component costs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, 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* will initially reflect a lower average per unit cost of materials, as previously expensed zero-cost inventory is utilized for commercial production and sold to customers. We expect the cost of goods sold for *neffy* to increase in relation to product revenues as we deplete these inventories. As of December 31, 2024, we had $11.7 million in zero-cost inventory remaining and based on our current forecast, we expect zero-cost inventory to be depleted by mid-2026.

The Company periodically evaluates zero-cost inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods as well as estimated sales trends. As of December 31, 2024, no zero-cost inventory was determined to be obsolete.

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:

- salaries, payroll taxes, benefits and stock-based compensation charges for personnel engaged in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or 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 third-party manufacturers;
- costs related to compliance with regulatory requirements and regulatory filings; and
- indirect expenses including insurance and facility-related expenses.

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, equity-based compensation expense, and indirect costs incurred in support of overall research and development, such as facilities-related costs.

We expect our research and development expenses to increase moderately in 2025 based on our planned clinical development and manufacturing activities. 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;
- 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, equity-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, market research costs, and insurance costs.

We expect our selling, general and administrative expenses to increase substantially in 2025. The increase in expenses is due to our sales force which was established in the third quarter of 2024, the development and commencement of our marketing campaigns and initiatives, 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, and net amortization and accretion associated with our short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023:

The following table summarizes our results of operations for years ended December 31, 2024 and 2023 (in thousands, except percentages):

	Year Ended December 31,		Dollar	%
	2024	2023	Change	Change
Revenue:				
Product revenue, net	$ 7,255	$ —	$ 7,255	* %
Revenue under collaboration agreements	81,529	30	81,499	*
Revenue under supply agreements	365	—	365	*
Total revenue	89,149	30	89,119	*
Operating expenses:				
Cost of goods sold	977	—	977	*
Research and development[(1)]	19,580	20,266	(686)	(3)
Selling, general and administrative[(1)]	71,675	47,284	24,391	52
Total operating expenses	92,232	67,550	24,682	37
Loss from operations	(3,083)	(67,520)	64,437	(95)
Other income, net	11,369	13,155	(1,786)	(14)
Income (loss) before income taxes	8,286	(54,365)	62,651	(115)
Income tax provision	288	—	288	*
Net income (loss)	$ 7,998	$ (54,365)	$ 62,363	(115)
Change in unrealized gains and losses on available-for-sale securities	171	(358)	529	(148)
Comprehensive income (loss)	$ 8,169	$ (54,723)	$ 62,892	(115) %

* Not meaningful

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

	Year Ended December 31,	
	2024	2023
Research and development	$ 2,955	$ 2,274
Selling, general and administrative	11,579	6,961
Total	$ 14,534	$ 9,235

Revenues. Revenues were $89.1 million and less than $0.1 million for the years ended December 31, 2024 and 2023. The revenues 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,* and $0.4 million in revenue under supply agreements. The revenues under collaboration agreements consists of $73.1 million under the ALK 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 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. The revenues for the year ended December 31, 2023 includes the recognition of revenue for the portion of upfront and clinical and regulatory milestone payments under our collaboration agreement with Alfresa that have been allocated to research and development services provided for during that period.

Cost of Goods Sold. Cost of goods sold were $1.0 million and $0.0 million for the years ended December 31, 2024 and 2023, respectively. Since prior to August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, the cost of goods sold for the year ended December 31, 2024 utilized zero-cost inventory and therefore consisted primarily of distribution fees, royalties, and intangible assets amortization.

Research and Development Expenses. Research and development expenses were $19.6 million and $20.3 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $0.7 million was primarily due to a $1.3 million decrease in product development expenses, a $1.2 million decrease in consulting fees, a $0.8 million decrease in clinical trial costs associated with *neffy,* a $0.4 million decrease in payroll-related expenses, and a $0.6 million decrease in other operating expenses. These aggregated decreases were partially offset by a $2.1 million increase in expense related to an EMA regulatory milestone under the Recordati Termination Agreement, a $0.8 million increase in outside services, and a $0.7 million increase in stock-based compensation,

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Clinical and regulatory	$ 8,033	$ 9,057
Manufacturing and non-clinical development	11,547	11,209
Total research and development expenses	$ 19,580	$ 20,266

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $71.7 million and $47.3 million for the years ended December 31, 2024 and 2023, respectively. The increase of $24.4 million was primarily due to a $11.8 million increase in marketing-related expenses, a $10.6 million increase in payroll-related expenses, a $4.6 million increase in stock-based compensation, a $2.3 million increase in outside services, a $1.6 million increase in legal fees, a $1.4 million increase in meals and travel-related expenses predominantly incurred by the sales team, a $0.4 million increase in professional fees for accounting, auditing and tax, and a $0.3 million increase in conference and seminar expenses. These aggregated increases were partially offset by a $6.6 million decrease in pre-commercial launch activities related to *neffy*, a $1.8 million decrease in consulting fees, and a $0.2 million decrease in other operating expenses.

Other Income, Net. Other income, net was $11.4 million and $13.2 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $1.8 million was primarily due to a $2.1 million decrease in interest income from our cash, cash equivalents, and short-term investments, a $0.3 million decrease from the sale of in-process research and development obtained in the Merger, which occurred in the year ended December 31, 2023, and a $0.3 million decrease in other items. These aggregated decreases were partially offset by a $0.9 million increase in net amortization and accretion associated with our short-term investments.

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 recognized limited net product sales since the commercial launch of *neffy* in September 2024. We have funded our operations to date primarily with proceeds from the Merger, the sale of preferred and common stock, revenue earned under collaboration, licensing, supply and distribution agreements with our commercialization partners, bank debt, and limited net product sales. From inception to December 31, 2024, we have raised $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs, from the Merger, net proceeds of $76.3 million from the issuance of convertible preferred and common stock, $181.0 million from our collaboration, licensing, supply and distribution arrangements, $10.0 million bank debt, and $7.3 million from net product sales, and $0.4 million in revenue under supply agreements. As of December 31, 2024, we had cash, cash equivalents, and short-term investments of $314.0 million.

Cash flows

The following table summarizes our cash flows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash and cash equivalents provided by (used in) operating activities	$ 13,548	$ (59,266)
Net cash and cash equivalents used in investing activities	(106,101)	(87,180)
Net cash and cash equivalents provided by financing activities	72,399	6,899
Net decrease in cash and cash equivalents	$ (20,154)	$ (139,547)

Operating Activities

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 liabilities of $18.5 million, an increase in our operating assets of $20.3 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 $7.3 million in net amortization of discounts on short-term investments.

During the year ended December 31, 2023, net cash used in operating activities was $59.3 million. This consisted primarily of a net loss of $54.4 million, a decrease in our operating liabilities of $5.9 million, an increase in our operating assets of $1.4 million, and non-cash charges of $2.4 million. The decrease in our operating liabilities was primarily due to a decrease in contract liability of $3.1 million and a decrease in accounts payable and accrued liabilities of $2.8 million. The increase in our operating assets was primarily due to an increase in prepaid and other assets of $1.4 million. The non-cash charges consisted of non-cash stock-based compensation of $9.2 million, partially offset by $6.9 million in net amortization of discounts on short-term investments.

