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DELTA REPORT

10-K

SPRY - ARS PHARMACEUTICALS, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4776
CHANGES	333
DELETIONS	2634
ADDITIONS	1809

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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, 2022 2023

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	**81-1489190**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11682 El Camino Real, Suite 120 San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206 858) 456-2900 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**

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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 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, 2023 March 18, 2024 there were 94,403,028 96,501,554 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 $102.9 381.8 million as of June 30, 2022 June 30, 2023 (the last trading day of the registrant’s most recently completed second quarter) based on the closing price of $4.24 $6.70 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

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Portions of the registrant's definitive proxy statement for its 2023 2024 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than May 1, 2023 April 29, 2024, 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:

- any statements regarding future economic conditions or performance;
- research and development plans, including planned clinical trials, for *neffy*, including for additional indications;
- the expected timing for reporting data;
- the design and potential benefits of *neffy*;
- our plans to complete a pharmacokinetic ("PK")/pharmacodynamic ("PD") study assessing repeat doses of *neffy* compared to repeat doses of an epinephrine injection product under allergen-induced rhinitis conditions to support approval of our New Drug Application ("NDA") resubmission for *neffy* with the U.S. Food and Drug Administration ("FDA") for the treatment of allergic reactions (Type I), including anaphylaxis for adults and children ≥30 kg;
- our expectations regarding the timing for resubmitting an NDA for *neffy* with the FDA for the treatment of allergic reactions (Type I), including anaphylaxis for adults and children ≥30 kg, the FDA's review of our NDA for *neffy*, including the classification of our NDA submission as Class 2 and the anticipated Prescription Drug User Fee Act ("PDUFA") target action date;
- our belief that additional testing for nitrosamine impurities based on new draft guidance issued after our NDA submission will not be a rate-limiting step for the resubmission to the FDA;
- our plans to submit a supplemental New Drug Application ("NDA") NDA to the U.S. Food and Drug Administration ("FDA") FDA and a post approval variation to the European Medicines Agency ("EMA") for 1.0 mg *neffy* and the timing thereof;
- our expectations regarding the timing for FDA review of our NDA for *neffy*, including the anticipated Prescription Drug User Fee Act ("PDUFA") target action date;
- our plans to submit regulatory filings for *neffy* in Japan and China in collaboration with our partners and the timing thereof;
- the expected timing for regulatory review decisions for *neffy*;
- the timing of the commercial launch of *neffy*, if approved;
- the commercial potential of and commercialization strategy for *neffy*;

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- the size of the markets for *neffy* and any other product candidates, the projected growth thereof, and our ability to capture and grow those markets;
- the rate and degree of market acceptance of *neffy* and any other product candidates;
- our expected competitive position;
- our expectations regarding our ability to achieve gross profit margins similar to small molecule drugs;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the likelihood of *neffy* attaining favorable coverage;
- the expected intellectual property protection for *neffy*;
- 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. 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.

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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 a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future.
- We have never generated revenue from product sales and may never be profitable.

- We have a limited operating history and only one current product candidate, *neffy*, which is in the clinical stage of development and has no commercial sales, which may make it difficult to evaluate the prospects for our future viability.
- 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.
- 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 currently depend on the success of *neffy*, which is our only current product candidate. If we are unable to obtain regulatory approval for, and successfully commercialize, *neffy*, or experience significant delays in doing so, our business will be materially harmed.
- If the FDA does not conclude that *neffy* or any future product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates 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.
- If we fail to develop and commercialize *neffy* for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.
- Competitive products may reduce or eliminate the commercial opportunity for *neffy* for its current or future indications. 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* may be adversely affected.
- We are dependent on international third-party licensees and assignees for the development and commercialization

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- We are dependent on international third-party licensees and assignees for the development and commercialization of *neffy* in several countries outside the United States. The failure of these third parties to meet their contractual, regulatory or other obligations could adversely affect our business.
- We may seek to enter into additional collaborations, licenses and other similar arrangements for *neffy* or any future product candidate and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.
- We currently have limited marketing, sales or distribution infrastructure. If we are unable to fully develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we may not be successful in commercializing our product candidates.
- The market for *neffy* and any future product candidates we may develop may be smaller than we expect.
- Any of our current and future product candidates for which we, or any current or future licensing and collaboration partners, obtain regulatory approval in the future will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, *neffy* and any future 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.
- Even if *neffy* or any future product candidate of ours receives regulatory approval, it 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 become profitable.

- Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for *neffy* or any of our future 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.

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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 development of our novel, potentially first-in-class product candidate, *neffy*® (previously referred to as ARS-1) for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy* to provide injection-like absorption of epinephrine at a low dose, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray.

Type I severe allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine injection, the only FDA-approved medication for these reactions. While epinephrine injection devices have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. Delay in treatment can allow 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.

There are approximately 25 to 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 16 million 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3.3 million 3.2 million currently have an active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency. In aggregate, we estimate that 90% of patients prescribed an epinephrine device are not achieving an optimal treatment outcome today.

We believe *neffy*'s "no needle, no injection" delivery that eliminates needle-related apprehension and injury concerns, with its small pocket size, ease of use, and high reliability would, if approved, increase prescriptions for epinephrine and make it more likely for patients and caregivers to 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* in more than 600 700 subjects demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products.

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Our Following the acceptance of our NDA was accepted in October 2022 for review by the FDA, on May 11, 2023, the FDA held a virtual meeting of its Pulmonary-Allergy Drugs Advisory Committee ("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 ≥30 kg for the emergency treatment of Type I allergic reactions including anaphylaxis, the PADAC voted 17 (yes) and 5 (no).

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On September 19, 2023, the FDA issued a 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. We reported topline data in February 2024 from this additional repeat dose study requested by the FDA, and plan to submit our response to the FDA's CRL early in the fourth second quarter of 2022 2024, with an anticipated mid-2023 PDUFA target action date and if in the middle of the second half of 2024. If our NDA is approved, we believe *neffy* will be the first "no needle, no injection" marketed epinephrine product for the emergency treatment of Type I allergic reactions. However, the timing for regulatory approvals is outside of our control and may be delayed and is uncertain.

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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 result in under-utilization by patients and may lead to serious complications and hospitalizations.

These limitations include:

- lack ease of portability with only 50% of patients filling prescriptions carrying the device;
- reluctance to use the device with approximately 25% to 50% 60% of patients carrying the device refusing to

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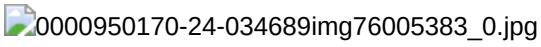
- reluctance to use the device with approximately 25% to 50% 60% of patients carrying the device refusing to administer;
- apprehension stemming from the use of a needle that leads to approximately 40% to 60% of patients delaying administration by up to 18 minutes even if they are carrying the device;
- a high rate of dosing errors, with meta-analyses reporting up to 35% 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 25 to 40 million patients at risk of severe Type I allergic reactions do not receive or fill prescriptions for intra-muscular injectables. Of 3.3 million 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 3.3 million 3.2 million patients who currently fill their prescriptions for an epinephrine injectable device, we estimate that approximately 2.5 million 3.3 million patients received a prescription, in the last 3 years, 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 3.3 million 3.2 million patients that do fill a prescription per year.

Notwithstanding their widespread lack of use, we estimate that net sales of intra-muscular injectable products approved for outpatient use in the United States was approximately $1 billion in 2021 2023 among the approximately 3.3 million 3.2 million patients who filled a prescription.

Our Approach



neffy™ is an investigational drug currently in clinical trials for the emergency treatment of allergic reactions (type I) including anaphylaxis.

neffy™ is not approved by the FDA, EMA or other health authorities.

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neffy is designed to address the shortcomings of intra-muscular injectable devices. *neffy* is 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* 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.

- ***Comparable PK and PD to injection products***. In our clinical trials, we observed that *neffy* has comparable pharmacokinetics (“PK”) PK and pharmacodynamics (“PD”)PD compared to marketed epinephrine injectables.
- ***Needle-free, easy-to-use, pocket-sized and highly reliable nasal spray.*** *neffy* is 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 trained untrained adults and trained untrained children were able to dose successfully self-administer *neffy* in two our human factors validation study with a total using the intended commercial instructions for use and quick reference guide. Dosing *neffy* also cannot be obstructed by common anaphylaxis co-morbidities such as vomiting or angioedema of 150 subjects. the lips, face, mouth or tongue. No inhalation or breathing is needed during administration of *neffy*.
- ***No risk of needle-related injuries***. *neffy* has 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.
- ***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* being a nasal spray.
- ***Low potent dose of epinephrine*.** Delivery of higher exposures of epinephrine increases the risk of overexposure and potential adverse events. events including gastrointestinal (GI) symptoms due to swallowing of the excess epinephrine that is not absorbed. *neffy* has 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*, the resulting exposure is expected to be tolerable. Due to its low dose of epinephrine and high bioavailability, *neffy* has 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* is expected to have a shelf-life at least comparable to the 18 month shelf-life of auto-injector products, but with improved stability and shelf-life at high-temperature than existing products in the market (up to 3 months at 50°C or 122°F) that allows *neffy* to retain potency even if

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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* clinical and 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 drugs assuming prices comparable to the marketed injectable products.
- ***Well positioned for regulatory submissions, and if approved, advance to commercialization.*** Our NDA was accepted for review response to the FDA's CRL is planned to be submitted early in the second quarter of 2024 following completion of the PK/PD study requested by the FDA in the fourth quarter its September 19, 2023 CRL. This study assessed repeat doses of 2022 with an anticipated mid-2023 PDUFA target action date and we believe that the completed trials are sufficient*neffy* compared to serve as the basis for its approval in the United States. repeat doses of epinephrine injection under allergen-induced allergic rhinitis conditions. In Europe, our Market Authorization Application ("MAA") was filed is under review and validated for review we anticipate a regulatory decision (CHMP Opinion) by EMA in the fourth quarter of 2022. mid-2024.

- ***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* has a 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 we believe supports the potential for favorable market access for *neffy* at net prices comparable to, or at a premium to, the approved intra-muscular injectables. We currently own or exclusively license a robust global intellectual property portfolio including issued composition of matter and method patents relating to *neffy* that are not expected to expire until 2038 before consideration of any potential patent term extension. adjustment.

Our Management Team, Financing History and Investors

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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., M.B.A. MBA. Pratik Shah, Ph.D. was our first external investor.

Mr. Lowenthal, our Co-Founder, and 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 Chairman 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). Harris Kaplan, Executive Vice President, Commercial Strategy has been involved in the development and launch of 125 new products totaling more than $300 billion in peak revenues, and Dan Relovsky, Senior Vice President of Marketing, has extensive and relevant launch experience across a number of therapeutic categories.

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 over $360 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, and Pediatrix Therapeutics (founded by F-Prime Capital, Eight Roads and Creacion Ventures) for Chinese rights. We previously entered into a licensing and collaboration agreement with Recordati for development and commercialization rights in the European Union ("EU"), Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom, Russia/CIS, Turkey, the Middle East and French-speaking African countries. In the first quarter of 2023, we entered into an agreement with Recordati to terminate our prior agreement with it and reacquire Recordati's rights to develop and commercialize *neffy*.

Our Pipeline: Suite of *neffy* Programs

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We are focused on advancing *neffy* through regulatory approvals for the emergency treatment of Type I allergic reactions, including anaphylaxis, and commercialization. *neffy* is an intranasal composition of epinephrine that is designed to address the limitations of epinephrine intra-muscular injectable products that are available on the market today.

We submitted Following the acceptance of our 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 2.0 mg 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 ≥30 kg 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 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. We reported topline results in February 2024 from this additional repeat dose for adults study requested by the FDA, and children greater than 30 kg in weight anticipate submitting our response to the FDA CRL early in the third second quarter of 2022. Our NDA was accepted for review by FDA in the fourth quarter of 2022 2024, with an anticipated mid-2023 PDUFA target action date. date in the middle of the second half of 2024. In the EU, our MAA for the 2.0 mg *neffy* dose for subjects greater than 30 kg in weight was filed and validated for review by EMA in the fourth quarter of 2022. 2022, and we expect a decision (CHMP Opinion) by mid-2024. We have also entered into partnerships for the development and commercialization of *neffy* in regions outside of the U.S., including our partnerships with Alfresa Pharma in Japan and Pediatrix Therapeutics in China to develop and commercialize *neffy* in those countries. Our partners expect to submit regulatory filings equivalent to an NDA in China and Japan by year end 2024.

Furthermore, we also plan to pursue additional expansion in our pediatric labeling with *neffy* and are conducting have completed a single-arm pharmacokinetic PK study in subjects 4 to 18 years of age. The interim pediatric data including subjects greater than 30 kg in weight is included in our initial NDA. We plan to submit a supplemental NDA (“sNDA”) for the 1 mg *neffy* dose for children weighing 15 to 30 kilograms to the FDA following the potential FDA approval of the 2.0 mg *neffy* dose in 2023. the middle of the second half of 2024. We also plan to submit a post-approval variation to EMA for 1.0 mg *neffy* following the potential approval of our MAA for the 2.0 mg *neffy* dose.

In addition, we believe *neffy* may be able to target other conditions in addition to Type I allergic reactions, and we have identified additional indications for further examination and potential future development.

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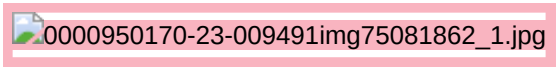

Our Strategy

Our strategy is focused on developing and commercializing *neffy* as a potentially first-in-class approved intranasal treatment for the approximately 16 million 20 million patients in the United States under the active care of physicians between 2020-2022 who have been diagnosed and experienced 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:

- ***Obtain FDA approval of neffy***. Our On September 19, 2023, the FDA issued a CRL for our NDA was accepted 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 on May 11, 2023 to approve *neffy* without need for review additional studies. We reported topline data in February 2024 from this additional repeat dose study requested by the FDA, and anticipate submitting our response to the FDA's CRL early in the fourth second quarter of 2022 2024, with an anticipated mid-2023 PDUFA target action date. date in the second half of 2024. If approved within our expected timeframe, *neffy* would be the first FDA-approved emergency treatment for Type I allergic reactions that is not an injection and that has no needle, which we believe would be an attractive treatment option for these patients. *neffy* has received Fast Track designation. However, the timing for regulatory approvals is outside ARS Pharma's control, may be delayed and is uncertain.
- ***Commercialize neffy in the United States***. If *neffy* is approved by the FDA, we plan to initially commercialize it in the United States by deploying 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 promotion will target high-prescribing allergists, pediatricians and primary care physicians through both traditional and non-traditional professional channels. Through these efforts, combined with 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 3.3 million 3.2 million patients in the United States who filled a prescription for an epinephrine intra-muscular injectable device in 2021. 2023. In addition, we believe that the potential for *neffy* to address the limitations of auto-injectors will allow us to expand the market opportunity for *neffy* over time to include the broader population of approximately 2.5 million 3.3 million patients who have received a prescription, but either refused or discontinued treatment, in the last three years, as well as the approximately 11 million 13.5 million patients who are diagnosed and under the care of physicians, but have not been prescribed an epinephrine intra-muscular injectable. injectable over the last three-years.

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- ***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. In Europe, our MAA was filed is under review, and validated for review we anticipate a decision (CHMP Opinion) by EMA in the fourth quarter of 2022. mid-2024. We intend to submit regulatory filings by year end 2024 equivalent to an NDA in Japan and China in collaboration with Alfresa Pharma and Pediatrix Therapeutics, respectively, to whom we have granted exclusive licenses in those regions for the development and commercialization of *neffy*.
- ***Conduct additional studies of neffy 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* 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 2 clinical trial in the outpatient urticaria setting during 2024.

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.

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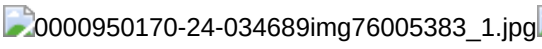
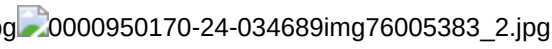
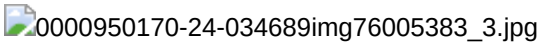
Table 1: Symptoms of Type I Allergic Reactions including Anaphylaxis

Body System	Common Symptoms of Type I Allergic Reactions
Respiratory	Chest tightness, wheezing, difficulty breathing ~50%+ frequency Upper airway or laryngeal angioedema 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 intra-muscular injectables are the only current out-of-hospital treatment for severe Type I allergic reactions and are 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.

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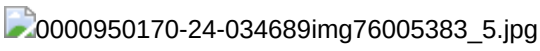
EpiPen epinephrine autoinjector was first approved by the FDA for the emergency treatment of Type I hypersensitivity reactions, including anaphylaxis, in December 1987. Other FDA-approved epinephrine intra-muscular injection products include Twinject® approved in May 2003, Adrenaclick® approved in November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

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

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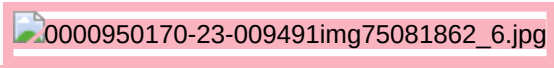
fear, frustration, worry and lack of control. A second dose of epinephrine is required for adequate treatment in about 10% of cases, irrespective of whether epinephrine was dosed using an auto-injector such as EpiPen or needle and syringe.

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 80% 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 15% 22% contain doses of 0.15 mg for persons between 15 to 30 kg and less than 5% 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 Epinephrine Products



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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 uptake 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 16 million 20 million people in the United States under the active care of physicians between 2020-2022 who have been diagnosed and experienced with Type I severe allergic reactions, only 3.3 million currently have 3.2 million had an active and filled epinephrine autoinjector prescription. prescription in 2022.

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

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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, if approved, could improve the management of severe Type I allergic reactions by addressing the current limitations of epinephrine intra-muscular injectable devices.

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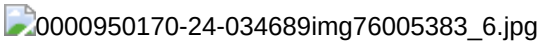
Clinical Development of *neffy*



neffy is designed to provide injection-like absorption of epinephrine at a 1.0 2.0 or 2.0 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. Based on our development work to date, 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.

We submitted our NDA to the FDA in the third quarter of 2022 based on a rigorous clinical development program agreed upon during pre-NDA meeting discussion with the FDA in mid-2021. Our NDA was accepted for review by FDA in

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the fourth quarter of 2022 with an anticipated mid-2023 PDUFA target action date. FDA. The FDA reference listed drug is intra-muscular needle-in-syringe injection products but there are several approved epinephrine intra-muscular injection products, including intra-muscular auto-injectors such as EpiPen, that establish a range of exposures that have indistinguishable efficacy, time to observed clinical effect and safety.

During our pre-NDA meeting in mid-2021, The FDA agreed that bracketing based on the primary parameters of C_{max}, t_{max} and early partial AUCs from the range of PKs observed in listed epinephrine injection products was the best approach to ensure efficacy and safety, while bracketing by AUC_{0-t} was considered an important parameter to ensure safety. PD measures of epinephrine activity such as systolic blood pressure and pulse rate were agreed to be supportive, and to be not meaningfully lower than injection. FDA also agreed that successfully demonstrating that *neffy* met these criteria in three primary studies described below would be sufficient to serve as a basis for our registration program for adults. Furthermore, FDA also agreed that a single study in pediatric subjects also described below would be sufficient to support our pediatric labeling. For our registrational program, EpiPen was agreed to be used as the upper bracket for exposures to ensure safety, while IM was agreed to be used as the lower bracket for exposures to ensure efficacy.

We have completed three registrational clinical trials in adults using our 2.0 *neffy* dose for which we submitted our NDA to the FDA in the third quarter of 2022. The adult registrational program using the 2.0 mg *neffy*was intended to generate bioavailability, PDs and safety data in three primary studies: (i) during single and repeat dosing in healthy subjects (EPI-15), (ii) during self-administration by subjects with severe Type I allergies (EPI-17), and (iii) during rhinitis induced by a nasal challenge with an allergen (EPI-16). EPI-15 was conducted in the United States on behalf of ARS Pharma by WCCT Global, Inc., a third-party contract research organization, and selected for 59 healthy male or female volunteers between the ages of 18 to 55 years. EPI-16 was conducted in the United States on behalf of ARS Pharma by Altasciences Clinical Los Angeles, Inc., a third-party contract research organization, and selected 36 male or female volunteers between the ages of 18 to 55 years with a positive history of seasonal allergic rhinitis related to tree or grass allergens as demonstrated by skin prick test and nasal allergen challenge at screening. EPI-17 was conducted in the United States on behalf of ARS Pharma by Novum Pharmaceutical Research Services, a third party contract research organization, and selected 45 male or female volunteers between the ages of 18 to 55 years who had an ongoing history of Type I allergies. To support our proposed pediatric labeling, we are also conducting have completed a single-arm pharmacokinetic PK study in subjects 4 to 18 years of age with either 1.0 mg or 2.0 mg of *neffy* depending on the subject's weight (EPI-10). EPI-10 is being conducted in the United States by ARS Pharma and selected 42 male or female subjects between the ages of 4 and 18 years who have Type I allergies that required that the subject or caregiver been prescribed an epinephrine product. The interim results of this study from 57 subjects including 16 subjects dosed with 2.0 mg *neffy* were included in our initial NDA that was accepted for review by FDA in the fourth quarter of 2022.

In addition, we have completed two proof of concept clinical studies that evaluated the bioavailability of our 2.0 mg *neffy* dose. These two earlier-stage studies were conducted in the United States on behalf of ARS Pharma by WCCT Global, Inc. and Altasciences Clinical Los Angeles, Inc, respectively, and selected a total of 26 healthy male or female volunteers between the ages of 18 to 55 years, and 42 male or female volunteers between the ages of 18 to 55 years who had an ongoing history of type I allergies.

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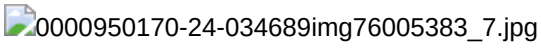
2.0 mg *neffy* is intended to be the dose that is comparable to approved 0.3 mg epinephrine intra-muscular injection products for persons greater than 30 kg in weight, which represents approximately 80% of the prescriptions in the United States. 1.0 mg *neffy* is intended to be the dose for persons 15 to 30 kg in weight. Our NDA for the 2.0 mg dose of *neffy* for adults and children 30 kg and greater in weight was accepted for review by FDA in the fourth quarter of 2022 with an anticipated mid-2023 PDUFA target action date. We plan to submit a supplemental NDA for the 1.0 mg dose of *neffy* in 2023 for subjects 15 to 30 kg in weight. 2022.

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 pharmacokinetic PK parameters (C_{max}, t_{max}, early partial AUCs, AUC_{0-t}). The An integrated data analysis graph summarizing the key outcomes for registration are 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



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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 600 700 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

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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 for each of with EpiPen, and Symjepi, approximately 14% of subjects dosed with EpiPen (auto-injector) and 2% of subjects dosed with Symjepi (pre-filled needle-in-syringe) 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 at a low dose of 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* *neffy* (people >30 kg in weight) and 1.0 mg *neffy* *neffy* (people 15 – 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.

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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 that of the 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* *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* *neffy* by type I allergy adult subjects (EPI-17). Zero percent error rate in two human factors factor validation studies with 150 persons, when used by trained adults or trained children intended commercial instructions for use and quick reference guide, when used by untrained passers-byers. 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.

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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* *neffy* has a shelf-life at least comparable to the 18 month shelf-life of EpiPen, but with high temperature stability, based on stability data from the 2.0 mg dose of *neffy* for 12 months and the 1.0 mg dose of *neffy* for 24 months. *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 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 ≥30 kg 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 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 intramuscular injection. The results are shown below:

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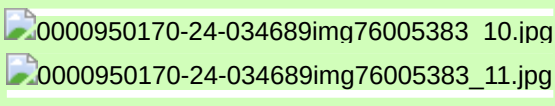

As part of the CRL, the FDA also requested additional information on nitrosamine impurities to be tested for based on new draft guidance issued in August 2023 after the *neffy* NDA submission. We have completed this updated testing, and no measurable levels of nitrosamine impurities were detectable.

We anticipate submitting our response to the FDA's CRL early in the second quarter of 2024, with an anticipated PDUFA target action date for 2.0 mg *neffy* in the middle of the second half of 2024. We anticipate filing 1.0 mg *neffy* as a supplemental NDA immediately following the potential approval of the 2.0 mg dose of *neffy* in the middle of the second half of 2024.

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 *neffy* supported by pharmacokinetic PK and pharmacodynamic PD data could enable the broader adoption of epinephrine in the outpatient setting for these other indications. We are conducting proof of concept studies evaluating *neffy* reported positive topline results demonstrating statistically significant and clinically meaningful improvements in additional allergy indications where *neffy* could potentially be used multiple times treatment-refractory chronic urticaria patients in February 2024, and anticipate initiating a year to treat acute episodes.

Phase 2 clinical trial in the outpatient urticaria setting.

Development outside the United States

In Europe, our MAA was filed and validated for review by EMA in the fourth quarter of 2022.In the Day 120 comments, 2022, and we received during EMA's review of our prior 1.0 mg dose *neffy* MAA submission, EMA required anticipate a preclinical dog anaphylaxis study, which we completed with data showing no meaningful differences in

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epinephrine absorption of *neffy* in dogs in a normal state or an anaphylactic state. In April 2022, we voluntarily withdrew our 1.0 mg *neffy* MAA submission to re-submit a 2.0 mg *neffy* MAA submission and allow EMA to review both our 2.0 mg *neffy* and preclinical dog anaphylaxis study results. decision (CHMP Opinion) by mid-2024.

We are also pursuing pediatric approval of *neffy* in Europe based on the same US pediatric study. We plan to submit a post-approval variation to EMA for the 1.0 mg *neffy* following the potential approval of the 2.0 mg *neffy*dose.

Our partners in Japan and China expect that they will file for regulatory approval in their respective regions at end of 2023 or early in 2024 following our anticipated the potential FDA approval of *neffy*.

Commercialization Opportunity and Commercialization Plan

Type I Allergy Market Overview

neffy is a needle-free, low-dose intranasal epinephrine nasal spray in clinical development 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.

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

Existing US Market Opportunity

We estimate approximately 25 to 40 million people in the United States have experienced Type I allergic reactions. Of this group, approximately 16 million 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only about 3.3 million 3.2 million of them filled a prescription in 2021 2022 for an epinephrine intra-muscular injectable device, including auto-injectors, equating to approximately 10 million devices. 5 million two-pack units.

Of those 3.3 million 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

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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 not only the approximately 3.3 million 3.2 million patients in the United States who currently fill intra-muscular injectable prescriptions, but also the more than 22 million 17 million eligible Type I allergy patients in the United States who are at risk of severe allergic reactions that are not prescribed or do not fill their epinephrine prescriptions, including approximately 2.5 million 3.3 million former injectable patients in the United States in the last three years that either refused to fill, or did not renew an intramuscular injectable device prescription.

Based on market access research and data from IQVIA, we estimate that 2021 2023 U.S. net sales for intra-muscular injectable devices were approximately $1 billion. Approximately 80% of the epinephrine intra-muscular injectables sold in the United States in 2021 2023 were for the 0.3 mg dose for adults and children greater than 30 kg in weight.

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 two independent quantitative market research studies including a total of 350 480 patients and 75 185 allergists, pediatricians and primary care physicians, approximately 80% 88% of patients with a current epinephrine auto-injector prescription stated that they would prefer *neffy*. Furthermore, 100% 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*.

- A majority indicated they would adopt *neffy* within three months of it coming to market,
- 69% 81% of patients indicated they would use *neffy* sooner than their current auto-injector device,
- 65 to 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.

These data suggest that *neffy* has the potential to be rapidly adopted by most of the approximately 3.3 million 3.2 million patients in the United States today who fill their epinephrine auto-injector prescription, if approved. These patients serve as our base estimate for the current epinephrine market for *neffy*.

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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 2007 2010 to 2021, 2023, the number of epinephrine intra-muscular injectable devices sold in the United States has increased by approximately 5% 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 payer payor coverage for *neffy*.
- **Targeting the approximately 2.5 million 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 100 88 former patients who refused to fill or renew a prescription, approximately 75% 89% indicated a willingness to return to the market and request *neffy* if approved. 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 currently obtain more than one pack (containing two devices) per year today.

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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 five six million patients who were recently prescribed an epinephrine injectable device, there are approximately 11 million 14 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 9 million 20 million patients not currently under the care of physicians.

- **Over time, targeting the approximately 11 million 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. device over the last three years.** In our market research, physicians indicated they would prescribe *neffy* to more than half of the patients who were eligible, but do not currently receive an intra-muscular injectable prescription.
- **Development in new allergy indications.** There are approximately 10 million patients with allergy conditions (e.g., urticaria flares and asthma exacerbations) where epinephrine has never been formally developed as a prescription product, despite being used in-hospital to resolve such acute symptoms. Such patients in other conditions experience multiple episodes each year, and we believe they would likely use multiple *neffy* each year to resolve their symptoms. Therefore, the market opportunity for treating such conditions may be as large as the type I allergy including anaphylaxis indication.

  We are conducting reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients in February 2024, and anticipate initiating a randomized, placebo-controlled proof of concept study evaluating the safety and efficacy of *neffy* in approximately 24 subjects with frequent urticaria flares. We expect to complete enrollment and report topline data from this study Phase 2 clinical trial in the second half of 2023. outpatient urticaria setting.

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*.
- In 2021, 2022, epinephrine intra-muscular injectable sales outside the United States were approximately $250 million $300 million based on IQVIA data. In Europe and Japan, sales of epinephrine injectable devices are approximately $160 million $220 million. 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.

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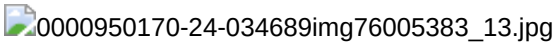
- Market research conducted in Europe with 120 patients who have an epinephrine auto-injector prescription indicated that 98% would prefer *neffy*, and that they would acquire approximately twice as many *neffy* devices compared to their current injectable device, if approved.
- To target these opportunities outside of the United States, we have entered into licensing and collaboration agreements 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*. We intend to pursue strategic partnerships for the commercialization of *neffy* in additional regions outside of the United States, subject to FDA approval of *neffy*.

- We previously entered into a licensing and collaboration agreement with Recordati for development and commercialization rights in the EU, Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom, Russia/CIS, Turkey, the Middle East and French-speaking African countries. In the first quarter of 2023, we entered into an agreement with Recordati to terminate our prior agreement with it and reacquire Recordati's rights to develop and commercialize *neffy*.

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 100% 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 plan to execute on our go-to-market strategy for *neffy* includes the following:

We plan to create healthcare professional and consumer awareness and anticipation prior to launch. We are refining our go-to-market strategy and creating awareness about our company and our technology. We expect to expand medical affairs capabilities prior to commercial launch to establish additional relationships with key opinion leaders and gain insight into current practice patterns and burdens. The medical affairs team will also collaborate with the commercial team

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to help payers payors fully understand *neffy's* value proposition and the limitations associated with needle injectors. We also plan to begin to raise awareness and support meaningful education through partnership with patient advocacy groups and medical societies as well as a disease education campaign including through social media and digital.

Based on the unmet needs that we identified, our pre-launch activities may be focused on delivering disease awareness and education surrounding the appropriate epinephrine use to prevent anaphylaxis to allergists and pediatricians as well as parents and patients in partnership with allergy and professional advocacy groups. These disease education efforts will more specifically reinforce the importance of early administration of epinephrine at the first sign of a severe Type I allergic reaction, help stakeholders understand the factors that are associated with hesitation to fill and use epinephrine earlier in a reaction, and the importance of alternative epinephrine delivery options to support those affected by severe allergic reactions. In our market research, 42% of patients who had used an epinephrine injectable device during a recent episode reported that they delayed use by an average of approximately 9 minutes. If *neffy* were available, these patients reported that they would reduce their average wait time to use by 45%. Additionally, 47% of patients reported they were more likely to fill prescriptions and 86% of patients reported they would carry *neffy* with them. We believe a broad understanding of this evidence will help to establish and increase the urgency to treat patients with *neffy* and support our rapid launch uptake following FDA approval, if achieved.

We plan to initially commercialize *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 promotion will focus the launch 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 plan to optimize our field representatives based on planned research on current market dynamics, geo-targeting and assessment of current professional-industry interaction preferences initially to reach these professionals. We expect significant reach to be achieved based on expanded use of non-personal promotional tactics and virtual sales representatives 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.

We intend to partner with patient advocacy organizations as well as influencers and leverage an omnichannel strategy including direct-to-patient and parent tactics, social and traditional media, digital presence, and additional public relations 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

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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.

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 payers payors will stimulate a high patient and parent desire to switch to or return to managing their condition with *neffy*.

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 plan to engage with payors to convey the clinical rationale and value proposition of *neffy*. To date, we have conducted extensive market research with approximately 50 decision-makers at payors to help forecast the potential commercial opportunity for *neffy* in the United States. Health insurers surveyed have indicated that *neffy* is perceived as differentiated brand from epinephrine auto-injector products, with its needle-free route of administration and increased likelihood of being carried as the most important product attributes. Based on these analyses and our planned contracting strategy, we believe payers payors can support favorable and broad market access for *neffy*. Further, we will offer comprehensive patient support programs in the form of co-pay buydowns to help ensure access and affordability for all patients.

We intend to expand the market beyond the 3.3 million 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 3.3 million 3.2 million patients currently filling epinephrine injection device prescriptions, adoption by the approximately 2.5 million 3.3 million patient that receive, but do not fill their prescription, and the 11 million 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

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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*, if approved, can make a significant difference in patient lives and outcomes.

If approved, we plan to establish a distribution channel in the United States for the commercialization of *neffy*. We expect to sell *neffy* to wholesalers, who, in turn, will sell our *neffy* to retailors retailers and other customers. We expect to use 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. We also plan to explore other non-traditional distribution channels including 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 and Pediatrix Therapeutics for China. We intend to pursue strategic partnerships for the commercialization of *neffy* in additional regions outside of the United States, subject to FDA approval of *neffy*. We anticipate that in certain markets additional clinical trials of *neffy* may be required to obtain regulatory approval and/or ensure market access.