Investing Activities

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, maturities of short-term investments of $258.0 million, payments of milestone obligations under license agreements of $7.5 million, and purchases of property and equipment of $0.6 million.

During the year ended December 31, 2023, the cash and cash equivalents used in investing activities was $87.2 million. This consisted primarily of purchases of short-term investments of $272.0 million, maturities of short-term investments of $185.0 million, and purchases of property and equipment of $0.2 million.

Financing Activities

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 the employee stock purchase plan.

During the year ended December 31, 2023, the cash and cash equivalents provided by financing activities was $6.9 million, which consisted of proceeds from stock option exercises and the employee stock purchase plan.

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:

- 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;
- revenue received from commercial sales of *neffy*;
- the timing and amount of any milestone and royalty payments under the ALK Agreement, Pediatrix Agreement, Aegis Agreement, Alfresa Agreement, Recordati Termination Agreement, and the Seqirus Agreement;
- 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;
- 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. 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 potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States, including due to bank failures, and worldwide resulting from macroeconomic factors. 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.

Material Cash Requirements

The total amount of unconditional purchase obligations related to the supply of raw materials is $64.9 million as of December 31, 2024. Payment obligations by year are as follows: 2025 ($8.2 million), 2026 ($10.5 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035.

The total amount of unconditional purchase obligations related to hosted software license subscription fees is $3.3 million as of December 31, 2024. Payment obligations by year are as follows: 2025 ($1.4 million), 2026 ($1.5 million), and 2027 ($0.4 million).

In August 2024, we entered into a corporate sponsorship agreement with Food Allergy Research and Education, Inc. pursuant to which we have payment obligations of $9.0 million over a 28-month period. Our remaining payment obligations as of December 31, 2024 are $7.0 million. Estimated payments by year are as follows: 2025 ($4.0 million), and 2026 ($3.0 million).

In June 2018, we entered into a License Agreement (the "Aegis Agreement") with Aegis Therapeutics, LLC ("Aegis"). 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*. Our remaining payment obligations to OrbiMed under the Aegis Agreement are contingent upon our achievement of certain commercial milestones and have been reduced to $11.0 million as of December 31, 2024. Under the Aegis Agreement, 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.

On February 22, 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"). Pursuant to which, we are obligated to make milestone payments to Recordati that are contingent upon our achievement of certain regulatory and commercial milestones. Our remaining milestone payment obligations to Recordati have been reduced to €5.0 million (approximately $5.2 million in U.S. dollars) as of December 31, 2024. Under the Recordati Termination Agreement, we are also required to make royalty payments to Recordati of up to €5.0 million (approximately $5.2 million in U.S. dollars) in the aggregate from sales of Recordati Licensed Product(s) in the Recordati Territory. 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, 2024, we have not recognized any reserves related to uncertain tax positions. As of December 31, 2024, we had no accrued interest or penalties related to uncertain tax positions.

Critical Accounting Policies and Significant Judgments and 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.

Net Product Revenue

Our revenues generally consist of product sales of *neffy* and licenses and milestone revenue generated from license and collaboration agreements.

We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers. 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) we satisfy each performance obligation. At contract inception, we assess the goods or services promised within each contract, determine whether each promised good or service is distinct and identify those that are performance obligations. We recognize 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 is recorded with each sale at wholesale acquisition cost, net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as "Gross-to-Net Adjustments." In accordance with ASC 606, the Company must make significant judgments to determine the estimates for certain Gross-to-Net Adjustments. Estimates for Gross-to-Net Adjustments are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net income in the period of adjustment.

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved.

Collaboration and License Agreements

The Company has entered into collaboration and licensing agreements, including supply and distribution, to license certain rights to *neffy* to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front 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, up-front 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 our repurchase would be accounted for as additional financing proceeds and would increase the financing obligation on our 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, up-front 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. 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 the distinct performance obligations included in the arrangement, 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, or 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.

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). The Company has not received any royalty or transfer price revenues as of December 31, 2024.

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.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earlier of: (i) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; and (ii) December 31, 2025.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year for which audited financial statements are available as of the date of determination and the market value of our stock held by non-affiliates is less than $700 million measured on the last business day of our most recently completed second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

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

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, 2024 and 2023, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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.

/s/ Ernst & Young LLP

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

San Diego, California
March 20, 2025

ARS Pharmaceuticals, Inc.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 50,817	$ 70,971
Short-term investments	263,205	157,389
Accounts receivable, net	8,175	—
Inventories	5,212	—
Prepaid expenses and other current assets	6,886	3,366
Total current assets	334,295	231,726
Long-term inventories	5,307	—
Right-of-use asset	37	250
Fixed assets, net	1,029	574
Intangible assets, net	7,371	—
Other assets	3,114	638
Total assets	$ 351,153	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $656 and $178, respectively)	$ 22,841	$ 2,154
Contract liability, current	557	—
Lease liability, current	42	237
Total current liabilities	23,440	2,391
Financing liability	69,383	—
Contract liability	1,532	—
Lease liability, net of current portion	—	37
Total liabilities	94,355	2,428
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2024 and 2023; 97,954,172 and 96,414,963 shares issued and outstanding at December 31, 2024 and 2023, respectively	10	10
Additional paid-in capital	379,873	362,004
Accumulated other comprehensive gain, net	220	49
Accumulated deficit	(123,305)	(131,303)
Total stockholders' equity	256,798	230,760
Total liabilities and stockholders' equity	$ 351,153	$ 233,188

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

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share information)

	Year Ended December 31,	
	2024	2023
Revenue:		
Product revenue, net	$ 7,255	$ —
Revenue under collaboration agreements	81,529	30
Revenue under supply agreements	365	—
Total revenue	89,149	30
Operating expenses:		
Cost of goods sold (including related party amounts of $241 and $0, respectively)	977	—
Research and development (including related party amounts of $2,066 and $1,796, respectively)	19,580	20,266
Selling, general and administrative (including related party amounts of $465 and $940, respectively)	71,675	47,284
Total operating expenses	92,232	67,550
Loss from operations	(3,083)	(67,520)
Other income, net	11,369	13,155
Income (loss) before income taxes	8,286	(54,365)
Income tax provision	288	—
Net income (loss)	$ 7,998	$ (54,365)
Change in unrealized gains and losses on available-for-sale securities	171	(358)
Comprehensive income (loss)	$ 8,169	$ (54,723)
Net income (loss) per share:		
Basic	$ 0.08	$ (0.57)
Diluted	$ 0.08	$ (0.57)
Weighted-average shares outstanding used in computing net income (loss) per share:		
Basic	96,936,661	95,215,322
Diluted	102,390,828	95,215,322