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* 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.

We expect that, if approved, *neffy* would compete 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.

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We anticipate that, if approved, *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 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 PKs bracketed by the approved injection products for all pharmacokinetic PK parameters requested by the FDA. We are also not aware of any “no needle, no injection” epinephrine product candidate for the pediatric population that is in clinical development.

We are aware of several companies developing higher dose intranasal candidates including Bryn Pharma, Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Nasus Pharma, Orexo AB and Orexo AB. Belhaven BioPharma. Amphastar Pharmaceuticals, Inc. is reported to be developing an intranasal candidate, but has not disclosed its dose. 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*, 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 preparation for 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, and we intend to launch with a second source of API and are in the process of qualifying this second API source. available.

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

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The unit dose sprayer device used to delivery drug product in *neffy* is produced by Aptar Pharma (“Aptar”). Aptar produces devices in France and we believe Aptar has sufficient capacity to satisfy our long-term requirements. The patent for the Aptar unit dose nasal spray device expired in early 2020, and we believe there will be generic supplies available soon after launch.

Manufacturing drug product for *neffy* is conducted by Renaissance Pharmaceuticals, Inc. (“Renaissance Pharma”), which has been actively involved in supporting the manufacture of *neffy* devices in our clinical development. 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.

Ongoing registration stability studies demonstrate that *neffy* is stable at room temperature for at least 18 24 months, based on stability data from the 2.0 mg dose of *neffy* for 12 24 months and the 1.0 mg dose of *neffy* for 24 months, and we plan to continue to conduct ongoing registration stability studies that months. If approved, we anticipate will enable us to indicate on that our label if approved, will indicate that *neffy* is stable at room temperature for 18 24 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.

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, 2022 December 31, 2023, 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 four six issued U.S. patents, one granted Australian patent, one granted Japanese patent, one granted Chinese patent, one granted patent patents in each of Australia, Canada, China, Hong Kong, Japan, Mexico, Singapore, South Korea, one granted European patent, three granted Europe, the United Kingdom, patents, three pending U.S. non-provisional patent applications, and over fifteen

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pending foreign patent applications directed to intranasal epinephrine formulations and methods of their use. 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 or patent term extensions for regulatory delay. adjustments.

In addition to patent protection, we also rely on trademark registration, 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, including the United Kingdom, European Union, and Japan. 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.*"

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, 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

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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

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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, and a $1.0 million payment to Aegis upon the FDA's acceptance of our US NDA filing, which occurred in the third quarter of 2022. We will be required to pay Aegis a milestone payment of $2.5 million contingent upon the FDA approval of the first Aegis Licensed Product and a milestone payment of $5.0 million contingent upon first commercial sale of the first Aegis Licensed Product. 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 and earned $5 million upon the achievement of a clinical milestone during 2021. We are eligible to receive regulatory milestones of up to $8.0 million in the aggregate. 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

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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

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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. 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 agreement commenced on the date it was entered into and continues (a) for Renaissance Product designated for commercial sale in the U.S. until the earlier of the fifth anniversary of the (i) target U.S. launch date and (ii) the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the EU and other countries, the earlier of the fifth anniversary of (i) the target EU launch date and (ii) 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) we have not submitted a regulatory filing for any Renaissance Product in the U.S. on or before June 30, 2022, (b) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before the target U.S. launch date, (c) the authorization and approval representing more than a targeted number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (d) we decided in our sole discretion to cease commercializing

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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.

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

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*, 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* are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulations applicable to medical devices.

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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 advisory committee 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.

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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

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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

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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

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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 the advisory 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 Complete Response Letter. CRL. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter 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 Complete Response Letter 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

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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

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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

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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

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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

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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

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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-

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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.

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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 CMS 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.

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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. Additionally, we may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our product candidates. 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.

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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 European Union 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 judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate

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a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") 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 Biden 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 2011which 2011 which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2031, 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Congress is considering 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, at the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject

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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 and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics 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 will take effect progressively starting in fiscal year 2023, 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, In response to the Biden administration released an additional administration’s October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three new models for lowering drug costs for Medicare testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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

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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 European Union's 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 European Union EU (Withdrawal) Act 2018 ("UK GDPR").HIPAA, . 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.

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In addition, Congress and various other states have enacted or are considering new laws and regulations regarding the privacy and security of heath 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.

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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

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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

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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.

The requirements and process governing the conduct of clinical trials are to a significant extent harmonized at the EU level, but could vary from country to country. 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.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures. The application used to file an NDA in the United States is similar to that required in the EU, but the exact requirements for authorization may vary.

Centralized Procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health or which contain a new active substance for indications other than those specified to be compulsory.

National Authorization Procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

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The EU also provides opportunities for market exclusivity. For example, upon receiving marketing authorization, 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. 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. 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.

The EMA grants orphan drug designation to promote the development of products for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening or chronically debilitating condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify the investment required to develop the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free or reduced-fee protocol assistance, fee reductions for marketing authorization applications and other post-authorization activities and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EU, early access mechanisms for innovative medicines (such as compassionate use programs and named patient supplies), pricing and reimbursement, and promotion and advertising, amongst other things, are subject to national regulations and oversight by national competent authorities and therefore significantly vary from country to country.

Sanctions for non-compliance with the aforementioned requirements, which may include administrative and criminal penalties, are generally determined and enforced at national level. However, under the EU financial penalties regime, the EMA can investigate and report on alleged breaches of the EU pharmaceutical rules by holders of a marketing authorization for centrally authorized medicinal products and the European Commission could adopt decisions imposing significant financial penalties on infringing marketing authorization holders.

The United Kingdom left the EU on January 31, 2020. Following the transition period which ended on December 31, 2020, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom in the coming years.

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.

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

Corporate Information

On November 8, 2022 (the "Closing Date"), Silverback Therapeutics, Inc., a Delaware corporation ("Silverback"), now known as ARS Pharmaceuticals, Inc., completed its reverse merger (the "Merger") with privately-held ARS Pharmaceuticals, Inc., in accordance with the terms of the agreement and plan of merger and reorganization, dated July 21, 2022, as amended on August 11, 2022 and October 25, 2022 (the "Merger Agreement"), whereby Sabre Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of Silverback, merged into ARS Pharma, with ARS Pharma surviving as Silverback's wholly-owned subsidiary. Pursuant to the Merger Agreement, Silverback changed its name to ARS Pharmaceuticals, Inc. See Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report and Note 3 - Merger and Related Transactions of our financial statements for the year ended December 31, 2023 included in Item 8 of this Annual Report for more information regarding the Merger.

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.

On November 8, 2022 (the "Closing Date"), Silverback Therapeutics, Inc., a Delaware corporation ("Silverback"), now known as ARS Pharmaceuticals, Inc., completed its reverse merger (the "Merger") with privately-held ARS Pharmaceuticals, Inc. ("ARS Pharma"), in accordance with the terms of the agreement and plan of merger and reorganization, dated July 21, 2022, as amended on August 11, 2022 and October 25, 2022 (the "Merger Agreement"), whereby Sabre Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of Silverback, merged into ARS Pharma, with ARS Pharma surviving as Silverback's wholly-owned subsidiary. Pursuant to the Merger Agreement, Silverback changed its name to ARS Pharmaceuticals, Inc. See Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report and Note 3- Merger and Related Transactions of our financial statements for the year ended December 31, 2022 included in Item 8 of this Annual Report for more information regarding the Merger.

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Employees

As of December 31, 2022 December 31, 2023, we had seventeen 24 full-time employees and three 2 part-time employees. Of these employees, two 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 Financial Position and Need for Capital

We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future.

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. Our only product candidate, *neffy*, is in the clinical stage of development. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period 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, 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 our stockholders' equity and working capital. Our net losses were approximately $54.4 million and $34.7 million and $20.2 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $76.9 million $131.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals and prepare for commercialization for our product candidate, *neffy*, an investigational, new formulation of epinephrine, for the emergency treatment of Type I allergic reactions and potential additional indications.

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

- continue to develop and conduct nonclinical studies and clinical trials for *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications;
- continue to develop and conduct nonclinical studies and clinical trials
- seek regulatory approvals in the United States, the EU and other geographic regions for *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications;

for the emergency treatment of Type I allergic reactions and other indications that successfully complete clinical development;

- seek regulatory approvals in the United States, the EU and other geographic regions for *neffy* for the emergency treatment of Type I allergic reactions and other indications that successfully complete clinical development;
- seek to identify additional product candidates;
- seek to identify additional product candidates;

initiate and continue research, preclinical and clinical development efforts for any future product candidates;

- initiate and continue research, preclinical and clinical development efforts for any future product candidates;

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ates;

- 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;

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- add clinical, scientific, operational, financial and management information systems and personnel, including

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personnel to support our product candidate development and potential future commercialization efforts and help us comply with our obligations as a public company;

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- maintain, expand and protect our intellectual property portfolio;

- maintain, expand and protect our intellectual property portfolio;

- establish or expand our sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any products for which we may obtain regulatory approval; and

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- acquire or in-license other product candidates and technologies.

• 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 *neffy*, or if we choose to develop any future product candidates.

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We have never generated revenue from product sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate significant revenue from product sales. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, *neffy* for its initial indication and potential additional indications. Successful commercialization of *neffy* will require achievement of many key milestones, which vary by jurisdiction and may include demonstrating safety and efficacy in clinical trials, and obtaining regulatory approval for *neffy*. If *neffy* is approved, we, or any of our current or future licensing and collaboration partners must also comply with post-approval requirements, such as those relating to marketing and manufacturing. Finally, obtaining adequate coverage and reimbursement for *neffy* from private or government payors will be crucial to *neffy*'scommercial success. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We and any current and future licensing and collaboration partners may never succeed in these activities and, even if we do, or any current or future licensing and collaboration partners do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations.

We have a limited operating history and only one current product candidate, neffy, which is in the clinical stage of development and has no commercial sales, which may make it difficult to evaluate the prospects for our future viability.

We are a biopharmaceutical company founded in 2015 as ARS Pharmaceuticals, Inc., and our operations to date have been limited to organizing, staffing and financing our company, raising capital, and conducting research and development activities, including preclinical and nonclinical studies and clinical trials, for our only product candidate, neffy.*neffy*. We have not yet demonstrated an ability to generate product revenues, obtain regulatory approvals, manufacture a commercial product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as us. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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REFINITIV

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We are preparing to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

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 our spending levels to increase in connection with seeking regulatory approval and preparing for commercialization of *neffy*for the emergency treatment of Type I allergic reactions. In addition, if we obtain regulatory approval for the marketing of *neffy*, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, marketing, manufacturing and distribution. Further, we expect to incur additional costs associated with operating as a public company. Even if our nonclinical and clinical development of *neffy* is successful and we are able to gain marketing approval for *neffy*for the emergency treatment of Type I allergic reactions in the timeframe we anticipate, we may require significant additional amounts of cash in order to launch and commercialize *neffy*for this indication in the United States or for any additional indications for which *neffy* receives regulatory approval. In addition, other unanticipated costs may arise in the course of our development efforts. Because the outcome of our ongoing and anticipated clinical trials and timeframe for regulatory approvals for *neffy* is highly uncertain, we cannot reasonably estimate the actual amounts of cash necessary to successfully complete the development and commercialization of *neffy*for any indication we are pursuing.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, as well as any future product candidates we may develop;
- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, and any future product candidates we may develop and pursue;

the number of future product

- the scope, progress, results and costs of researching and developing *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, as well as any future product candidates we may develop;

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costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

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regulatory approval, revenue received from commercial sales of *neffy*

for any approved indications or from future product candidates, if any;

- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, and any future product candidates we may develop and pursue;

- the amount and timing of potential royalty and milestone payments to our current or future licensing and collaboration partners;

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- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- subject to receipt of regulatory approval, revenue received from commercial sales of *neffy* for any approved indications or from future product candidates, if any;
- our headcount growth and associated costs as we expand our personnel, including personnel to support our product candidate development and potential future commercialization efforts and help us comply with our obligations as a public company;

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- 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

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- the extent to which we in-licenses or acquire rights to other products, product
- our headcount growth and associated costs as we expand our personnel, including personnel to support our product candidate development
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including
- the ongoing costs of operating as a public company.
- the ongoing costs of operating as a public company.

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candidates or technologies;	and potential future commercialization efforts and help us comply with our obligations as a public company;	enforcing and defending intellectual property related claims; and

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, increases in unemployment rates, inflation, bank failures 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 or potential commercialization of *neffy*for additional indications. 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.

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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 *neffy*, 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.

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, that 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 development and potential future commercialization of *neffy*.

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 and the U.S. Treasury Department. 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.

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Risks Related to the Development of *neffy* or Any Future Product Candidates

We have never commercialized a product and may experience delays or unexpected costs or difficulties in obtaining regulatory approval for neffy for its initial indication or potential additional indications.

We have never obtained regulatory approval for, or commercialized, a pharmaceutical product. It is possible that the FDA and the EMA may refuse to accept any or all of our submitted or planned NDAs and MAAs for substantive review or may conclude after review of our data that an application is insufficient to obtain regulatory approval for *neffy* or any future product candidates. As we announced on September 19, 2023, the FDA issued a CRL for our NDA for *neffy* for the treatment of allergic reactions (Type I) including anaphylaxis for adults and children ≥ 30 kg. In the CRL, the FDA requested completion of a PK/PD study assessing repeat dosing of *neffy* compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis condition in order to support approval. We reported topline date from this additional repeat dose study requested by the FDA, and plan to submit our response to the FDA's CRL in the second quarter of 2024. In October 2023, we held a Type A meeting with the FDA to discuss the CRL, during which the FDA reiterated that no other information is required beyond the contents of the CRL and that the resubmission of our NDA will be classified as Class 2, with an action expected within six months of receipt date. There can be no assurances that the FDA will not later require other information that was not contemplated by the CRL, including follow up requests based on the information provided in response to the CRL. Additionally, there can be no assurances that our resubmission will be classified as Class 2 and that an action will occur within six months of the receipt date. If we resubmit our NDA, further material delays in the approval of our resubmitted NDA or the issuance by the FDA of another CRL, would likely cause a material adverse effect to our business. Additionally, the EMA required us to submit our preclinical animal anaphylaxis study results during the review process of our prior 1.0 mg dose of *neffy* MAA submission. If the FDA and the EMA do not initially approve any of our submitted or planned NDAs or MAAs, such regulatory authorities may require that we conduct additional clinical, nonclinical or manufacturing validation studies before they will reconsider future applications. Such additional clinical, nonclinical or manufacturing validation studies may impact our cash runway and require us to raise additional capital. Depending on the extent of these or any other required studies, approval of any NDA, MAA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing *neffy* for any indication or any other product candidate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or EMA to approve any NDA, MAA or other application that we submit. For example, the FDA has indicated that the ongoing pediatric clinical trial, EPI-10, would be sufficient to support a submission of our NDA for pediatric approval of a 2.0 mg dose of *neffy* for children weighing more than 30 kg, and to support a separate submission for pediatric approval of a 1.0 mg dose of *neffy* for children weighing between 15 and 30 kg; however, the FDA has not reviewed our complete clinical data, to date, and therefore there is no guarantee that the FDA will determine that any future NDA is sufficient for issuing a marketing approval of *neffy* for the emergency treatment of Type I allergic reactions in children. If any of these outcomes occur, we may be forced to abandon the development of *neffy* or any future product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for applications in other foreign jurisdictions. In addition, difficulties in obtaining approval of *neffy* for the emergency treatment of Type I

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allergic reactions could adversely affect our efforts to seek approval from regulatory authorities for *neffy* for use in other potential indications.

We currently depend on the success of neffy, which is our only current product candidate. If we are unable to obtain regulatory approval for, and successfully commercialize, neffy, or experiences experience significant delays in doing so, our business will be materially harmed.

We currently only have one product candidate, *neffy*, and our business and future success depends entirely on our ability to develop, obtain regulatory approval for, and then successfully commercialize, *neffy*, which is currently in clinical development for the emergency treatment of Type I allergic reactions in adults and children age 4 to 18 years. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development that may be able to better sustain failure of a lead product candidate.