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

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain, Net	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	93,943,316	$ 9	$ 349,408	$ 407	$ (76,938)	$ 272,886
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	2,471,647	1	6,899	—	—	6,900
Stock-based compensation	—	—	9,347	—	—	9,347
Removal of retrospective insurance policy acquired in the Merger	—	—	(3,650)	—	—	(3,650)
Net loss and comprehensive loss	—	—	—	(358)	(54,365)	(54,723)
Balance at December 31, 2023	96,414,963	$ 10	$ 362,004	$ 49	$ (131,303)	$ 230,760
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	1,539,209	—	3,017	—	—	3,017
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

The accompanying notes are an integral part of these financial statements

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 7,998	$ (54,365)
Non-cash adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation expense	14,534	9,235
Depreciation	79	73
Amortization and accretion, net	(7,254)	(6,848)
Changes in operating assets and liabilities:		
Accounts receivable	(8,175)	—
Inventories	(5,945)	—
Prepaid and other assets	(6,191)	(1,435)
Accounts payable and accrued liabilities (including related party amounts of $478 and $162, respectively)	16,432	(2,777)
Operating right-of-use assets and lease liabilities, net	(19)	(12)
Contract liability	2,089	(3,137)
Net cash provided by (used in) operating activities	13,548	(59,266)
Cash flows from investing activities:		
Purchases of short-term investments, available-for-sale	(356,038)	(272,005)
Maturities of short-term investments, available-for-sale	258,000	185,000
Payments of milestone obligations under license agreements	(7,500)	—
Purchase of property and equipment	(563)	(175)
Net cash used in investing activities	(106,101)	(87,180)
Cash flows from financing activities:		
Financing liability	69,383	—
Proceeds from exercise of common stock options and employee stock purchase plan	3,016	6,899
Net cash provided by financing activities	72,399	6,899
Net change in cash and cash equivalents	(20,154)	(139,547)
Cash and cash equivalents at beginning of period	70,971	210,518
Cash and cash equivalents at end of period	$ 50,817	$ 70,971
Supplemental cash flow information:		
Removal of retrospective insurance policy acquired in the Merger, included in prepaid and other current assets and other assets, and related reduction in additional paid in capital	$ —	$ 3,649
Stock-based compensation capitalized into inventory	$ 319	$ —
Purchases of inventories included in accounts payable	$ 4,255	$ —
Purchases of property and equipment reclassed from prepaid expenses and other current assets	$ —	$ 174

The accompanying notes are an integral part of these 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* (previously referred to as ARS-1 and currently identified in the EU by the trade name *EURneffy*) for the needle-free intranasal delivery of epinephrine for the 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 since its inception and had an accumulated deficit of $123.3 million as of December 31, 2024. The Company had cash, cash equivalents, and short-term investments of $314.0 million as of December 31, 2024 and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily with proceeds from the merger with Silverback in November 2022 (the "Merger"), the issuance of convertible preferred stock, payments earned under collaboration agreements, bank debt, and limited net product sales. The Company's currently available cash, cash equivalents, and short-term investments as of December 31, 2024 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, 2024, 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 ever achieve profitability, 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 consolidated statements of operations and comprehensive income (loss). All adjustments considered necessary for a fair presentation have been included.

Use of Estimates

The preparation of the Company's consolidated financial statements requires it 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 relate to revenue recognized for its collaboration agreements, accruals for variable components of product revenue, and accruals for research and development expenses and valuation of equity awards. 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.

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.

Trade Accounts Receivable and Allowance

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. Trade accounts receivable 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 based on each customer's trade accounts receivable balance and age, their financial condition, and the general economic environment. The Company must also use professional judgment because *neffy* was commercially launched in September 2024 and historical data is limited. The Company is currently operating under the Title Agreement (as defined in Note 4 - Revenue) with its 3PL Agent (as defined in Note 4 - Revenue) and the 3PL Agent retains all credit and collection risk on sales to the Company's wholesale distributors and pharmacy customers.

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. No allowance for credit losses was deemed necessary at December 31, 2024.

Investments

The Company invests excess cash in investment grade fixed income securities. These investments are included in short-term investments on the 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 net income or loss.

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, accounts payable, accrued liabilities, and contract liability, are considered to be representative of their respective fair values because of the short-term nature of those instruments.

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 trade accounts receivable from product sales. *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 extends credit to its customers in the normal course of business after evaluating their overall financial condition. As stated above, the Company is currently operating under the Title Agreement with its 3PL Agent (as defined in Note 4 - Revenue) and the 3PL Agent retains all credit and collection risk on sales to the Company's wholesale distributors and pharmacy customers. As of December 31, 2024, the Company's 3PL Agent made up 93% of its trade accounts receivable balance. For the year ended December 31, 2024, the Company's seven largest customers combined made up 94% of its gross product sales. Historically, the Company has not experienced any credit losses from product sales. For the year ended December 31, 2024, the Company's three largest customers combined made up 100% of its revenue under collaboration agreements.

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 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 which 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.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment 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, 2024.

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 consolidated statements of operations and comprehensive income (loss).

Intangible Assets

Intangible assets are measured at fair value as of the acquisition date or, in the case of commercial 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.

Revenue Recognition

The Company's revenues consist of product sales of *neffy* and revenue derived from its collaboration and out-licensing agreements. See Note 4 - Revenue for more detail on product revenue, and Note 9 - Collaboration and Out-Licensing for more detail on revenue from collaboration and out-licensing agreements.

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.

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including 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* will initially reflect 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 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.

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 when the advertisement occurs. The Company's advertising expense was $12.5 million for the year ended December 31, 2024.

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 on existing agreements are charged to research and development expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use.

Acquired in-process research and development expense

Acquired in-process research and development expense ("IPR&D") is expensed on the acquisition date if there is no alternative future use. Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration becomes payable. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

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.

Comprehensive Income (Loss)

Comprehensive income (loss) 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 income or loss 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 November 2023, the FASB issued ASU 2023-07, Segment Reporting (ASU 2023-07), which requires issuers to make additional disclosures with respect to segment expenses, including required disclosure on an annual and interim basis for significant segment expenses and other segment items. ASU 2023-07 also permits the disclosure of more than one measure of a segment's profit or loss. ASU 2023-07 was effective for the Company on January 1, 2024 for annual periods and on January 1, 2025 for interim periods. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements — Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for the Company beginning in fiscal year 2025, with early adoption permitted. The Company does not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on the financial statements and related disclosures.

3. Net Income (Loss) Per Share

Basic net income (loss) per share attributable to common stockholders is calculated using the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net income (loss) per share attributable to common stockholders is calculated using the weighted-average number of common stock outstanding and, when dilutive, potential shares of common stock outstanding during the period. The impact of potential shares of common stock outstanding is generally antidilutive during periods of net loss.