We currently have no products approved for marketing and are investing the majority of our efforts and financial resources in the development of our sole product candidate, *neffy*, for the emergency treatment of Type I allergic reactions and potential other indications. Successful continued development and ultimate regulatory approval of *neffy* for our initial indication and potential additional indications is critical to the future success of our business. We will need to successfully complete our clinical development of *neffy* for the emergency treatment of Type I allergic reactions and other indications. The future regulatory and commercial success of *neffy* and any future product candidates 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 *neffy* or any future product candidates 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 *neffy* or any future product candidates;

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- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of *neffy* or any future product candidates;

- successful completion of nonclinical studies and clinical trials;

entry into collaborations to further the development of *neffy*

or any future product candidates;

- successful patient enrollment in clinical trials;

establishing sales, marketing and distribution capabilities and

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launching commercial sales of any approved products, whether alone or in collaboration with others;

- successfully launching commercial sales

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of *neffy* or any future product candidates, if and when approved;

- successful data from our nonclinical studies and clinical trials that support an acceptable risk-benefit profile of *neffy* or any future product candidates in the intended populations and indications;
- acceptance of *neffy* or any future product candidates, if and when approved, by patients, the medical community and third-party payors;
- satisfaction of applicable regulatory requirements, including to satisfy applicable rules governing combination products;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- potential unforeseen safety issues or adverse side effects;
- products, following approval, maintaining a continued acceptable safety profile;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- effectively competing with other therapies;
- remaining in compliance with post-marketing regulatory requirements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for *neffy* or any future
- ensuring that we promote and distribute our products consistent with all applicable healthcare laws; and

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future product candidates;

- making entry into hiring sufficient launch chinging arrangements collaborations, licensing, marketing, distribution, commercialization of *neffy* or any future product candidates, if and when obtaining product approval, by patients, the medical community and third-party payors, establishing successful launch of *neffy* or any third-party product with *neffy* or any future product candidates, acceptance of *neffy* or any future product candidates, if and when obtaining product approval, by patients, the medical community and third-party payors, establishing successful launch of *neffy* or any third-party product with *neffy* or any future product candidates, if and when obtaining third-party coverage and adequate reimbursement, manufacturing, sales and marketing capabilities and any other expenses; enforcing and defending intellectual property rights and claims.

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Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission and review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any current or future collaboration partner. If we are unable to develop, receive regulatory approval for, or successfully commercialize *neffy* for the indications we are developing it for, or if we experience delays as a result of any of these risks or otherwise, our business will be materially harmed.

In addition, of the large number of products in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA or a MAA to the EMA, and even fewer are approved for marketing and commercialization. Furthermore, even if we receive regulatory approval to market *neffy* for any indication, any such approval may be subject to limitations on the indications or uses or the patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development activities, we cannot assure you that we will successfully develop or commercialize *neffy* for any indication. If we or any of our current or future licensing and collaboration partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize *neffy* for its initial indication or potential additional indications, we may not be able to generate sufficient revenue to continue our business. In addition, our failure to satisfy other regulatory requirements could adversely affect our development efforts for *neffy* in other indications.

The denial of regulatory approval for neffy could mean that we need to delay or even cease operations, and a delay in obtaining such approval would delay commercialization of neffy and adversely impact our ability to generate revenue, business and results of operations.

If we are not successful in commercializing *neffy*, or are significantly delayed in doing so, our business will be materially harmed, and we may need to curtail or cease operations. We currently have no pharmaceutical products approved for marketing, and we may never obtain regulatory approval to market and commercialize *neffy* for any indication. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products are subject to extensive regulation by the FDA, the EMA, and other regulatory agencies in the United States, EU and other countries, and such regulations differ from country to country. We are not permitted to market *neffy* until we receive approval or marketing authorization from the relevant regulatory authority. The FDA, the EMA or any other foreign regulatory agency can delay, limit or deny approval to market *neffy* for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA, the EMA or any other applicable foreign regulatory agency that *neffy* is safe and effective for the requested indication;

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- our inability to gain agreement from applicable foreign regulatory authorities that *neffy* is appropriate for approval under applicable regulatory pathways;
    - our inability to demonstrate to the satisfaction of the FDA, the EMA or any other applicable foreign regulatory agency that *neffy* is safe and effective for the requested indication;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's disagreement with the interpretation of data from nonclinical and clinical studies and trials;

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- • the FDA's, the EMA's or any other applicable foreign regulatory agency's disagreement with the interpretation of data from nonclinical and clinical studies and trials;

our inability to demonstrate that the clinical and other benefits of

- • our inability to demonstrate that the clinical and other benefits of *neffy* outweigh any safety or other perceived risks;

neffy

- • our inability to enroll an adequate number of patients in and successfully complete our ongoing and any future clinical trials, including our pediatric clinical study EPI-10;

outweigh any safety or other perceived risks;

- • the FDA's, the EMA's or any other applicable foreign regulatory agency's requirement for additional nonclinical or clinical studies or trials, including studies to satisfy applicable rules governing combination products;

- our inability to enroll an adequate number of patients in and successfully complete our ongoing and any future clinica trials, including our pediatric clinical study EPI-10;

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used in our clinical trials;

- the FDA's, the EMA's or any other applicable foreign regulatory agency's requirement for additional nonclinical or clinical studies or trials, including studies to satisfy applicable rules governing combination products;
- the FDA's

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- the FDA's, the EMA's or any other applicable foreign regulatory agency's having differing requirements for the trial protocols used in our clinical trials;

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- • the potential for approval policies or regulations of the FDA, the EMA or any other applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

the FDA's, the EMA's or any other applicable foreign regulatory agency's non-approval of the formulation, labeling and/or the specifications of *neffy*;

- the FDA's, the EMA's or any other applicable foreign regulatory agency's failure to accept the manufacturing processes or third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, the EMA or any other applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of pharmaceutical products in development, only a small percentage successfully complete the FDA, the EMA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receives receive approval of an NDA, MAA or other foreign marketing authorization for *neffy*, the FDA, the EMA or other applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA, the EMA or other applicable foreign regulatory agency may also approve *neffy* for a more limited indication and/or a narrower patient population than we originally request, and the FDA, the EMA or any other applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of *neffy*. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would delay or prevent commercialization of *neffy* and would materially adversely impact our business and prospects.

We have never commercialized a product and may experience delays or unexpected costs or difficulties in obtaining

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regulatory approval for neffy for its initial indication or potential additional indications. 52

We have never obtained regulatory approval for, or commercialized, a pharmaceutical product. It is possible that the FDA and the EMA may refuse to accept any or all of our submitted or planned NDAs and MAAs for substantive review or may conclude after review of our data that an application is insufficient to obtain regulatory approval for *neffy* or any future product candidates. For example, the EMA required us to submit our preclinical dog anaphylaxis study results during the review process of our prior 1.0 mg dose of *neffy* MAA submission. If the FDA and the EMA do not initially approve any of our submitted or planned NDAs or MAAs, such regulatory authorities may require that we conduct additional costly clinical, nonclinical or manufacturing validation studies before they will reconsider future applications. Depending on the extent of these or any other required studies, approval of any NDA, MAA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing *neffy* for any indication or any other product candidate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or EMA to approve any NDA, MAA or other application that we submit. For example, the FDA has indicated that the ongoing pediatric clinical trial, EPI-10, would be sufficient to support a submission of our NDA for pediatric approval of a 2.0 mg dose of *neffy* for children weighing more than 30 kg, and to support a separate submission for pediatric approval of a 1mg dose of *ne*ffy for children weighing between 15 and 30 kg; however, the FDA has not reviewed our complete clinical data, to date, and therefore there is no guarantee that the FDA will determine that the NDA currently under review by the FDA for approval of a 2.0 mg dose of *neffy* for children weighing more than 30 kg or any future NDA is sufficient for issuing a marketing approval of *neffy* for the emergency treatment of Type I allergic reactions in children. If any of these outcomes occur, we may be forced to abandon the development of *neffy* or any future product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for applications in other foreign jurisdictions. In addition, difficulties in obtaining approval of *neffy* for the emergency treatment of Type I allergic reactions, could adversely affect our efforts to seek approval from regulatory authorities for *neffy* for use in other potential indications.

The regulatory approval processes of the FDA, the EMA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for neffy or any future product candidates, our business will be substantially harmed.

We, and any current and future licensing and collaboration partners, are not permitted to commercialize, market, promote or sell any product candidate in the United States or the EU without obtaining regulatory approval from the FDA or the EMA, respectively. Regulatory authorities in other jurisdictions may have similar requirements. The time required to obtain approval by the FDA, the EMA and other comparable foreign regulatory authorities is unpredictable, but typically

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takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of such regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, other than the NDA for *neffy* that we submitted to the FDA in the third quarter of 2022 and our MAA for *neffy* that was filed and validated for review by the EMA in the fourth quarter of 2022, we have not submitted any product approval submissions for *neffy* or any other product candidate to the FDA, EMA or other comparable foreign regulatory authorities for *neffy* and there can be no assurance that we will receive such approval from such regulatory authorities after submitting any product approval application. The FDA issued a CRL to our NDA on September 19, 2023 and there can be no assurance that following our resubmission of our NDA for *neffy* that we will not receive another CRL rather than approval.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of *neffy* or any future product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate safety or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA, the EMA or any other comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. For example, the repeat-dose PK/PD trial that we are conducting as requested in the FDA's CRL may not yield results that are expected or consistent with the prior product profile of *neffy*, which may have the effect of further delaying or preventing our approval pathway. Additionally, our expenses could increase if it is required by the FDA, the EMA or any other comparable foreign regulatory authority to perform clinical trials or studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of *neffy* for additional indications. It is possible that even if *neffy* or any future product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of *neffy* or any future product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by *neffy* or any future product candidate, or mistakenly believe that *neffy* or any future product candidates are toxic or not well-tolerated when that is not in fact the case.

neffy and any future product candidates could fail to receive regulatory approval for many reasons, including the following:

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- the FDA, the EMA or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication and, if necessary, that a product candidate and any active components thereof are safe and effective for the proposed indication;
- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with regards to the formulation components or specifications of *neffy,* including, without limitation, with respect to appearance, identity, impurities, or particle size;
    - the FDA, the EMA or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- the results of clinical trials may not meet the level of evidence or criteria required by the FDA, the EMA or other comparable foreign regulatory authorities for approval;

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- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;

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- the FDA, the EMA and comparable authorities in other countries may disagree with our interpretation of data from clinical trials or nonclinical studies and may require additional trials or studies to support marketing approval;

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• we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

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• the FDA, the EMA and comparable authorities in other countries may disagree with our interpretation of data from clinical trials or nonclinical studies and may require additional trials or studies to support marketing approval;

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• the data collected from clinical trials of *neffy* or any future product candidates may not be sufficient to support the submission of an NDA or other submission to the FDA or to obtain regulatory approval in the United States, the EU or elsewhere;

or any future product candidates may not be sufficient to support the submission of an NDA or other submission to

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the FDA or to obtain regulatory approval in the United States, the EU or elsewhere;

- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with clinical trial sites or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with clinical trial sites or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

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- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in us failing to obtain regulatory approval to market *neffy* or any future product candidate we develop, which would significantly harm our business, results of operations and prospects. Although we have successfully completed a pre-NDA meeting with the FDA, there is no assurance that the endpoints and trial designs used for the approval of a new formulation of epinephrine for the emergency treatment of Type I allergic reactions will be acceptable for *neffy*. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from current or future clinical trials of *neffy* or any future product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

There can be no assurance that the FDA and other regulatory agencies, including the EMA, will not require additional clinical trials or studies to support an application for the marketing of *neffy* in the emergency treatment of Type I allergic reactions or any other indication. This may be the case particularly as these regulatory authorities may consult with one another or as we may be required to apprise the respective agencies of studies we are conducting of *neffy* in conjunction with our requests for marketing approval or in response to requests and updates from the respective agency.

However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where

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a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. 54

With respect to new sites or facilities in the European Economic Area ("EEA"), which have never had a current Good Manufacturing Practices ("cGMP") inspection or authorization, the EMA has stated that a distant assessment may be conducted in order to evaluate if the site could be authorized without an on-site pre-approval inspection. If an approval is granted, it should be indicated that the certificate has been granted on the basis of a distant assessment and an on-site inspection should be conducted when circumstances permit. If a cGMP certificate cannot be granted as a result of the distant assessment, a clock-stop in the regulatory approval process will be imposed until an on-site inspection is possible. In addition, even if we were to obtain approval, regulatory authorities may approve *neffy* or any future product candidates for fewer or more limited indications, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for *neffy* or any future product candidates.

If the FDA does not conclude that neffy or any future product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates 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.

While we believe that we will have the necessary supporting data to submit a marketing application under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Section 505(b)(2)") regulatory pathway to the FDA for *neffy* for the emergency treatment of Type I allergic reactions for adults and children greater than 30 kg in weight, and upon completion of our ongoing pediatric study, EPI-10, for children between 15 and 30 kg in weight, there can be no assurance that the FDA will agree that the Section 505(b)(2) pathway is appropriate or will approve any such application or any future application for additional indication or future product candidates.

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 our future product candidates by

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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 pursue the Section 505(b)(2) regulatory pathway as anticipated, 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 *neffy* or any future product candidate, 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. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that *neffy* or any future product candidates we develop 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. For example, on June 12, 2023, Viatris submitted a Citizen Petition requesting that the FDA require additional PK/PD data before making a determination of whether our NDA meets the requirements for approval. The FDA has not responded to the Viatris Citizen Petition. 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. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval. Finally, a competitor might receive FDA approval before *neffy* and obtain non-patent market exclusivity, which could delay approval of *neffy*.

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We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neffy or any future product candidates.

To obtain the requisite regulatory approvals to market and commercialize *neffy* and any future product candidates, 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 *neffy* or any future product candidates we develop, including:

- regulators, or IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, o 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 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 *neffy* in an indication or any future product candidate 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 any future product candidates 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 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 or other reviewing bodies may fail to approve 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 *neffy* or any future product candidate or other materials necessary to conduct clinical trials of *neffy* or any future product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and

- regulators, or IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;

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- the potential for approval policies or regulations of the FDA, the EMA or any other applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

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Regulators, IRBs 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 *neffy* for other indications. While data from our studies of *neffy* 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 *neffy* for its initial indication or potential additional indications, or any future product candidate. If later stage clinical trials, including our ongoing pediatric clinical study, EPI-10, do not produce favorable results that meet regulatory authority criteria, our ability to obtain regulatory

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approval for *neffy* for the emergency treatment of Type I allergic reactions or potential additional indications, or any future product candidate, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of *neffy* for the emergency treatment of Type I allergic reactions or potential additional indications and to demonstrate the efficacy and safety of *neffy*, necessary to obtain regulatory approval to market *neffy* 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 *neffy* or any future product candidates 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 *neffy* or any future 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 *neffy*or any future 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.

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neffy or any future product candidate 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 any future product candidate, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA 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 any future product candidate 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 arise in the development of *neffy* or any future product candidates, we, the FDA, the EMA 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 or deny approval of *neffy*or any future product candidates for any 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. Undesirable side effects or adverse events in one of our clinical trials for *neffy* in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of *neffy* in other indications. Additionally, there may be negative findings regarding components of *neffy* or future product candidates by other parties. Any negative findings by third parties may impact the future approvability or labeling of *neffy* or other product candidates we may develop. 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 any future product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

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In addition, clinical trials of *neffy* are 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 *neffy* or a future product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Finally, *neffy* is 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 *neffy* has been used to deliver several drugs approved by the FDA and other regulatory authorities, including VALTOCO®, TOSYMRA® and NARCAN®. Even if *neffy* were to receive marketing approval or be commercialized, we would continue to be subject to the risks that the FDA, EMA 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.

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 *neffy* is being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following regulatory approval of *neffy*, if any. 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 (“FTC”), 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 our product candidates. 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, *neffy* or future product candidates. 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.

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If we fail to develop and commercialize neffy for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of *neffy* for the emergency treatment of Type I allergic reactions is our current primary focus, as part of our longer-term growth strategy, we plan to evaluate *neffy* for use in other indications and may develop other product candidates. We intend to evaluate internal opportunities from *neffy* and may do so for other potential product candidates or choose to in-license or acquire other product candidates as well as commercial products to treat other indications like Type I allergic reactions. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, the EMA and/or other applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Research activities to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research activities may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;

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- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

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- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

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If we are unsuccessful in identifying and developing *neffy* for additional indications or other product candidates, its potential for growth and achieving its strategic objectives may be impaired.

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Even if neffy is approved for the emergency treatment of Type I allergic reactions, there remains significant uncertainty as to whether neffy will be successfully developed and ultimately approved for any other indication we are exploring or pursuing.

As part of our longer-term growth strategy, we plan to evaluate and potentially develop *neffy* for other indications. indications, including urticaria. Our programs for such other indications are at a very early stage and there remains significant uncertainty as to whether *neffy* will be successfully developed and ultimately approved for any other indication we are exploring or pursuing. Even if *neffy* is approved for the emergency treatment of Type I allergic reactions, there will remain significant uncertainty regarding whether *neffy* will be successfully developed or approved for any other indication. indication, including urticaria. If we are unable to successfully develop, or if regulatory authorities do not approve, *neffy* for any other indication, our potential for growth and achieving our strategic objectives may be impaired.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate neffy in the future. We may expend our limited resources to pursue a particular indication or formulation for neffy 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.

Because we have limited financial and managerial resources, we are focused on specific indications for *neffy*. As a result, we may fail to generate additional clinical development opportunities for *neffy* for a number of reasons, including, that *neffy* 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. Furthermore, research activities to identify additional indications for *neffy* require substantial technical, financial and human resources. We may not be able to develop *neffy* for any additional indications, including urticaria, 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.