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

	As of December 31,	
	2024	2023
Net income (loss) per share, basic:		
Net income (loss)	$ 7,998	$ (54,365)
Shares used in computation:		
Weighted-average common shares outstanding, basic	96,936,661	95,215,322
Net income (loss) per share, basic	$ 0.08	$ (0.57)
Net income (loss) per share, diluted:		
Net income (loss)	$ 7,998	$ (54,365)
Shares used in computation:		
Weighted-average common shares outstanding, basic	96,936,661	95,215,322
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	—
Diluted weighted-average common shares outstanding	102,390,828	95,215,322
Net income (loss) per share, diluted	$ 0.08	$ (0.57)

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

	As of December 31,	
	2024	2023
Warrants to purchase common stock	—	45,456
Common stock options granted and outstanding	6,265,948	11,493,481
Restricted stock units	—	4,144
	6,265,948	11,543,081

4. Revenue

The Company's revenues consist primarily of product sales of *neffy* and revenue derived from its collaboration and out-licensing agreements. See Note 9 - Collaboration and Out-Licensing for further discussion related to those arrangements.

Product Revenue

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 uses a third party logistics provider ("3PL Agent") to fulfill orders of *neffy* to the Company's customers. The 3PL Agent provides services to the Company that include warehousing, distribution, order and accounts receivable management, and data management.

The Company entered into a title model agreement ("Title Agreement") with the 3PL Agent so that the 3PL Agent may purchase and take title to *neffy* and then sell it to the Company's wholesale distributors and pharmacy customers that have contracted to make a purchase. Under the Title Agreement, the economic substance of the transaction is such that the Company does not recognize revenue until *neffy* is sold and title has transferred from the 3PL Agent to a wholesale distributor or pharmacy.

The Company also entered into sales agreements with pharmacies that are not subject to the Title Agreement. Under these agreements, the pharmacy holds *neffy* under consignment. Under the consignment model, the Company recognizes revenue when *neffy* is sold to a patient, at which point title transfers from the Company directly to the patient.

Product revenue is recorded with each sale at the transaction price, net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as "Gross-to-Net Adjustments." Estimates for Gross-to-Net Adjustments are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net income in the period of adjustment. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Trade Accounts Receivable and Allowance policy in Note 2 - Summary of Significant Accounting Policies.

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain Gross-to-Net Adjustments. The specific considerations that the Company uses in estimating the amounts related to Gross-to-Net Adjustments are as follows:

Distribution services 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 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 purchased amount. These discounts are recorded as contra trade accounts receivable on the 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 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 cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the 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 in rebates 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 at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the 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 being recognized for product that remains in the distribution channel at the end of each reporting period. Co-payment programs estimates are recorded as other current liabilities on the 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 lack of historical sales and returns data, the Company used professional judgment and industry data to estimate returns. A reserve for potential product returns is recorded as other current liabilities on the consolidated balance sheets.

5. Inventories

The Company began to capitalize the inventory costs associated with *neffy* upon FDA approval in August 2024 when future commercialization was considered probable and it was determined that the inventory had a probable future economic benefit. These inventory costs consist primarily of purchased materials, third-party manufacturing costs, and packaging and serialization services. Noncurrent inventory consists of inventory anticipated to remain on hand for more than one year from the balance sheet date.

Capitalized inventories consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Finished goods	$ 5,212	—
Total inventory, current	5,212	—
Raw materials, noncurrent	4,674	—
Work in process, noncurrent	19	—
Finished goods, noncurrent	614	—
Total inventory	$ 10,519	$ —

Prior to FDA approval in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which upon approval resulted in zero-cost inventory. The Company had $11.7 million in zero-cost inventory remaining as of December 31, 2024, none of which was determined to be obsolete.

6. 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, the 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):

December 31, 2024	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair Value
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
December 31, 2023					
Cash and cash equivalents - Money market mutual funds	1	$ 69,938	$ —	$ —	$ 69,938
Short-term investments - U.S. Treasury securities	2	157,340	61	(12)	157,389
Total		$ 227,278	$ 61	$ (12)	$ 227,327

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 year ended December 31, 2024, the Company purchased $356.0 million in short-term investments, and there was $258.0 million in maturities of short-term investments. During the year ended December 31, 2023, the Company purchased $272.0 million in short-term investments, and there was $185.0 million in maturities of short-term investments.

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 a $0.2 million net unrealized gain on available-for-sale securities for the year ended December 31, 2024 and a $0.4 million net unrealized loss on available-for-sale securities for the year ended December 31, 2023. For the year ended December 31, 2023, $0.3 million was reclassified from accumulated other comprehensive gain to other income. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of December 31, 2024 were primarily attributable to current economic and market conditions and not credit risk. As of December 31, 2024 and 2023, no allowance for credit losses was recorded. 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 on the Company's available-for-sale securities was $1.0 million as of December 31, 2024 and is included in prepaid expenses and other current assets in the accompanying consolidated balance sheet.

As of December 31, 2024 and 2023, the Company did not have any liabilities that were measured at fair value on a recurring basis.

7. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Prepaid expenses	$ 3,406	$ 1,124
Prepaid insurance	1,261	904
Interest receivable	987	686
Other	1,232	652
Total	$ 6,886	$ 3,366

Fixed assets, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Equipment	$ 950	$ 590
Furniture and fixtures	255	81
Leasehold improvements	24	24
Less accumulated depreciation	(200)	(121)
Total	$ 1,029	$ 574

Depreciation expense was $0.1 million for the years ended December 31, 2024 and 2023.

Other long-term assets consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Prepaid supply agreement fee	$ 2,800	$ —
Capitalized software implementation costs	314	617
Security deposit	—	21
Total	$ 3,114	$ 638

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

	December 31, 2024	December 31, 2023
Accounts payable	$ 9,870	$ 759
Accrued inventory	4,255	—
Accrued compensation	2,293	315
Accrued gross-to-net adjustments	2,179	—
Accrued marketing related expenses	1,855	42
Other	2,389	1,038
Total	$ 22,841	$ 2,154

8. Intangible assets, net

As described in Note 11 - In-Licensing and Supply, under the Aegis Agreement the Company capitalized a $2.5 million milestone payment in August 2024 and a $5.0 million milestone payment in September 2024. The assets are amortized on a straight-line basis over the estimated life of the intellectual property of 14.5 years, beginning from the first commercial sale of *neffy* in September 2024.

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

	December 31, 2024	December 31, 2023
Capitalized milestone payments	$ 7,500	$ —
Less accumulated depreciation	(129)	—
Total	$ 7,371	$ —

The amortization expense for the year ended December 31, 2024 was $0.1 million.

As of December 31, 2024, estimated future amortization expense for capitalized intangible assets is as follows for the next five years (in thousands):

	Amount
2025	$ 517
2026	517
2027	517
2028	517
2029	517
Total	$ 2,585

9. Collaboration and Out-Licensing

The Company has entered into collaboration and licensing agreements, including supply and distribution, to license certain rights to *neffy* to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front 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, up-front 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 would be accounted for as additional financing proceeds and would increase the financing obligation on the Company's 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, up-front 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. 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.

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). The Company has not received any royalty or transfer price revenues as of December 31, 2024.

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 for the rights pursuant to the LOI. Under the 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 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 addition to the $2.0 million received under the LOI, the Company was initially eligible to receive up to $13.0 million of milestone payments upon achievement of certain clinical and regulatory milestones. Further, the Company is eligible to receive a negotiable transfer price expected to be in the low-double-digit percentage on net sales subject to the regulatory approval to commercialize *neffy* in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy* and research and development services, both of which have been completed. The Company determined the initial transaction price to be $7.0 million, which includes a clinical milestone as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the regulatory and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be reassessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation.

In July 2020, the Company earned a $5.0 million milestone payment upon the completion of a clinical milestone in Japan. In November 2024, the Company earned a $6.0 million milestone payment upon the completion of a regulatory milestone in Japan. Of the $13.0 million in milestone payments that the company was eligible to earn, $11.0 million in milestone payments has been earned and a final $2.0 million regulatory milestone remains. The Company recognized $6.0 million and less than $0.1 million in revenue for the years ended 2024 and 2023, respectively, in the accompanying consolidated statements of operations and comprehensive income (loss). There was no contract liability as of December 31, 2024.

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 terms of the Recordati Agreement, the Company received an upfront payment of $11.8 million and a regulatory milestone payment of $6.0 million during 2020.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy* in the defined territory and the research and development services. The Company determined the initial transaction price to be the $11.8 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, at inception of the contract, the variable consideration associated with future milestone payments was fully constrained and excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. In November 2020, the Company earned a regulatory milestone of $6.0 million.

On February 22, 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 has 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 a Recordati Licensed Product in the Recordati Territory, and (iii) royalty payments of up to €5.0 million in the aggregate from sales of Recordati Licensed Product(s) 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 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 accompanying consolidated statements of operations and comprehensive income (loss). 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 income (loss). The Company paid the EMA regulatory milestone to Recordati in July 2024.

Pediatrix Agreement

In March 2021, the Company entered into a Collaboration and Distribution 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. Under the 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 defined 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 agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue as long as Pediatrix has commercial sales of *neffy* in the region, or 10 years after the first commercial sale.

Under the terms of the agreement, the Company received an upfront payment of $3.0 million. In addition, the Company is eligible to receive up to $84.0 million of milestone payments upon achievement of certain regulatory and commercial sales milestones. The next eligible milestone is a $4.0 million regulatory milestone. Subject to regulatory approval, the Company will earn tiered royalties in the low-double-digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Pediatrix.

At the commencement of this collaboration, the Company identified performance obligations related to the delivery of the license for *neffy* in the defined territory and manufacturing of product for clinical studies and commercial supply. The Company concluded that the license was distinct from potential supply obligation. The supply provisions are effectively options granted to Pediatrix to purchase future goods and did not contain a material right. The Company determined the initial transaction price to be the $3.0 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be reassessed at each reporting period. The Company recognized revenue of the full $3.0 million during the year ended December 31, 2021.

Seqirus Agreement

In March 2024, the Company entered into a License and Distribution Agreement (the "Seqirus Agreement") with Seqirus Pty, Ltd. ("Seqirus") 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.

Under the terms of the Seqirus Agreement, the Company received an upfront payment of $0.5 million in May 2024. In addition, the Company was eligible to receive up to $4.5 million of milestone payments upon achievement of certain event milestones. Subject to regulatory approval in Australia and New Zealand, the Company will also receive a per unit supply price for the sale of commercial supply to Seqirus.

At the commencement of this collaboration, the Company identified one performance obligation which is the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how. The Company determined that the option to purchase the commercial supply does not represent a material right. The Company determined the initial transaction price to be the $0.5 million upfront payment. Due to the uncertainty in the achievement of all the regulatory milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. The variable consideration will be reassessed at each reporting period. In May 2024, the Company delivered the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how and recognized $0.5 million in revenue. In August 2024, the first milestone event was met and the Company recognized $1.5 million in revenue. In summary, the Company recognized $2.0 million in revenue for the year ended December 31, 2024 in the accompanying consolidated statements of operations and comprehensive income (loss).

ALK Agreement

In November 2024, the Company entered into a Collaboration, License and Distribution Agreement (the "ALK Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the ALK 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 Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Agreement, the Company is obligated to transfer to ALK the existing marketing authorizations for the Products in ALK's 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 ALK's 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 ALK's territory. Following such approval for a Product in each indication within specified countries within ALK's 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 Agreement.

Under the ALK Agreement, ALK made a $145.0 million upfront payment to the Company in November 2024. The Company is eligible to receive regulatory and commercialization milestones of up to $20.0 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 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 Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Agreement for convenience upon 12 months' prior written notice or for a safety or regulatory concern. The Company may terminate the ALK 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 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 Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

In connection with the ALK Agreement, the Company and ALK also entered into a commercial supply agreement (the "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 Supply Agreement is coterminous with the ALK Agreement. Either the Company or ALK may terminate the Supply Agreement in the event of an uncured material breach of the other party.

Accounting Assessment

The Company concluded that the ALK Agreement and the 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 Agreement, and (ii) the promises under the 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, 2024, 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 has 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.

Revenue should be recognized when, or as, an entity satisfies a performance obligation by transferring a promised good or service to a customer, i.e., when the customer obtains control of the good or service. The licenses granted to ALK are being accounted for as distinct performance obligations. The licenses relate to functional intellectual property for which revenue is recognized at a point in time. In the case of the EEA License, the Company evaluated the impact of the Company's Repurchase Option, and determined that, as a result of the Company's ability to repurchase the license, control of the EEA License has not been transferred to ALK under ASC 606. The Company determined that the transaction price allocated to the EEA License should be accounted for as a financing liability, due to the repurchase price being greater than the original selling price of this performance obligation. Control of the EEA License will not be considered transferred to ALK until such time that the Repurchase Option lapses, which under the terms of the ALK Agreement, will occur upon the expiration of the contract, or exercise by the Company of the Repurchase Option. The Company recognized the transaction price allocated to the EEA License of $69.4 million as a financing liability in its consolidated balance sheet as of December 31, 2024.

In the case of the ROW License, the point in time for recognition of revenue was shortly after the inception of the contract because the customer obtained control of the license and was able to use and benefit from its right to use the intellectual property at that point. The Company recognized the transaction price allocated to the ROW License of $73.1 million as revenue under collaboration agreements in its consolidated statements of operations and comprehensive income (loss) for the year ended December 31, 2024.

The development and regulatory services performance obligations under the ALK Agreement each represent a separate performance obligation. The development and regulatory services, which are transferred to the customer over time, were provided to ALK from inception of the agreement and are expected to continue through 2028. Revenue related to the development and regulatory services performance obligations was initially recorded as contract liability and is being 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. The Company recognized $0.5 million of revenue related to the development and regulatory services performance obligations during the year ended December 31, 2024 on its consolidated statements of operations and comprehensive income (loss). As of December 31, 2024, the accompanying consolidated balance sheet includes a contract liability of $0.6 million classified as current and $1.5 million classified as noncurrent, associated with these performance obligations, based on the expected period of performance for the development and regulatory services.