Additionally, we may pursue in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular

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product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit.

For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Competitive products may reduce or eliminate the commercial opportunity for neffy for its current or future indications. 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 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 *neffy* and will face competition with respect to any future indications of *neffy* 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. If approved, 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, and Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Orexo AB and Belhaven BioPharma. Amphastar Pharmaceuticals is reported to be developing an intranasal candidate with an undisclosed dose, and Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine. If *neffy* is approved for other indications, it 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 any future 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 any future product candidates that we may develop, which could render such product candidates obsolete and noncompetitive.

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If we obtain approval for *neffy* or any other future product candidate, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, 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 product candidates that receive regulatory approval. If the FDA or the EMA approves the marketing and commercial sale of *neffy* or any future product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products 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 candidates receive regulatory approval but 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-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 EMA or other comparable foreign regulatory authorities approve generic versions of neffy or any future product candidate of ours 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

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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.

Competition that neffy or any future products, if approved, may face from competitor versions of such products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates. Obtaining and maintaining regulatory approval of neffy or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of those product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of *neffy* and any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while 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 if a regulatory authority, such as the EMA, grants marketing approval of *neffy*, comparable regulatory authorities in the United States and other foreign jurisdictions must also approve the manufacturing, marketing and promotion of *neffy* 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 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

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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 do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in either domestic or international markets. If we 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* or any future product candidates will be harmed.

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 treatment of Type I allergic reactions and may in the future request Fast Track designation for additional indications for *neffy* or for any future 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 neffy or a future product candidate, 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.

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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 *neffy* and any future 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 any future product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of *neffy* by us and any current and future licensing and collaboration partners in clinical trials, and the sale of *neffy*, if approved, in the future, 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 approved products. If we cannot successfully defend ourself against any such claims, we may incur substantial liabilities or be required to limit commercialization of *neffy*or any future product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- 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 commercialize *neffy* or any future product candidates.

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- 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 commercialize *neffy* or any future 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* was to cause adverse events or side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects, side effects, and patients who should not use *neffy* or any of our future product candidates. If any of our current or future product candidates, including *neffy*, are approved for marketing and commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. 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 $5.0 million in the aggregate, including 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. We will need to increase our insurance coverage if we commercialize *neffy* or any future product candidate that receives regulatory approval. 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 any future product candidates, which could harm our business, financial condition, results of operations and prospects.

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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.

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

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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* or any future product candidates 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* and any of our future product candidates and activities 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 any future product candidates, or our failure to obtain any required import or export authorization for *neffy* or any future 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 any future product candidates may create delays in the introduction of our product candidates in international markets or, in some cases, prevent the export of our 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 any future product candidates by, or in our decreased ability to export *neffy* or any future product candidates to existing or potential customers with international operations. Any decreased use of *neffy* or any future product candidates or limitation on our ability to export or sell access to *neffy* or any future product candidates would likely adversely affect our business.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our licensing and collaboration partners, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, our licensing and collaboration partners, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology (“IT”) systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber

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incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. These threats pose a risk to the security of our, our licensing and collaboration partners', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our licensing and collaboration partners, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that maybe imposed; and could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed, ongoing or future clinical trials for *neffy*or any of our future product candidates 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.

Risks Related to Our Dependence on Third Parties

We intend to rely completely on third parties to manufacture and distribute our supply of neffy and intend to rely on third parties to manufacture and distribute any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute commercial quantities of *neffy*. Our ability to commercially supply *neffy*, if approved, depends, in part, on the ability of third-party manufacturers to supply and manufacture *neffy*, the raw materials, API and other important components related to the manufacture of *neffy*, including Intravail® and our nasal sprayer apparatus. We also intend to rely on third parties to label and package the finished product. These third-party manufacturers may have limited experience manufacturing *neffy*, the raw materials and API for *neffy* to be supplied to patients in the United States. While we will work with our third-party suppliers and manufacturers to optimize the manufacturing process for *neffy* and any future product candidates, if approved, 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* or any future product candidate, if approved.

We have entered into a commercial supply agreement with Renaissance Lakewood LLC ("Renaissance"), which has been actively involved in supporting the manufacture of *neffy* in our clinical development, and we intend to rely on Renaissance as the primary source for drug product manufacturing and final packaging. Unless and until we can secure an

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alternative source for drug product manufacturing and final packaging, our dependence on Renaissance will subject us to the possible risks of shortages, interruptions and price fluctuations if *neffy* is approved for commercialization.

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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 any future 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 products or product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production 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 *neffy* or another product;

- the failure of the third party to manufacture *neffy* or any future 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 products or product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the failure of the third party to manufacture our product candidates according to our specifications;

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- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;

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- 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

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agreements with the;

- the misappropriation of our proprietary information, including our trade secrets and know-how.
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- the failure of the third party to manufacture our product at
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- clinical supplies not being manufactured in accordance with applicable regulatory requirements;
- the misappropriation of our proprietary information, including our trade secrets and know-how.

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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 and the strict regulatory requirements of the FDA and other foreign regulatory authorities, this could affect the review of the NDA submitted for *neffy* or post-approval sales. In addition, other than to conduct audits, we do not have 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 *neffy* or any future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approvals for or commercialize *neffy* or any future product candidate. 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 or withdrawal of approvals, license revocation, import alerts, seizures or

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recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of *neffy* or any of our future product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of *neffy* or any future product candidates or drugs may adversely affect our future profit margins and our ability to commercialize *neffy* or any future product candidate that receives marketing approval on a timely and competitive basis.

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 seek or obtain regulatory approval for or commercialize neffy or any future 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 all of our product candidates 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

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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 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. Any such delay or rejection could prevent us from commercializing *neffy*or any future product candidates.

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.

We are dependent on international third-party licensees and assignees for the development and commercialization of neffy in several countries outside the United States. The failure of these third parties to meet their contractual, regulatory or other obligations could adversely affect our business.

We have entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Alfresa Pharma in Japan and Pediatrix Therapeutics in China, Macau, Hong Kong and Taiwan. As a result, we are dependent on these parties to achieve regulatory approval of *neffy* for marketing in these countries and for the commercialization of *neffy*, if approved. The timing and amount of any milestone and royalty payments we may receive under these agreements, as well as the commercial success of *neffy* in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources and successful commercialization of *neffy* by Alfresa Pharma and Pediatrix Therapeutics. We also depend on such licensing and collaboration partners to comply with all applicable laws relative to the development and commercialization of *neffy* in those countries. They may take actions or fail to take actions that result in safety issues with *neffy* in their licensed territory, and such safety issues could negatively impact *neffy* 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.

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The failure of our licensing and collaboration partners to devote sufficient time and effort to the development and commercialization of *neffy*; 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.*neffy*. 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. We intend to pursue strategic partnerships for the commercialization of *neffy* in additional regions outside of the United States, subject to FDA approval of *neffy*, including the regions previously licensed to Recordati, but there can be no assurance that we would be able to identify a suitable partner or transaction on terms that are favorable to us. In addition, under the termination agreement with Recordati (the "Termination Agreement"), we are obligated to pay certain milestone and royalty payments to Recordati.

We may seek to enter into additional collaborations, licenses and other similar arrangements for neffy or any future product candidate and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of *neffy* in other geographic regions or of any future product candidates, due to capital costs required to develop or commercialize *neffy* or any future product candidate or manufacturing constraints. Such collaborative efforts may not be profitable. We may not be successful in our efforts to establish or maintain such collaborations for *neffy* or any future product candidates because our research and development pipeline may be insufficient, our product candidates may

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be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential licensing and collaboration partners. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, the development or approval of *neffy* or any future product candidate is delayed, the safety of *neffy* or any future product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of *neffy* or any future product candidate, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to *neffy* or any future product candidate, could delay the development and commercialization of *neffy* or any future product candidate and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

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 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.

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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 Commercialization of *neffy* or Any Future Product Candidates

We currently have limited marketing, sales or distribution infrastructure. If we are unable to fully develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we may not be successful in commercializing our product candidates.

We are currently building our marketing, sales or distribution capabilities. As a company we have not commercialized or marketed any products to date. If *neffy* is approved for the emergency treatment of Type I allergic reactions or other future indications or any future product candidate is approved, we will need to expand our sales and marketing organization, on our own and in collaboration with third parties, and add further technical expertise and supporting distribution capabilities to commercialize the approved product in key territories, which will require substantial additional resources. Some or all of these costs may be incurred in advance of any approval of *neffy* or any future product candidate. There are risks involved with both establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a commercial organization is expensive and time consuming and could delay any product launch. If the commercial launch of *neffy* or any future product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of *neffy* and any future product candidates.

Factors that may inhibit our efforts to commercialize *neffy* or any future product candidate on its own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of allergists, pediatricians and other physicians
- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

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to prescribe any future products;

- the inability of sales personnel to obtain access to or our failure to educate adequate numbers of allergists, pediatricians and other physicians on the benefits of our future products;
- the lack of commitment by our pro

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- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantag relative to companies with more extensive product lines;

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- unforeseen costs and expenses associated with building out an independent sales and

the availability of adequate coverage by and reimbursement from third-party payors; and

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independent sales and marketing organization.

- unforeseen costs and expenses associated with building out an independent sales and marketing organization.

We entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Alfresa Pharma in Japan and Pediatrix Therapeutics in China, Macau, Hong Kong and Taiwan. These licensing and collaboration partners have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. We may enter into additional licensing and collaboration agreements in other territories for the commercialization of *neffy* or any future product candidates, however, we may be unable to enter into such agreements on favorable terms, if at all. Our product revenue may be lower than if we directly marketed or sold our products, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control.

We also compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of *neffy* and any future product candidates, if approved. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we do not expand our sales and marketing capabilities successfully, on our own and in collaboration with third parties, we will not be successful in commercializing *neffy* or any future product candidates. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

Furthermore, our efforts to educate patients, caregivers, allergists, pediatricians and other physicians, and payors on the benefits of *neffy* or any future product candidates may require more resources than we anticipate and may never be successful. Even if *neffy* or any future product candidates are approved, if we are unable to successfully market our products successfully, we will not be able to generate significant revenues from such products, if approved.

The market for neffy and any future product candidates we may develop may be smaller than we expect.

We have focused our development of *neffy* 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

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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 device sales. If we are unable to advance *neffy*, including with respect to the emergency treatment of Type I allergic reactions and other potential indications, or any future product candidates with attractive market opportunities or if our market opportunities are smaller than we expected, our future product revenues may be smaller than anticipated, which would adversely affect our business, financial condition, results of operations and prospects.

Any of our current and future product candidates for which we, or any current or future licensing and collaboration partners, obtain regulatory approval in the future will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, neffy and any future 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*or any future product candidates for which we, or any current or future licensing and collaboration partners, obtain regulatory approval, as well as the manufacturing processes, post-approval studies, labeling, post-approval pharmacovigilance monitoring, advertising and promotional activities for such product, among other things, will be 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 of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. 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.

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The FDA, the EMA and 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 any of our future product candidates for which we, or they, receive regulatory approval for only their 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;

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- 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;
- suspension 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.

Even if we, or any current or future licensing and collaboration partners, obtains regulatory approvals for neffy or any future product candidate, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer and distributor are subject to ongoing review and extensive regulation. We, and any current and future licensing and collaboration partners, must therefore comply with requirements concerning advertising and promotion for *neffy* or any future product candidate for which we or they obtain regulatory approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any current and future licensing and collaboration partners will not be able to promote any products we develop for indications or uses for which they are not approved.

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In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA, EMA and other foreign regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any current and future licensing and collaboration partners and their contract manufacturers would be subject to periodic unannounced inspections by the FDA, the EMA and other foreign regulators to monitor and ensure compliance with cGMPs. Despite our efforts to inspect and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, the EMA or other foreign regulators to be not in compliance with cGMP regulations, which may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

Accordingly, assuming we, or any current or future licensing and collaboration partners, receive regulatory approval for *neffy* or one or more future product candidates, we, and any current and future licensing and collaboration partners, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any current and future licensing and collaboration partners, are not able to comply with post-approval regulatory requirements, we, and any current and future licensing and collaboration partners, could have the regulatory approvals for *neffy* or any future products withdrawn by regulatory authorities and our, or any current or future licensing and collaboration partners', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Even if neffy or any future product candidate of ours receives regulatory approval, it 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 become profitable.

We have never commercialized a product, and even if *neffy* for the treatment of any indication, or any future product candidate of ours, is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors

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and others in the medical community. Physicians may be reluctant to prescribe *neffy* in place of well-established epinephrine intra-muscular injectable devices. 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 if we are able to demonstrate *neffy*'s or any future product candidate's safety and efficacy to the FDA, the EMA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate patients, caregivers, the medical community and third-party payors on the benefits of *neffy* and any future product candidates may require more resources than we anticipate, including management time and financial resources, and may not be successful. If *neffy* or any future product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of *neffy* and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the efficacy and safety of the product;
- 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 prevalence and severity of any side effects;
- our ability, or the ability of any current or future licensing or collaboration partners, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by *neff**neffy* y or any future product candidate of ours that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize neffy or any future 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 any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell *neffy* or any future 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, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning 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.

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Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") 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 Biden 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 2031, 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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, in July 2021, the Biden administration released an

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executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Humans Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, 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 and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics 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 will take effect progressively starting in fiscal year 2023, 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, In response to the Biden administration released an additional administration’s October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three new models for lowering drug costs testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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 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.

These laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to

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successfully develop and commercialize *neffy* or any future product candidates.
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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 *neffy* or any future product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. 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 *neffy* or any future product candidates in those countries would be negatively affected.

The successful commercialization of neffy or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

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The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as *neffy* or any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for *neffy* or any future product candidate that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider *neffy* or any future product candidate as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with *neffy* or any future product candidates, pricing of existing drugs may limit the amount we will be able to charge for *neffy* or any future product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize or obtain a satisfactory financial return on *neffy* or any future product candidates that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. Generally, third-party payors limit coverage and

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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. Additionally, we may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for *neffy* or any future product candidates. 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. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for *neffy* or any future product candidates. 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.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can 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 our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of *neffy* or any future product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for *neffy* or any future product candidates. Accordingly, in markets outside the United States, the reimbursement for *neffy* or any future product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for *neffy* or any future product candidates. We expect to experience pricing pressures in connection with the sale of *neffy* or any future product candidates due to the

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trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

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 any future 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 any future 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;
- 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 o

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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;
- the federal Health Insurance Portability and Accountability Act of 1996 ("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;

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- 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;

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- federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and

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of 2018 (“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 of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 (“CPRA”) expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. 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.

Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These state laws and the CCPA provide individuals with certain rights concerning their personal information, including the right to access, correct, or delete certain personal information, and 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 our products and services. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

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

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For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 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.

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Furthermore, we also conduct clinical trials in Asia and have operations in Japan and may be subject to new and emerging data privacy regimes in Asia, including China’s Personal Information Protection

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Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

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.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating regulatory 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 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 on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely 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; and orders to destroy or not use personal data. data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in

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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.

If our information technology systems or data, or those of third parties upon which we rely, 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 upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely 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 upon which we rely. 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 upon which we rely 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 produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks,

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software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

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In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, 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.

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 third-party service providers to provide other products, services, parts, or otherwise to operate our business. 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 our third-party partners' supply chains 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 upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

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We may expend significant resources or modify our business activities (including clinical trials) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require 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 to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These Unremediated critical or high risk vulnerabilities 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 to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience 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 prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

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.

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Risks Related to Our Intellectual Property

Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for neffy or any of our future 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* or any of our future product candidates. If we are unable to obtain or maintain patent protection with respect to *neffy* or any of our future product candidates, and their 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* or any of our future 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 candidates 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 product candidates 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.

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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 of our 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 our 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 with the European Patent Office with respect to EP 3678649, and we may be subject to a new or

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additional third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, derivations, reexaminations, or inter parties 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, 2023 we co-own or exclusively license four six issued United States U.S. patents, one granted patents in each of Australia, patent, one granted Japanese patent, one granted Chinese patent, one granted Canada, China, Hong Kong, Japan, Mexico, Singapore, South Korea, patent, one granted European patent, Europe, and three granted the United Kingdom patents for directed to *neffy* and its uses, among other things, three pending U.S. non-provisional patent applications, in the United States, Europe, Japan, Australia, China, South Korea, and other over fifteen pending foreign jurisdictions for 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 candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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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. As an example, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). The option of a Unitary Patent will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. 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 candidates. 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* or any of our future 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 candidates. 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* or any of our future 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.

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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. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of the patents or patent applications that we own, co-own or exclusively license, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing the inventions that we own, co-own or exclusively license in Russia or from selling or importing products made using the inventions that we own, co-own or exclusively license in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Recent patent 82

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 candidates, and the prior art allow the technology we use for our 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,

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we cannot be certain that we were the first to either file any patent application related to our product candidates or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes 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 or any of our future product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our 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.