Contract Liability

A reconciliation of contract liability from collaboration and licensing agreements is as follows (in thousands):

Balance at December 31, 2023	$	—
Contract liability at inception under the ALK Agreement		2,563
Revenue recognized under the ALK Agreement		(474)
Balance at December 31, 2024	$	2,089

10. Commitments and Contingencies

Leases

In October 2021, the Company entered into a 38-month noncancelable lease for its current headquarters location consisting of 4,047 rentable square feet of office space in San Diego, California. Under the terms of the agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. Monthly rental payments due under the lease commenced on December 6, 2021 and escalate through the lease term. The Company prepaid the first month's rent upon execution of the lease, and the lease agreement provided full rent abatement for the second and third months of the rental term. As of December 31, 2024, the remaining lease term of the Company's operating lease was 2 months, and the discount rate on the Company's operating lease was 8%. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates. The Company's operating lease expense was $0.2 million for each of the years ended December 31, 2024 and 2023. The Company's variable lease expense was immaterial for each of the years ended December 31, 2024 and 2023. Cash paid for amounts included in the measurement of lease liabilities was $0.2 million for each of the years ended December 31, 2024 and 2023.

As of December 31, 2024, future minimum noncancelable operating lease payments are as follows (in thousands):

Year ending December 31,	Amount
2025	$ 42
Total lease payments	42
Less imputed interest	—
Lease liability	42
Less current portion of lease liability	(42)
Lease liability, net of current portion	$ —

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 August 12, 2021, Amphastar Pharmaceuticals, Inc. ("Amphastar") filed a Petition for Inter Partes Review with the United States Patent and Trademark Office ("USPTO"), seeking to invalidate claims 1-20 of United States Patent No. 10,682,414 (the "'414 patent"). The '414 patent issued on June 16, 2020 and is entitled "Intranasal Epinephrine Formulations and Methods for the Treatment of Disease." The claims of the '414 patent are directed to methods of treating a type-1 hypersensitivity reaction, including anaphylaxis, using an aqueous nasal spray pharmaceutical formulation containing epinephrine or a salt thereof in a single dose. On February 9, 2023, the USPTO issued a Final Written Decision finding claims 3-6 and 18-20, which encompass the Company's *neffy* product candidate, patentable, and claims 1-2 and 7-17 unpatentable. On April 12, 2023, Amphastar filed a notice of appeal with the United States Court of Appeals for the Federal Circuit. On March 5, 2025, following the completion of briefing by the parties, Amphastar stipulated to the dismissal of its appeal. As a result, the USPTO's Final Written Decision stands – affirming the validity of claims 3-6 and 18-20 of the '414 patent.

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. The Company filed a response to the notice of opposition on December 15, 2023. The EPO scheduled oral proceedings on October 7, 2025, and the Company will continue to vigorously defend the EP '649 Patent. The results of any notice of opposition are inherently unpredictable and uncertain, and could result in the EPO finding the patent to be invalid or unenforceable.

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, 2024.

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.

The total amount of unconditional purchase obligations related to the supply of raw materials is ($64.9) million as of December 31, 2024. Payment obligations by year are as follows: 2025 ($8.2 million), 2026 ($10.5 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035. During the year ended December 31 2024, the Company made $0.2 million in purchases under these obligations.

The total amount of unconditional purchase obligations related to hosted software license subscription fees is $3.3 million as of December 31, 2024. Payments by year are as follows: 2025 ($1.4 million), 2026 ($1.5 million), and 2027 ($0.4 million). During the year ended December 31 2024, the Company made $0.6 million in payments under this agreement.

The total amount of commitments related to a corporate sponsorship agreement with Food Allergy Research and Education, Inc. is $7.0 million as of December 31, 2024. Payments by year are as follows: 2025 ($4.0 million) and 2026 ($3.0 million). During the year ended December 31 2024, the Company made $2.0 million in payments under this agreement.

The amounts above do not represent the entire anticipated spend 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 statement of operations.

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 consolidated statement 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. Since the approval of *neffy* in August 2024, regulatory milestone payments have been capitalized as intangible assets in the accompanying consolidated balance sheets. Amortization expense has been recorded to cost of goods sold, in the accompanying consolidated statements of operations and comprehensive income (loss), on a straight-line basis over the estimated life of the intellectual property of 14.5 years. In August 2024, a $2.5 million milestone was met for achieving FDA approval of *neffy*. In September 2024, a $5.0 million milestone was met for the first commercial sale of *neffy*. As a result, the Company capitalized $7.5 million as intangible assets in the accompanying consolidated balance sheets in the third quarter of 2024. The Company paid the $2.5 million milestone for achieving FDA approval of *neffy* in September 2024, and paid the $5.0 million milestone for the first commercial sale of *neffy* in October 2024. The next milestone payment of $2.0 million is due upon the achievement of certain annual net sales.

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*. Therefore the Company will make all future payments under the Aegis Agreement to OrbiMed. As described in Note 16 - 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 patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. There were no expenses recognized in connection with legal patent fees for the years ended December 31, 2024 and 2023.

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. Under the Aegis Supply Agreement, the Company paid $0.7 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

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 and September 2024 (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 (a) for Renaissance Product designated for commercial sale in the U.S., on December 31 immediately following the fifth anniversary of the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the EU, on December 31 immediately following the fifth anniversary of the initial EU launch date ("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.

Supply Agreement with Ompi

In October 2024, the Company entered into a supply agreement (the "Ompi Agreement") with Nuova Ompi S.r.l. ("Ompi"), pursuant to which Ompi has agreed to supply glass microvials to support the Company's manufacture and commercialization of *neffy*. Under the Ompi Agreement, the Company has committed to purchase, and Ompi has committed to supply, specified annual minimum quantities of glass microvials, which may be increased with prior notice by the Company or through the rolling forecast process, subject to a specified annual cap. Ompi is obligated to establish the relevant manufacturing force, assets and capabilities needed to comply with its supply obligations.

In December 2024, as partial consideration for the supply arrangement, the Company made an upfront payment of €3.0 million (approximately $3.2 million in U.S. dollars) to Ompi. The supply price for the glass microvials is specified in the Ompi Agreement, subject to an annual adjustment that is capped at a specified percentage except in the case of material and extraordinary increase in Ompi's cost of manufacturing the glass microvials.

The Ompi Agreement will expire on December 31, 2035, and may be terminated (i) upon the parties' mutual written consent, (ii) by the Company for any reasonable business reasons (in which case the termination will become effective at the end of the following calendar year), or (iii) by the non-breaching party if the other party is in material breach of the Ompi Agreement and fails to cure such breach within 90 days after receipt of notice thereof from the non-breaching party.