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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

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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 candidates, 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 on for neffy or for any of our future 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 our product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order for our product candidates to become profitable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years. 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 of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, 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* are expected to expire as early as 2038, absent any patent term adjustments. The API in *neffy* is epinephrine, a generic API that is used in FDA-approved intra-muscular injectables. If *neffy* is approved by the FDA under the 505(b)(2) regulatory pathway, our U.S. patents for *neffy* will not be 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*.

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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 patents and patent applications in our portfolio relating to our product candidates*neffy* 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* or any of our future product candidates or uses thereof; and/or
    - if and when patents may issue based on the patent applications we own, co-own or exclusively license;
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

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We cannot be certain that the claims in our pending patent applications directed to *neffy* or any of our future 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 our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our 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 or any of our products. future product candidates.

As the pharmaceutical industry expands and more patents are issued, the risk increases that our 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 our product candidates in any jurisdiction.

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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 any of our future 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 any of our products. future 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 any of our future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market *neffy* or any of our products. future 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.

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If we are sued for infringing 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 any of our future product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell *neffy* or any of our future 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 any of our products future 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 our 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.

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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 our 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 inter partes review appeal from a Final Written Decision in an Inter Partes Review of U.S. Patent No. 10,682,414 B2 that was instituted on February 14, 2022, and to an opposition proceeding with the

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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

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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 invalid or 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. trademarks and pay for damages.

Even if we established 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.

Our product candidate neffy, or any of our future product candidates, may face competition sooner than expected, and our patents may be challenged.

Our success will depend in part on our ability to obtain and maintain patent protection for *neffy* or any of our future product candidates and 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. However, 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 patents that sufficiently cover our formulations and 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 do not expect to receive non-patent regulatory exclusivity for *neffy* if 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. In seeking approval for a drug product under the 505(b)(2) regulatory pathway, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug product listed in the Orange Book or an NDA submitted under the 505(b)(2) regulatory pathway referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; 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. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which

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the ANDA or 505(b)(2) application refers. Although we expect that our patents will be vigorously defended 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, results of operations and financial condition in the future.

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 our product candidates or as a result of questions

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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, European Union, EU, and Japan. We may not be able to obtain applicable corresponding health regulatory approval to use these trademarks for our product. Our future 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.

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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 any of our future 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;
- it is possible that our pending patent applications will not lead to issued patents;
- 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;
- others may be able to make formulations that are similar to
  - 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;

  neffy
  - we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;

  or any of our future product candidates but that are not covered by the claims of our patent rights;
  - others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- the patents of third parties may have an adverse effect on our business;
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- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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- it is possible that our pending patent applications will not lead to issued patents;
- we may not develop additional proprietary technologies that are patentable; and
- 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;

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- 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 our 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 our 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

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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 in the development, manufacture and distribution of our products and provision of our services, 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.

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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 our 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 our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, 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 our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;

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- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

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- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly

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- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficien resources to or otherwise not perform satisfactorily in carrying out these activities;

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- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our

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- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;

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- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;

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- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and

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- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

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 a resurgence of COVID-19 or 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* 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

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supply of *neffy* and any future 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 our product candidates, if approved, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

COVID-19 affected and a resurgence of COVID-19 or other public health crisis 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 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

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outside the United States, the EU or other relevant local geographies.

- 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.

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Any negative impact a resurgence of COVID-19 or other public health crisis has on patient enrollment or treatment, or the development of *neffy* and any future product candidates, could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize *neffy* and any future product candidates, if approved, increase our operating expenses, which could have a material adverse effect on our financial results. COVID-19 also 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 further market dislocation. Any such increased 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 renewed 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 resurgence of COVID-19 or any 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.

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 and medical 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* or any future product candidates will be limited.

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We only have a limited number of employees to manage and operate our business.

As of December 31, 2022 December 31, 2023, we had seventeen 24 full-time employees and three 2 part-time employees. Our focus on the development of *neffy* requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that it will be able to hire and/or retain adequate staffing levels to develop *neffy* or to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

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;

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- 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
- 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

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- 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, 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 expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational

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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 anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation 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. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of *neffy* for additional indications or future product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of *neffy*or any future product candidates.

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 pre-commercial 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:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
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- failure of any of our product candidates, if approved, to achieve commercial success;

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- failure of any of our product candidates, if approved, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- 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 our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- adverse regulatory authority decisions;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;

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- failure to meet or exceed financial and development projections we may provide to the public;
- adverse regulatory authority decisions;
- failure to meet or exceed the financial and development projections of the investment community;
- 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;
- failure to meet or exceed financial

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- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or ou competitors;

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- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our product candidates;

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- additions or departures of key personnel;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our product candidates;
- 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;

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- changes in the market valuations of similar companies;
- significant lawsuits, including patent or stockholder litigation;
- general market or macroeconomic conditions;
- 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;
- sales of our common stock by us or our stockholders in the future;
- changes in the market valuations of similar companies;
- trading volume of our common stock;
- general market or macroeconomic conditions;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack

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thereof, significant contracts, commercial relationships or capital commitments;

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stockholders in the future;

- adverse publicity generally, including with respect to other products and potential products in such markets;
- trading volume of our common stock;
- announcements by the introduction of technological innovations or new therapies that compete with potential products of ours;

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- changes in the structure of health care payment systems; and
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- 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.

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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. For example, following a decline in Silverback's stock price, a federal securities class action complaint was filed on November 5, 2021 against Silverback and certain of its former officers and directors in the U.S. District for the Western District of Washington, captioned Dresner v. Silverback Therapeutics, Inc., et al., Case No. 2:21-cv-01499, which alleges violations of (i) Sections 11 and 15 of the Securities Act; and (ii) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder. Defendants filed a motion to dismiss the action in May 2022. The court held a hearing on October 28, 2022 and issued an order granting defendants' motion to dismiss without prejudice on November 4, 2022. Plaintiffs were given leave to amend and filed a Second Amended Complaint ("SAC") on December 5, 2022, which asserted Section 11 claims only with respect to Silverback's December 3, 2020 IPO and Section 10(b) claims during a shorter class period of March 29, 2021 through March 31, 2022. Defendants filed a motion to dismiss the SAC on January 2, 2023. Lead plaintiff filed an opposition brief on January 23, 2023, and defendants filed a reply brief January 27, 2023. The court is expected to issue a ruling on the motion to dismiss in the first half of 2023.Even if we are successful in defending against this action or any similar claims that may be brought in the future, such litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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.

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

We will incur significant legal, accounting and other expenses that we did not incur as a private company prior to the Merger, including costs associated with public company reporting requirements. We will also incur 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 increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, our management team consists of the executive officers of ARS Pharma prior to the Merger, some of whom have not previously managed and

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operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations also may make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers, which may adversely affect investor confidence in us and could cause our business or stock price to suffer.
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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;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to chang
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- 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;

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- 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;

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- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
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- 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;

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- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstandin 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

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- 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

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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

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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.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for our common stock. An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

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.

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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.

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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. As a private company prior to the Merger, we have never been required to test our internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

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.

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 irrevocably elected not to avail ourself of use this exemption from new or revised accounting standards, and, therefore, will

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be subject to extended transition period under the same new or revised accounting standards as other public companies that are not “emerging growth companies.” JOBS Act.

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 in taxable years beginning after December 31, 2020, 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 Pharmaceuticals, Inc. (“ARS Pharma”) 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. Consequently, even if we achieve profitability, 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.

Item 1B. Unresolved Staff Comments.

None.

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

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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.

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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 upon which we rely, 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.

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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. This existing lease will expire on February 28, 2025. We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. See Note 7- 7 - 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

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. Silverback's shares of common stock were listed on the Nasdaq Global Market from December 4, 2020 through the close of business on

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November 8, 2022 under the ticker symbol “SBTX.” On November 9, 2022, we began trading on the Nasdaq Global Market under the ticker symbol “SPRY.”

Holders of Common Stock

As of March 17, 2023 March 18, 2024, there were approximately 29 20 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, we Silverback commenced our 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 our 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 our 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 us, 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 our the Silverback directors or officers (or their associates) or persons owning 10% or more of any class of our Silverback’s equity securities or to any other affiliates. The underwriters for our 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.

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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, 2022 December 31, 2023, approximately $95.7 million $161.6 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, and (iv) an estimated $27.2 million $47.0 million was used for the development and pre-commercial launch activities related to *neffy*, and (v) an estimated $46.0 million was used for working capital and general corporate purposes.

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 continue to intend to use the remaining net proceeds from the IPO, together with our existing cash and cash equivalents, to fund the development and, if approved, commercialization of *neffy* for the emergency treatment of Type I allergic reactions and other indications, 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 in-license, 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."

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Overview

We are a biopharmaceutical company focused on the development of our novel, potentially first-in-class ARS-1 (brand name *neffy*), a proprietary product candidate *neffy* (previously referred to as ARS-1) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy*is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy*to provide intranasal delivery of epinephrine.

We believe *neffy*'s "no needle, no injection" approach will address a significant unmet need in the use of epinephrine, which is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 25 to 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 16 million 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3.3 million 3.2 million currently have an 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 90% of patients prescribed an epinephrine device are not achieving an optimal treatment outcome today. These drawbacks include the use of needles in the devices, 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. Intra-muscular injections also 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 "no needle, no injection" delivery that eliminates apprehension, pain and safety concerns, small size allowing for ease of portability, ease of use, and high reliability provide it with a user-friendly profile that will increase prescriptions for epinephrine and make it more likely for patients and caregivers to 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* demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products. Our products, and produced statistically significant responses compared to injection on pharmacodynamic surrogates for efficacy even one minute after dosing with *neffy*.

Following the acceptance of our NDA was accepted in October 2022 for review by the FDA, on May 11, 2023, the FDA held a virtual meeting of its Pulmonary-Allergy Drugs Advisory Committee ("PADAC"). At that meeting, on the question of whether the data from our *neffy* pharmacokinetic ("PK")/pharmacodynamic ("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 ≥30 kg for the emergency treatment of Type I allergic reactions including anaphylaxis, the PADAC voted 17 (yes) and 5 (no). Although the FDA considers the recommendations of the PADAC, the recommendation by the PADAC is non-binding.

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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 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, we had aligned with the FDA in May 2023, and re-confirmed in August 2023 to conduct this repeat-dose study under allergen-induced allergic rhinitis study as a post-marketing requirement as informative for labeling. The CRL also requested additional information on nitrosamine impurities to be tested based on new draft guidance issued in August 2023 after the fourth*neffy* NDA submission. Our testing, based on methods in the older guidance, did not detect any nitrosamines above or close to the recommended acceptable daily intake limit for chronic exposure. *neffy* is for acute use.

We held a type A meeting with the FDA to discuss the contents of the CRL on October 24, 2023. The FDA reiterated that no other information is required beyond the contents of the CRL. The FDA also confirmed that the previously agreed design for the repeat-dose clinical study to evaluate the similarity of twice dosing injection and twice dosing *neffy* under allergen-induced allergic rhinitis will generate the necessary data to answer its outstanding questions regarding *neffy*. In addition, the *neffy* resubmission will be classified as Class 2, with an action expected within six months of receipt date.

We reported topline data in February 2024 from this additional repeat dose study requested by the FDA, and plan to submit our response to the FDA's CRL early in the second quarter of 2022 2024, with an anticipated mid-2023 PDUFA target action date in the middle of the second half of 2024. We have also completed the additional nitrosamine testing based on the new draft guidance issued by the FDA in August 2023, and if our NDA is no measurable levels of nitrosamines were detected. If approved, we believe *neffy* will be the first "no needle, no injection" marketed epinephrine product for the emergency treatment of Type type I allergic reactions. However,

Our marketing authorization application for *neffy* is also under review by the timing European Medicines Agency ("EMA") with a decision expected by mid-2024 following a grant of an extension to respond to additional requests for regulatory approvals is outside our control, may be delayed data and is uncertain. analysis.

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 2 clinical trial in the outpatient urticaria setting during 2024.

Since our inception in 2015 as ARS Pharmaceuticals, Inc., we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, performing research and

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development activities, pre-commercial activities, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any product sales. We have funded our operations primarily with proceeds from the Merger (as more fully described below), private placement of convertible preferred stock, licensing, supply and distribution arrangements with our commercialization partners, and bank debt. From inception to December 31, 2022 December 31, 2023, we have raised $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs, from the Merger, Merger; net proceeds of $76.3 million from the issuance of convertible preferred and common stock, stock; $27.8 million from our collaboration, licensing, supply and distribution arrangements, arrangements; and $10.0 million from bank debt. As of December 31, 2022 December 31, 2023, we had cash, cash equivalents, and short-term investments of $274.4 million $228.4 million.

We have incurred net losses from operations since our inception. Our net loss was losses were $54.4 million and $34.7 million for the year years ended December 31, 2022 December 31, 2023 and as 2022, respectively. As of December 31, 2022 December 31, 2023 we had an accumulated deficit of $76.9 million $131.3 million. 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 pre-commercial activities to establish sales, marketing and distribution capabilities for our product candidates, and our ability to earn potential regulatory and commercial milestones under our collaboration arrangements. We expect our expenses and operating losses will increase substantially as our product candidate, *neffy*potentially is approved by the FDA and we commence commercialization efforts, any future product candidates advance through clinical trials, and we expand our clinical, regulatory, quality, manufacturing and pre-commercial sales and marketing capabilities, and incur additional costs to operate as a public company following the completion of the Merger. capabilities. If we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution activities, and added expenditures to expand our operational, financial and management systems and increase personnel to support these operations.

We do not expect to generate any revenues from product sales unless and until we successfully obtain regulatory approval for one or more product candidates, if ever. Until such time, if ever, as 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

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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, reduce or terminate our research and development programs or other operations, or grant rights to develop and market 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 we expect to continue to do so to meet our nonclinical, clinical and any commercial activities. Our third-party manufacturers are required to manufacture our product candidates under cGMP requirements and other applicable laws and regulations.

Merger

On November 8, 2022 (the "Closing Date"), privately-held ARS Pharmaceuticals, Inc. ("ARS Pharma) merged with Silverback Therapeutics, Inc., a Delaware corporation ("Silverback"), a publicly traded company. In now known as ARS Pharmaceuticals, Inc., completed its reverse merger (the "Merger") with privately-held ARS Pharmaceuticals, Inc., in accordance with the terms of the agreement and plan of merger and reorganization, dated July 21, 2022, as amended on August 11, 2022 and October 25, 2022 (the "Merger Agreement"), whereby Sabre Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of Silverback, merged into ARS Pharma, with ARS Pharma surviving as Silverback's wholly-owned subsidiary. At the completion of the Merger, the prior ARS Pharma equityholders owned 62% and the prior Silverback equityholders owned 38% of the combined company, in each case on a fully diluted basis using the treasury stock method and excluding out-of-money options of Silverback. Upon completion of the Merger, Silverback changed its name to ARS Pharmaceuticals, Inc. As, among other facts, the stockholders of privately-held ARS Pharma owned a majority of the combined company, the Merger was treated for accounting purposes as if ARS Pharma had acquired Silverback. As a result of the Merger being accounted for as if ARS Pharma had acquired Silverback, the all financial statements prior to the Merger are of ARS Pharma are presented as the historical financial statements of the combined company for all periods presented.Pharma.

At the effective time of the Merger (the "Effective Time"), each share of ARS Pharma common stock outstanding immediately prior to the Effective Time, after giving effect to the automatic conversion of all shares of preferred stock of ARS Pharma into shares of ARS Pharma common stock immediately prior to the Effective Time, (the "Preferred Stock Conversion"), (excluding shares held as treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and dissenting shares) were automatically converted into the right to receive shares of Silverback common stock equal to the exchange ratio of 1.1819. Outstanding and unexercised options and warrants to purchase shares of ARS Pharma common stock were converted into options and warrants to purchase shares of Silverback common stock.

Recent Events Recordati Termination Agreement

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In September 2020, we entered into a license and supply agreement (the “Recordati License and Supply Agreement”) with Recordati Ireland, Ltd (“Recordati”). Pursuant to the Recordati License and Supply Agreement, we granted Recordati an exclusive, royalty-bearing, sublicensable license under our patents relating to *neffy* to (i) perform Recordati’s development activities on the epinephrine compositions (“Recordati Licensed Compositions”) and related products (“Recordati Licensed Products”) for commercialization in the EU, United Kingdom, and certain countries in the Middle East, Africa and Eurasia (the “Recordati Territory”), (ii) manufacture (or have manufactured) the Recordati Licensed Products for commercialization in the Recordati Territory, (iii) file and hold regulatory approvals for the Licensed Products in the Recordati Territory, and (iv) commercialize the Recordati Licensed Products in the Recordati Territory (collectively, the “Recordati Rights”).

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On February 22, 2023, we entered into the Termination Agreement with Recordati, pursuant to which, among other things, we and Recordati agreed to terminate the Recordati License and Supply Agreement. Pursuant to the Termination Agreement, we will reacquire reacquired all of the Recordati Rights, and have agreed to pay paid Recordati a one-time upfront payment of €3.0 million, and have 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) milestone royalty payments of up to €5.0 million in the aggregate from sales of Recordati Licensed Product(s) in the Recordati Territory.

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Reduction in Force

On September 19, 2023, the FDA issued a CRL regarding our NDA for *neffy*. On September 29, 2023, we initiated a 20% reduction in force (“RIF”) in order to conserve our cash resources and manage operating expenses until the anticipated PDUFA target action date in the middle of the second half of 2024. We provided severance payments, continuation of group health insurance coverage, and other benefits for a specified period to the affected employees. We incurred costs of $0.6 million for termination benefits resulting from the RIF, of which $0.1 million remains accrued for as of December 31, 2023.

Financial Overview

Revenues

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To date, we have not generated any revenues from the commercial sale of any products, and we may not generate revenues from the commercial sale of any products. We have signed collaboration and license agreements including supply and distribution for *neffy* with Alfresa Pharma in Japan and Pediatrix in China. 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. In addition, we previously entered into the Recordati License and Supply Agreement, which was terminated in February 2023. We expect revenues 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 US and the licensed regions, US product sales, 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.

Research and Development Expenses

To date, our research and development expenses have been related primarily to clinical development, process development and manufacturing costs of our product candidate. 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 our 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 our clinical stage product candidate consists consist primarily of fees, materials and other costs paid to CROs, CMOs, consultant and contractors. Our clinical, trials regulatory, manufacturing, and manufacturing 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.

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We expect that our research and development expenses will likely decrease in 2023 2024 based on our planned clinical development and manufacturing activities, as we plan to transition to commercialization efforts for the potential launch of our first product that year. in the second half of 2024. However, the timing for regulatory approvals is outside our control, may be delayed and is uncertain. 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 our 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. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. 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 our product candidates 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 our product candidates, and candidates;
- the cost to seek regulatory approvals for any product candidates that successfully complete clinical trials 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 our product candidates following approval, if any, of our 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

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- 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 any of our product candidates could significantly change the costs and timing associated with the development of that 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 our product candidates or any future candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for our product candidates or any future candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' or any future candidates' development, which could increase our research and development expenses.

General and Administrative

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. General and administrative expenses also include pre-commercial launch activities, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, facility costs, market research costs, and insurance costs.

We anticipate expect that our general and administrative expenses will increase substantially in 2023 2024 as we add sales and marketing personnel, infrastructure and programs to support pre-commercial activities, and if our product candidates receive marketing approval, commercialization activities. We also anticipate increased general and administrative personnel to support our operations, and higher patent and facility related costs. We also expect to continue to incur added 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, and investor relations costs associated with operating as a public company, following the Merger. patent costs and defense, and general and administrative personnel.

Other Income, net

Total Other Income (Expense)

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Total other income, (expense) net consists primarily of interest expense from bank debt, interest income from our cash, cash equivalents, and short-term investments, and changes in the fair value of net amortization and accretion associated with our warrant liability prior to the Merger. As a result of the Merger, the warrant liability was reclassified to equity and fair value adjustments are no longer required.short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2022 December 31, 2023 and 2021: 2022:

The following table summarizes our results of operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands, except percentages):

	Years Ended December 31,		Dollar Change	% Change	Year Ended December 31,		Dollar Change	% Change
	2022	2021			2023	2022		
Revenue under collaboration agreements	$ 1,316	$ 5,506	$ (4,190)	(76%)	$ 30	$ 1,316	$ (1,286)	(98%)
Operating expenses:								
Research and development(1)	18,376	20,273	(1,897)	(9)	20,266	18,376	1,890	10
General and administrative(1)	18,456	4,687	13,769	294	47,284	18,456	28,828	156
Total operating expenses	36,832	24,960	11,872	48	67,550	36,832	30,718	83
Loss from operations	(35,516)	(19,454)	(16,062)	83	(67,520)	(35,516)	(32,004)	90
Total other income (expense):	834	(789)	1,623	(206)				
Total other income:					13,155	834	12,321	*
Net loss	(34,682)	(20,243)	(14,439)	71	(54,365)	(34,682)	(19,683)	57

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Unrealized gain on available-for-sale securities	407	—	40 7	10 0
Comprehensive loss attributable to common stockholders	(34, $ 275)	(20, $ 243)	(14 ,03 $ 2)	69%
Change in unrealized gains and losses on available-for-sale securities			(358)	407	(765)	(188)
Comprehensive loss			$ (54,723)	$ (34,275)	$ (20,448)	60%

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

* Not meaningful

	Years Ended December 31,	
	2022	2021
Research and development	$ 213	$ 2,114
General and administrative	5,630	715
Total	$ 5,843	$ 2,829

	Year Ended December 31,	
	2023	2022
Research and development	$ 2,274	$ 213
General and administrative	6,961	5,630
Total	$ 9,235	$ 5,843

Revenues.

Revenues Revenue . Revenues under collaboration agreements was were less than $0.1 million and $1.3 million and $5.5 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The revenues for the years ended December 31, 2022 December 31, 2023 and 2021 2022 include the recognition of revenue for the portion of upfront and clinical and regulatory milestone payments under our collaborations collaboration agreement with Alfresa and Recordati that have been allocated to research and development services provided for during these periods. The

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revenues for the years. Revenue under these collaboration agreements decreased $1.2 million from 2021 to 2022. The remaining decrease from 2021 to 2022 is due to the recognition of an upfront payment of $3.0 million years ended December 31, 2022 also included similar revenues under our collaboration and distribution agreement with Pediatrix signed in March 2021 relating to the issuance and delivery of a technology license, with no comparable activity in 2022. Recordati. We expect revenues 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 these agreements.

Research and Development Expenses. Expenses. Research and development expenses were $18.4 million $20.3 million and $20.3 million $18.4 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The decrease increase of $1.9 million was primarily due to a $3.1 million $2.1 million increase in stock-based compensation, a $1.1 million increase in payroll-related expenses, a $0.9 million increase in consulting fees, and a $0.5 million increase in other operating expenses. These aggregated increases were partially offset by a $1.0 million decrease in license milestone expenses, a $0.9 million decrease in in-process research and development expenses, a $0.5 million decrease in clinical trial costs associated with *neffy,* and a $1.9 million $0.3 million decrease in stock-based compensation. These aggregated decreases were partially offset by $1.1 million in in-process regulatory filing fees.

The following table summarizes our research and development acquired in the Merger, a $1.0 million increase in license fees expenses for the milestone payment to Aegis upon the FDA's acceptance of our US NDA filing, years ended December 31, 2023 and a $0.9 million increase in regulatory consulting costs. 2022 (in thousands):

	Years Ended December 31,	
	2022	2021
Clinical trials	$ 8,894	$ 10,560
Manufacturing and non-clinical development	9,482	9,713
Total research and development expenses	$ 18,376	$ 20,273

	Year Ended December 31,	
	2023	2022
Clinical and regulatory	$ 9,057	$ 8,894
Manufacturing and non-clinical development	11,209	9,482
Total research and development expenses	$ 20,266	$ 18,376

General and Administrative Expenses. General and administrative expenses were $18.5 million $47.3 million and $4.7 million $18.5 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The increase of $13.8 million $28.8 million was primarily due to a $4.9 million $13.6 million increase in pre-commercial launch

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activities related to *neffy*, a $6.8 million increase in payroll-related expenses, a $2.6 million increase in consulting fees, a $1.3 million increase in stock-based compensation, of which $3.0 million was for the replacement of stock awards held by Silverback employees and directors in connection with the Merger and $1.3 million for the vesting of previously issued performance-based options, a $3.6 million $0.7 million increase in outside services associated with marketing and consulting, insurance costs, a $2.3 million $0.7 million increase in legal fees, expenses, a $2.2 million $0.7 million increase in payroll and related expenses, and general overhead, a $0.6 million increase in insurance costs.conference expenses, a $0.5 million increase in recruiting fees, a $0.3 million increase in professional fees for accounting, auditing and tax, and a $1.0 million increase in other operating expenses.

Total Other Income, (Expense). Net. Total other Other income, net was $13.2 million and $0.8 million for the year years ended December 31, 2022 December 31, 2023 and total other expense was $0.8 million for the year ended December 31, 2021. 2022, respectively. The difference increase of $1.6 million $12.3 million was primarily due to a $1.8 million $11.7 million increase in interest income from our cash, cash equivalents, and short-term investments, partially offset by a $0.1 million loss $0.6 million decrease in interest expense due to the change Silicon Valley Bank loan payoff in fair value November 2022, and $0.3 million from the sale of in-process research and development obtained in the preferred stock warrant liability.
Merger.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since our inception, we have not generated any revenue from any product sale and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates until the second half of 2023 2024 or after, if at all. 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, and bank debt. From inception to December 31, 2022 December 31, 2023, 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, $27.8 million from our collaboration, licensing, supply and distribution arrangements, and $10.0 million from bank debt. As of December 31, 2022 December 31, 2023, we had cash, cash equivalents, and short-term investments of $274.4 million $228.4 million.

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Cash flows

The following table summarizes our cash flows for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Years Ended December 31,	
	2022	2021
Net cash and cash equivalents used in operating activities	$ (40,078)	$ (17,561)
Net cash and cash equivalents used in investing activities	(199)	(55)
Net cash and cash equivalents provided by financing activities	190,732	53,158
Net increase in cash and cash equivalents	$ 150,455	$ 35,542

	Year Ended December 31,	
	2023	2022
Net cash and cash equivalents used in operating activities	$ (59,266)	$ (40,078)
Net cash and cash equivalents used in investing activities	(87,180)	(199)
Net cash and cash equivalents provided by financing activities	6,899	190,732
Net (decrease) increase in cash and cash equivalents	$ (139,547)	$ 150,455

Operating Activities

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.

During the year ended December 31, 2022, net cash used in operating activities was $40.1 million. This consisted primarily of a net loss of $34.7 million and, a decrease in our operating liabilities of $11.6 million, an increase in our operating assets and liabilities of $12.8 million $1.2 million, partially offset by non-cash charges of $7.4 million. The increase decrease in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued liabilities of $10.3 million, and a decrease in contract liability of $1.3 million. The increase in our operating assets was primarily due to an increase in prepaid and other assets of $1.2 million, and a decrease in contract liability of $1.3 million. The non-cash charges primarily consisted of non-cash stock-based compensation of $5.8 million, expense of acquired in-process research and development of $1.1 million, depreciation, amortization and accretion expense of $0.3 million, and change in fair value of warrant liability of $0.1 million.

Investing Activities

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During the year ended December 31, 2021 December 31, 2023, net the cash and cash equivalents used in operating investing activities was $17.6 million $87.2 million. This consisted primarily of a net loss purchases of $20.2 million short-term investments of $272.0 million, maturities of short-term investments of $185.0 million, and an increase in our operating assets purchases of property and liabilities of $0.4 million, partially offset by non-cash charges of $3.0 million. The increase in our operating assets and liabilities was primarily due to a decrease in contract liability of $2.5 million, partially offset by a decrease in prepaid and other assets of $1.2 million and an increase in accounts payable and accrued liabilities of $1.0 million. The non-cash charges primarily consisted of stock-based compensation of $2.8 million and depreciation, amortization and accretion expense equipment of $0.2 million.

Investing Activities

During the year ended December 31, 2022, the cash and cash equivalents used in investing activities was primarily $0.2 million due to $0.2 million in purchases of property and equipment. During the year ended December 31, 2021, the cash and cash equivalents used in investing activities was primarily due to $0.1 million in purchases of property and equipment.

Financing Activities

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. During the year ended December 31, 2022, the cash and cash equivalents provided by financing activities was primarily due to $190.7 million which consisted of $198.8 million in net proceeds from the Merger. In addition, we acquired $63.5 million in short-term investments through Merger, $0.6 million of proceeds from stock option exercises and the Merger. Also, during the year ended December 31, 2022, we used cash of employee stock purchase plan, partially offset by $8.7 million for repayment of the bank note. During the year ended December 31, 2021, the cash and cash equivalents provided by financing activities was primarily due to $54.8 million of proceeds from the issuance of Series D convertible preferred stock in August 2021 plus $0.2 million from common stock option exercises, partially offset by $1.8 million repayments on the bank note.

Future Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements through at least the next three years. In particular, we expect our cash, cash equivalents, and short-term investments will allow us to fund our expenses related to resubmission and the FDA's review of our NDA for *neffy*, fund proof of concept clinical trials of *neffy* for additional indications, fund pre-commercial manufacturing and sales and marketing activities, and if and when *neffy* is approved by the FDA, fund our commercial launch. 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,

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the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the scope and costs of manufacturing our product candidates and commercial manufacturing activities;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the timing and amount of any milestone and royalty payments under the Aegis License Agreement and the Termination 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 establish 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.

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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

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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 US, including due to recent bank failures, and worldwide resulting from macroeconomic factors. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Material Cash Requirements

Under our license agreement with Aegis, we paid an aggregate $1.5 million for an upfront license fee and meeting certain regulatory milestones, and have remaining payment obligations of up to $20.0 million $18.5 million contingent upon our achievement of certain other regulatory and commercial milestones and milestones. We are also required to make royalty payments in connection with the sale of products developed under that agreement. We are unable to estimate the timing or likelihood of achieving additional milestones or royalty payments under this agreement. We are also responsible for reimbursing Aegis for patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products.

Pursuant to the Termination Agreement with Recordati, we made a one-time upfront payment of €3.0 million, and have remaining payment obligations of up to €10.0 million €7.0 million contingent upon our achievement of certain regulatory and commercial milestones, and up to €5.0 million based on a low double-digit percentage of sales of sales of Recordati Licensed Product(s) in the Recordati Territory Territory. We are unable to estimate the timing or likelihood of achieving these milestones and sales-based payments under this agreement.

In October 2021, we entered into a lease agreement to rent office space with a lease commencement date of December 2021. The lease has a term of 38 months. Annual rent expense is $0.2 million and is subject to annual increases of 3%, plus our share of operating expenses and taxes.

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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.

To date, we have not recognized any reserves related to uncertain tax positions. As of December 31, 2022 December 31, 2023, we had no accrued interest or penalties related to uncertain tax positions.

Critical Accounting Policies and Significant Judgements Judgments and Estimates

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

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

Revenue

Our revenues generally consist of licenses and research services under license and collaboration agreements.

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess 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.

The upfront payments and fees received prior to satisfying the relevant revenue recognition criteria are recorded as contract liability in the balance sheet and recognized as revenue when the related revenue recognition criteria are met.

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Collaboration agreements typically contain multiple elements, or performance obligations, including research and development services and technology licenses. Our assessment of what constitutes a separate performance obligation requires us to apply judgement. Specifically, we have to identify which goods and services we are required to provide under the contract are distinct. For our collaboration agreements, we have identified several performance obligations at the inception of the contract since the delivered elements are deemed capable of being distinct within the context of the contract. Accordingly, the initial transaction price is allocated to the various performance obligations where we recognized revenue related to the license, which was delivered upon contract inception, and the remaining performance obligation is recognized as the underlying services are provided under the cost-based input method over the research terms. Using the cost-based input method, we recognize revenue based on actual costs incurred as a percentage of total estimated costs as we complete our performance obligations. Any cumulative effect of revisions to estimated costs to complete our performance obligations is recorded in the period in which changes are identified and amounts can be reasonably estimated. This approach requires us to use significant judgement and make estimates of future expenditures. If our estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that it recognizes in the current and future periods.

The transaction price for a contract represents the amount to which we are entitled in exchange for providing goods and services to the customer. The transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment and certain milestones, all other fees we may earn under our collaborative agreements are subject to significant uncertainties of product development and commercial sales targets. The transaction price of an agreement is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied.

Accrued Research and Development

We have entered into various agreements with CROs, CMOs, and other service providers. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, our estimated accruals have not differed materially from actual costs incurred.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of equity awards recognized in the period using the Black-Scholes option pricing model. We recognize the expense for equity awards on a straight-line basis over the

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requisite service periods of the awards, which is usually the vesting period. Forfeitures are recognized as they occur. Estimating the fair value of equity awards pursuant to the Black-Scholes option pricing model requires us to make assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. We determine these assumptions in the following manner:

- ***Fair Value of Common Stock.*** Prior to the Merger, since there was no public market for our common stock, our board of directors, with input from management, determined the fair value of our common stock on each grant date by considering a number of objective and subjective factors, including the most recent independent third-party valuation of our common stock, sales of our convertible preferred stock to unrelated third-parties, our operating and financial performance, the lack of liquidity of our capital stock and general and industry-specific economic outlook, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and that may have changed from the date of the most recent valuation through the date of the grant. Historically, these independent third-party valuations of our equity instruments were generally performed contemporaneously with identified value inflection points. Following the Merger, the fair market value of our common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which our 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 we have concluded that our stock option exercise history does not provide a reasonable basis upon which to estimate expected term.
- ***Expected Volatility.*** Given our limited historical stock price volatility data, we derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within our peer group that were deemed to be representative of future stock price trends as we have limited trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our 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.*** We have never paid dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Therefore, we used an expected dividend yield of zero.