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

Common stock reserved for future issuance consisted of the following:

	December 31, 2024	December 31, 2023
Common stock options granted and outstanding	15,161,180	11,493,481
Restricted stock units granted and outstanding	2,763	4,144
Common stock reserved for future awards or option grants	5,905,773	6,220,866
Warrants to purchase common stock	45,456	45,456
Total	21,115,172	17,763,947

13. Stock-Based Compensation

Stock-based compensation expense recognized for all equity awards has been reported in the consolidated statements of operations and comprehensive income (loss) as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expense	$ 2,955	$ 2,274
Selling, general and administrative expense	11,579	6,961
Total stock-based compensation expense	$ 14,534	$ 9,235

During the years ended December 31, 2024 and 2023, $0.3 million and no stock compensation expense was capitalized into inventory, respectively.

As of December 31, 2024, the total unrecognized stock-based compensation expense related to outstanding employee options was $41.1 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.52 years.

There were 2,763 and 4,144 and restricted stock units outstanding as of December 31, 2024 and 2023, 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"). During the years ended December 31, 2024 and 2023, there were 69,686 and 44,961 shares of common stock purchased under the ESPP, respectively.

As of December 31, 2024, 20,839,408 shares were authorized under the 2016 and 2020 Equity Incentive Plans, of which 5,608,428 shares were available for future grant, and 10,721,740 shares were outstanding. As of December 31, 2024, 6,634,333 shares were authorized under the 2018 Equity Incentive Plan, of which 297,345 shares were available for future grant, and 4,442,203 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 four-year period, with vesting either occurring at a rate of 25% at the end of the first year and thereafter in 36 equal monthly installments or on a monthly basis. In the case of awards granted to the Company's non-employee board members, vesting generally occurs on a monthly basis over three years or in full on an annual basis. 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, 2024 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, 2023	11,493,481	$ 5.32		
Granted	5,315,325	$ 8.36		
Exercised	(1,468,142)	$ 1.83		
Forfeited	(179,484)	$ 13.01		
Outstanding at December 31, 2024	15,161,180	$ 6.63	7.80	$ 71,497
Exercisable at December 31, 2024	8,092,985	$ 5.21	6.86	$ 51,185

The exercisable shares subject to options outstanding at December 31, 2024 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, 2024. The aggregate intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $14.7 million and $8.5 million, respectively.

The weighted-average grant date fair value per share of option grants for the years ended December 31, 2024 and 2023 was $6.51 and $6.31, respectively. The total fair value of shares vested during the years ended December 31, 2024 and 2023 was $14.1 million and $4.5 million, respectively.

The fair value of stock options granted was estimated using a Black-Scholes option-pricing model ("Black-Scholes") with the following weighted-average assumptions:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	6.0	6.0
Expected volatility	93.8%	95.3%
Risk-free interest rate	3.9%	3.9%
Expected dividend yield	—	—

The fair value of stock options was determined using the Black-Scholes assumptions below. Each of these inputs is subjective and generally requires significant judgment.

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

Income tax (benefit) expense consisted of the following (in thousands):

	Years Ended December 31,	
	2024	2023
Current:		
Federal	$ 260	$ —
State	28	—
Foreign	—	—
Total current	288	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Income tax provision	$ 288	$ —

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate is as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Tax computed at federal statutory rate	$ 1,740	$ (11,416)
State income taxes, net of federal benefit	47	(22)
Officers compensation (Sec 162(m))	1,741	745
Equity compensation	(135)	749
FDII deduction	(161)	—
Research and development credits	(1,008)	(1,179)
Other	(66)	(88)
Valuation allowance	(1,870)	11,211
Provision for income taxes	$ 288	$ —

Significant components of the Company's net deferred tax assets were as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating losses	$ 12,834	$ 16,127
Research and development credits	4,364	4,143
Intangible assets	17,201	7,322
Equity compensation	2,283	1,498
Other	319	66
Total deferred tax assets	37,001	29,156
Deferred tax liabilities:		
ROU asset	(8)	(53)
Other	(130)	(59)
Total deferred tax liabilities	(138)	(112)
Gross deferred tax assets	36,863	29,044
Valuation allowance	(36,863)	(29,044)
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, 2024 was an increase of $7.8 million.

At December 31, 2024, the Company had federal and state net operating loss carryforwards (NOL) of $60.5 million and $2.8 million, respectively. Federal NOL carryforwards of $60.5 million, generated after 2017, may be carried forward indefinitely but can only be utilized to offset 80% of future taxable income. The state NOL carryforwards begin expiring in 2036. State NOLs totaling $1.9 million may be carried forward indefinitely. In addition, the Company has federal and state research and development credit carryforwards totaling $3.7 million and $0.8 million, respectively. The federal research and development credit carryforwards will begin to expire in 2036 unless previously utilized. Of the total state research credits, $0.3 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 evaluation of uncertainty in a tax position is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position are derived from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2024 and 2023 (in thousands):

	Years Ended December 31,	
	2024	2023
Unrecognized tax benefits – beginning	$ 2,946	$ 1,520
Gross increases – tax positions in prior period	3,499	951
Gross increase – current-period tax positions	583	475
Unrecognized tax benefits – ending	$ 7,028	$ 2,946

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 does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

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. As of December 31, 2024, 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. The Company does not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date.

15. Employee Benefit Plans

In June 2022, the Company adopted a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code of 1986, as amended, for the Company's U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service (the "IRS") annual limits. The Company matches up to 5% of an employee's pay that they contribute to the plan, subject to IRS limitations. Expenses associated with the Company's matching contribution totaled $0.6 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively.

16. 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 expense related to this agreement totaling $2.2 million and $1.9 million during the years ended December 31, 2024 and 2023, respectively.

In September 2018, the Company entered into a consulting agreement with Marlinspike Group, LLC ("Marlinspike Group") to provide management, business consulting services and business development support. The managing member of Marlinspike Group is the Chair of the Board of Directors of the Company and one of its stockholders. The Company incurred expenses related to this agreement totaling $0.2 million for both of the years ended December 31, 2024 and 2023.

In April 2021, the Company entered into a consulting agreement, as amended in April 2022, with a member of the Board of Directors of the Company for general advice and assistance with the development of *neffy* and any future product candidates. As compensation for the consulting services the Company granted the member of the Board of Directors 590,950 stock options that vest over a four-year period. The Company incurred stock-based compensation expense related to this agreement totaling $0.1 million for both of the years ended December 31, 2024 and 2023.

As described in Note 11 - In-Licensing and Supply, the Company is required to make milestone payments to Aegis upon achievement of certain regulatory and commercial milestones, and royalty payments to Aegis based on net product sales of *neffy*. In November 2024, OrbiMed entered into an agreement with Aegis to purchase the rights, royalty interests, and related sales milestone payments on net product sales of *neffy*. A member of the Company's Board of Directors is a General Partner at OrbiMed. The Company incurred $0.2 million in expense to OrbiMed for the year ended December 31, 2024.

17. Segment Information

The Company reports segment information using the management approach and views its operations and manages its business as a single operating segment. Revenue is generated in the United States through product sales. Outside of the United States, revenue is generated through collaboration and license agreements including supply and distribution. For the year ended December 31, 2024, the Company had six customers that each accounted for more than 10% of the Company's gross product revenue. Those customers' revenue amounts for the year ended December 31, 2024 were: $2.2 million, $1.7 million, $1.3 million, $1.2 million, $1.1 million, and $1.1 million. For the year ended December 31, 2024, the Company had one customer, ALK, which accounted for more than 10% of the Company's revenue under collaboration agreements. Under the ALK agreement, the Company recognized $73.5 million during the year ended December 31, 2024.

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, potential licensing opportunities, segment operating expenses, and consolidated net income, as reflected in the accompanying consolidated statements of operations and comprehensive income (loss), which is the segment measure of profit or loss.

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 provided to the CODM for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Revenue:		
Product revenue, net	$ 7,255	$ —
Revenue under collaboration agreements	81,529	30
Revenue under supply agreements	365	—
Total revenue	89,149	30
Segment operating expenses:		
Cost of goods sold	977	—
Clinical	6,113	7,513
Development	8,485	10,275
Medical affairs	2,462	1,504
Sales and marketing	36,679	24,622
General and administrative	22,849	14,230
Stock-based compensation	14,534	9,235
Other	133	171
Total segment operating expenses	92,232	67,550
Loss from operations	(3,083)	(67,520)
Other income, net	11,369	13,155
Income (loss) before income taxes	8,286	(54,365)
Income tax provision	288	—
Net income (loss)	$ 7,998	$ (54,365)

18. Subsequent Events

Lease Amendment

On January 24, 2025, the Company entered into a lease amendment for its headquarters location lease ("Headquarters Amendment"), pursuant to which the Company will relocate to a new premises located in the same building which consists of 9,254 rentable square feet of office space. The Company will take possession of the new office space when the landlord's work is substantially complete, which is estimated to be July 1, 2025. The Company must vacate its current office space within 15 days of taking possession of the new premises.

Under the Headquarters Amendment, the term of the lease will be extended to 36 full calendar months following the date the Company takes possession of the new office space. The monthly lease payments will increase when the Company takes possession of the new space and escalate through the lease term, resulting in an annualized payment of $0.6 million. The Company remains subject to additional charges for common area maintenance and other costs. The Company has one option to extend the lease for an additional term of three years. The monthly payment amounts would be determined by the landlord at the then-prevailing rate.

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, 2024. 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, 2024, 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, 2024.

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, 2024 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, 2024, 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.

			Type of Trading Arrangement			
Name and Position	**Action**	**Adoption/Termination Date**	**Rule 10b5-1[(1)]**	**Non-Rule 10b5-1[(2)]**	**Total Shares of Common Stock to be Sold**	**Expiration Date**
Eric Karas, Chief Commercial Officer	Adoption	November 22, 2024	X		60,000	January 30, 2026
Alexander Fitzpatrick, Chief Legal Officer	Termination[(3)]	November 26, 2024	X		120,000	December 31, 2024
Alexander Fitzpatrick, Chief Legal Officer	Adoption	November 27, 2024	X		100,000	December 31, 2025
Alexander Fitzpatrick, Chief Legal Officer	Termination[(4)]	December 13, 2024	X		100,000	December 31, 2025
Alexander Fitzpatrick, Chief Legal Officer	Adoption[(4)]	December 13, 2024	X		100,000	December 31, 2025
Brian Dorsey, Chief Operating Officer	Adoption	December 13, 2024	X		300,000	December 31, 2025

[(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) adopted on March 31, 2023 and amended on September 29, 2023.
[(4)] Represents the modification, as described in Rule 10b5-1(c)(1)(iv) under the Exchange Act, of a written plan adopted on November 27, 2024 that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

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 2025 annual meeting of stockholders to be filed with the Securities and Exchange Commission on or before April 30, 2025 (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.

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 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).
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+	Non-Employee Director Compensation Policy, as amended (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2024).
10.10‡*	Termination Agreement, dated as of February 22, 2023, by and between ARS Pharmaceuticals, Inc. and Recordati Ireland, Ltd (incorporated by reference to Exhibit 10.10 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
10.11‡*	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).
10.12‡*	Collaboration and License Agreement, dated as of April 30, 2020, by and between ARS Pharmaceuticals, Inc. and Alfresa Pharma Corporation (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.13‡*	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).
10.14‡*	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).
10.15+	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).
10.16+	Executive Employment Agreement, dated as of February 9, 2022, by and between ARS Pharmaceuticals, Inc. and Kathleen Scott (incorporated by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.17+	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).
10.18+	Executive Employment Agreement, as of February 16, 2022, by and between ARS Pharmaceuticals, Inc. and Eric Karas (incorporated by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.19+	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).
10.20+	Executive Employment Agreement, by and between the ARS Pharmaceuticals, Inc. and Brian T. Dorsey, effective as of October 1, 2018 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K, filed with the SEC on December 9, 2022).
10.21+	Executive Employment Agreement, by and between ARS Pharmaceuticals, Inc. and Alex Fitzpatrick, effective as of December 1, 2022 (incorporated by reference to Exhibit 10.21 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
10.22+	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).
10.23+	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).
10.24+	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).

10.25‡*	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)
10.26‡*	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).
10.27‡*	Collaboration, License and Distribution Agreement, dated November 9, 2024, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló A/S.
10.28‡*	Supply Agreement, dated November 9, 2024, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló A/S.
10.29‡*	Supply Agreement, dated as of October 8, 2024, by and between ARS Pharmaceuticals, Inc. and Nuova Ompi S.r.l.
10.30*	Letter Agreement, dated December 6, 2024, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC (amends the Manufacturing Agreement, dated as of September 9, 2020, as amended July 25, 2023 and as further amended September 17, 2024, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC).
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 (see signature page).
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. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

* 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 20, 2025

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

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 20, 2025
/s/ Kathleen D. Scott Kathleen D. Scott	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2025
/s/ Pratik Shah Pratik Shah, Ph.D.	Chairman of the Board of Directors	March 20, 2025
/s/ Peter Kolchinsky Peter Kolchinsky, Ph.D.	Director	March 20, 2025
/s/ Rajeev Dadoo Rajeev Dadoo, Ph.D.	Director	March 20, 2025
/s/ Brenton L. Saunders Brenton L. Saunders	Director	March 20, 2025
/s/ Phillip Schneider Phillip Schneider	Director	March 20, 2025
/s/ Michael Kelly Michael Kelly	Director	March 20, 2025
/s/ Laura Shawver Laura Shawver, Ph.D.	Director	March 20, 2025
/s/ Peter A. Thompson Peter A. Thompson, M.D.	Director	March 20, 2025
/s/ Saqib Islam Saqib Islam, J.D.	Director	March 20, 2025