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.

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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 earliest to occur of: (i) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (ii) the date upon which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) 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 and the market value of our stock held by non-affiliates is less than $700 million measured on the last business day of our 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.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2022 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders’ equity (deficit) and cash flows for each of the two years

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in the period ended December 31, 2022 December 31, 2023, 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, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 December 31, 2023, 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 23, 2023 21, 2024

ARS Pharmaceuticals, Inc.

CONSOLIDATED BALANCE SHEETS

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(In thousands, except par value and share amounts)

	December 31,		December 31,	December 31,
	2022	2021	2023	2022
Assets				
Current assets:				
Cash and cash equivalents	2 1 0, 5 1 $ 8	 6 0, 0 6 $ 3	$ 70,971	$ 210,518
Short-term investments	6 3, 8 6 3	 —	157,389	63,863
Prepaid expenses and other current assets	3, 3 1 9	 6 6 7	3,366	3,319
Total current assets	2 7 7, 7 0 0	 6 0, 7 3 0	231,726	277,700
Right-of-use asset	4 4 5	 2 1	250	445
Fixed assets, net	3 2 9	 7 2	574	329

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Other assets	2,962	2,613	638	2,961
Total assets	$ 281,435	$ 281,443	$ 233,188	$ 281,435
Liabilities, convertible preferred stock and stockholders' equity (deficit)				
Liabilities, convertible preferred stock and stockholders' equity				
Current liabilities:				
Accounts payable and accrued liabilities (including related party amounts of $16 in 2022 and $159 in 2021)	$ 14,930	$ 13,107		
Accounts payable and accrued liabilities (including related party amounts of $178 and $16, respectively)			$ 2,154	$ 4,931
Lease liability, current	230	214	237	230
Contract liability, current	282	145	—	283
Note payable, current	—	3,479		
Total current liabilities	15,442	16,945	2,391	5,444

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Lease liability, net of current portion	2 5 1	4 8 0	37	251
Contract liability, net of current portion	2, 8 5 4	2, 9 9 6	—	2,854
Note payable, net of current portion	 —	4, 9 3 0		
Preferred stock warrant liability	 —	8 3		
Total liabilities	 8, 5 4 9	1 6, 6 7 6	2,428	8,549
Commitments and contingencies (Note 7)				
Convertible preferred stock and stockholders' equity (deficit):				
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—		
Series A convertible preferred stock, $0.01 par value; no shares and 4,764,000 shares authorized at December 31, 2022 and 2021, respectively; no shares and 4,764,000 shares issued and outstanding at December 31, 2022 and 2021, respectively	 —	3 6 5		
Series B convertible preferred stock, $0.01 par value; no shares and 606,060 shares authorized at December 31, 2022 and 2021, respectively; no shares and 606,060 shares issued and outstanding at December 31, 2022 and 2021, respectively	 —	1, 0 0 0		
Series C convertible preferred stock, $0.01 par value; no shares and 7,749,999 shares authorized at December 31, 2022 and 2021, respectively; no shares and 7,692,309 shares issued and outstanding at December 31, 2022 and 2021, respectively	 —	1 9, 8 6 8		

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Series D convertible preferred stock, $0.01 par value; no shares and 9,337,066 shares authorized at December 31, 2022 and 2021, respectively; no shares and 9,337,066 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	5 4, 8 0 6		
Stockholders' equity (deficit)				
Common stock, $0.0001 par value; 200,000,000 and 56,000,000 shares authorized at December 31, 2022 and 2021, respectively; 93,943,316 and 30,369,413 shares issued and outstanding at December 31, 2022 and 2021, respectively	9	3		
Stockholders' equity				
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022			—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2023 and 2022; 96,414,963 and 93,943,316 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively			10	9
Additional paid-in capital	3 4 9, 4 0 8	 1 0, 9 8 4	362,004	349,408
Accumulated other comprehensive gain	4 0 7	 —		
Accumulated other comprehensive gain, net			49	407
Accumulated deficit	(7 6, 9 3 8)	(4 2, 2 5 6)	(131,303)	(76,938)

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Total stockholders' equity (deficit)	2 7 2, 8 8 6	(3 1, 2 6 9)		
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	2 8 1, 4 3 $ 5	6 1, 4 4 $ 6		
Total stockholders' equity			230,760	272,886
Total liabilities, convertible preferred stock and stockholders' equity			$ 233,188	$ 281,435

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

ARS Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share information)

	Years Ended December 31,	
	2022	2021
Revenue under collaboration agreements	$ 1,316	$ 5,506
Operating expenses:		

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Research and development (including related party amounts of $2,144 in 2022 and $1,072 in 2021)	18,376	20,273
General and administrative (including related party amounts of $603 in 2022 and $476 in 2021)	18,456	4,687
Total operating expenses	36,832	24,960
Loss from operations	(35,516)	(19,454)
Other income (expense):		
Other income (expense), net	974	(789)
Change in fair value of financial instruments	(140)	—
Total other income (expense):	834	(789)
Net loss	$ (34,682)	$ (20,243)
Unrealized gain on available-for-sale securities	407	—
Comprehensive loss attributable to common stockholders	$ (34,275)	$ (20,243)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (0.70)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	39,956,043	28,872,242

	Year Ended December 31,	
	2023	2022
Revenue under collaboration agreements	$ 30	$ 1,316
Operating expenses:		
Research and development (including related party amounts of $1,796 and $2,144, respectively)	20,266	18,376
General and administrative (including related party amounts of $940 and $603, respectively)	47,284	18,456
Total operating expenses	67,550	36,832
Loss from operations	(67,520)	(35,516)
Other income, net	13,155	974
Change in fair value of financial instruments	—	(140)
Net loss	$ (54,365)	$ (34,682)
Change in unrealized gains and losses on available-for-sale securities	(358)	407
Comprehensive loss	$ (54,723)	$ (34,275)
Net loss per share, basic and diluted	$ (0.57)	$ (0.87)

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Weighted-average shares outstanding used in computing net loss per share, basic and diluted	95,215,322	39,956,043

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

ARS Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	4,764,000	$ 36,605	606,060	$ 1,000	7,692,309	$ 19,868	—	$ —	26,411,772	$ 3	$ 7,958	$ —	$ (22,013)	$ (14,052)
Issuance of Series D convertible preferred stock for cash, net of issuance costs of $194	—	—	—	—	—	—	9,337,066	54,806	—	—	—	—	—	—

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Vesting of restricted common stock	—	—	—	—	—	—	—	—	3,756,226	—	28	—	—	28
Exercise of stock options	—	—	—	—	—	—	—	—	201,415	—	169	—	—	169
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	2,829	—	—	2,829
Net loss and comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	—	(20,243)	(20,243)
Balance at December 31, 2021	4,764,000	36,545	606,060	1,000	7,692,309	19,868	9,337,066	54,806	30,369,413	3	10,984	—	(42,256)	(31,269)
Conversion of preferred stock to common stock as a result of the Merger	(4,764,000)	(36,545)	(606,060)	(1,000)	(7,692,309)	(19,868)	(9,337,066)	(54,806)	26,473,899	3	76,036	—	—	76,039
Issuance of common stock to Silverback stockholders as a result of the Merger	—	—	—	—	—	—	—	—	36,535,541	3	255,758	—	—	255,761
Reclassification of warrant liability to equity	—	—	—	—	—	—	—	—	—	—	223	—	—	223

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Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	—	—	—	—	—	—	—	—	564,463	—	564	—	—	564
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	5,843	—	—	5,843
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	407	(34,682)	(34,275)
Balance at December 31, 2022	—	$ —	—	$ —	—	$ —	—	$ —	93,943,316	$ 9	$ 408,349	$ 407	$ (76,938)	$ 272,886

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain, Net	Accumulated Deficit	Total Stockholders' Equity

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Balance at December 31, 2021	4,764,000	$ 365	606,060	$ 1,000	7,692,309	$ 19,868	9,337,066	$ 54,806	30,369,413	$ 3	$ 10,984	$ —	$ (42,256)	$ (31,269)
Conversion of preferred stock to common stock as a result of the Merger	(4,764,000)	(365)	(606,060)	(1,000)	(7,692,309)	(19,868)	(9,337,066)	(54,806)	26,473,899	3	76,036	—	—	76,039
Issuance of common stock to Silverback stockholders as a result of the Merger	—	—	—	—	—	—	—	—	36,535,541	3	255,758	—	—	255,761
Reclassification of warrant liability to equity	—	—	—	—	—	—	—	—	—	—	223	—	—	223
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	—	—	—	—	—	—	—	—	564,463	—	564	—	—	564
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	5,843	—	—	5,843
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	407	(34,682)	(34,275)
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

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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

The accompanying notes are an integral part of these financial statements

ARS Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2023**	**2022**
Cash flows from operating activities:				
Net loss	$ (34,682)	$ (20,434)	$ (54,365)	$ (34,682)
Non-cash adjustments to reconcile net loss to net cash provided by (used) in operating activities:				
Non-cash adjustments to reconcile net loss to net cash used in operating activities:				

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Stock-based compensation expense	5,843	2,829	9,235	5,843
Acquired in-process research and development	1,056	—	—	1,056
Depreciation			73	34
Amortization and accretion, net			(6,878)	285
Change in fair value of warrant liability	140	(4)	—	140
Depreciation, amortization and accretion expense	319	213		
Changes in operating assets and liabilities:				
Prepaid and other assets	(1,186)	1,173	(1,435)	(1,186)
Accounts payable and accrued liabilities (including related party amounts of $(143) in 2022 and $13 in 2021)	(10,285)	974		
Donation of equipment			30	—
Accounts payable and accrued liabilities (including related party amounts of $162 and $(143), respectively)			(2,777)	(10,285)
Operating right-of-use assets and lease liabilities, net	33	4	(12)	33
Contract liability	(1,316)	(2,507)	(3,137)	(1,316)
Net cash used in operating activities	(40,078)	(17,561)	(59,266)	(40,078)
Cash flows from investing activities:				
Purchases of short-term investments, available-for-sale			(272,005)	—
Maturities of short-term investments, available-for-sale			185,000	—
Purchase of property and equipment	(199)	(55)	(175)	(199)
Net cash used in investing activities	(199)	(55)	(87,180)	(199)
Cash flows from financing activities:				

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Cash proceeds from the Merger, net of transaction costs	198,843	—	—	198,843
Proceeds from exercise of common stock options	570	169		
Proceeds from exercise of common stock options and employee stock purchase plan			6,899	570
Repayment of bank note payable	(8,681)	(1,817)	—	(8,681)
Proceeds from issuance of preferred stock, net	—	54,806		
Net cash provided by financing activities	190,732	53,158	6,899	190,732
Net change in cash and cash equivalents	150,455	35,542	(139,547)	150,455
Cash and cash equivalents at beginning of year	60,063	24,521		
Cash and cash equivalents at end of year	$ 210,518	$ 60,063		
Cash and cash equivalents at beginning of period			210,518	60,063
Cash and cash equivalents at end of period			$ 70,971	$ 210,518
Supplemental cash flow information:				
Conversion of Series A, B, C, and D convertible preferred stock to common stock	$ 76,039	$ —	$ —	$ 76,039
Short-term investments assumed in the Merger	$ 63,473	$ —	$ —	$ 63,473
Prepaid expense and other current assets assumed in the Merger	$ 4,404	$ —	$ —	$ 4,404

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Accounts payable and accrued liabilities assumed in the Merger	12,01			
	$ 7	$ —	$ —	$ 12,017
Reclassification of warrant liability to equity	22			
	$ 3	$ —	$ —	$ 223
Interest paid			$ —	$ 366
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	$ —
Purchases of property and equipment included in accounts payable	$ 91	$ —	$ —	$ 91
Interest paid	36	57		
	$ 6	$ 6		
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 Financial Statements

1. Nature of Business

Description of Business

ARS Pharmaceuticals, Inc. (“ARS”, “ARS Pharma” or the “Company”) is focused on the development of ARS-1 (brand name *neffy*®), a proprietary product candidate for the needle-free intranasal delivery of epinephrine for the emergency treatment of type 1 Type I allergic reactions including anaphylaxis. The Company incorporated in Delaware in January 2016

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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, which survived the Merger as more fully described below. 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.

Merger Transaction

On November 8, 2022 (the "Closing Date"), Silverback Therapeutics, Inc., a Delaware corporation ("Silverback"), now known as ARS Pharmaceuticals, Inc., completed its reverse merger (the "Merger") with privately-held ARS Pharmaceuticals, Inc. ("ARS Pharma"), Pharma, in accordance with the terms of the agreement and plan of merger and reorganization, dated July 21, 2022, as amended on August 11, 2022 and October 25, 2022 (the "Merger Agreement"), whereby Sabre Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly-owned subsidiary of Silverback, merged into ARS Pharma, with ARS Pharma surviving as Silverback's wholly-owned subsidiary. ARS Pharma was renamed ARS Subsidiary, Inc., and then subsequently renamed ARS Pharmaceuticals Operations, Inc.

At the effective time of the Merger (the "Effective Time"), each share of ARS Pharma common stock outstanding immediately prior to the Effective Time, after giving effect to the automatic conversion of all shares of preferred stock of ARS Pharma into shares of ARS Pharma common stock immediately prior to the Effective Time (excluding shares held as treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and dissenting shares), was automatically converted into the right to receive shares of Silverback common stock equal to the exchange ratio of 1.1819. At the completion of the Merger, the prior ARS Pharma equityholders owned 62% and the prior Silverback equityholders owned 38% of the combined company, in each case on a fully diluted basis using the treasury stock method and excluding out-of-money options of Silverback.

The Merger was accounted for as a reverse recapitalization, with ARS Pharma being treated as the acquirer for accounting purposes. Pursuant to the Merger Agreement, Silverback changed its name to ARS Pharmaceuticals, Inc., and changed its corporate ticker symbol on the Nasdaq Global Market to "SPRY". See discussions of the transactions in connection with the Merger at Note 3- 3 - Merger and Related Transactions.

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 $76.9 131.3 million as of December 31, 2022 December 31, 2023. The Company had cash, cash equivalents, and short-term investments of $274.4 228.4 million as of December 31, 2022 December 31, 2023 and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily with proceeds from the Merger, the issuance of convertible preferred stock, payments earned under collaboration agreements and bank debt. The Company's currently available cash, cash equivalents, and short-term investments as of December 31, 2022 December 31, 2023 are sufficient to meet its anticipated cash requirements for at least the 12 months following the date the these financial statements are issued.

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From August 5, 2015 (inception) through December 31, 2022 December 31, 2023, the Company has devoted substantially all of its efforts to developing intellectual property, and conducting product development and clinical trials, raising capital, and building infrastructure. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. If the Company does not successfully commercialize any product candidates for which it receives regulatory approval, it will be unable to generate recurring product revenue or achieve profitability. 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.

The novel coronavirus-2019 ("COVID-19") epidemic and geopolitical events have resulted in a significant disruption of global financial markets. The Company's ability to raise additional capital may be adversely impacted by potential worsening should the global economic conditions and worsen or as a result of further disruptions to, and volatility in, the credit and financial markets in the United States, including recent bank failures, and worldwide resulting from a resurgence of COVID-19, future health epidemics or pandemics, geopolitical actions or other macroeconomic factors. If such further disruption occurs, the Company could experience an inability to access additional capital. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

Reduction in Force

On September 19, 2023, the FDA issued a CRL regarding our NDA for *neffy*. On September 29, 2023, we initiated a 20% reduction in force ("RIF") in order to conserve our cash resources and manage operating expenses until the anticipated PDUFA target action date in the middle of the second half of 2024. We provided severance payments, continuation of group health insurance coverage, and other benefits for a specified period to the affected employees. We incurred costs of $0.6 million for termination benefits resulting from the RIF, of which $0.1 million remains accrued for as of December 31, 2023.

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

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the Accounting Standards Codification (“ASC”), and Accounting Standards Update (“ASU”), of the Financial Accounting Standards Board (“FASB”). The consolidated Company’s financial statements are presented on a consolidated basis, which include the accounts of the Company ARS Pharmaceuticals, Inc., ARS Pharmaceuticals Operations, Inc. and ARS Pharmaceuticals IRL, Limited for the year ended December 31, 2022. 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 (expense) in the consolidated statements of operations and comprehensive loss. All adjustments considered necessary for a fair presentation have been included.

Since ARS Pharma was determined to be the accounting acquirer in connection with the Merger, for periods prior to the Merger the consolidated financial statements were prepared on a stand-alone basis for ARS Pharma and did not include the combined entities activity or financial position. Subsequent For periods subsequent to the Merger, the consolidated financial statements as of and for the year ended December 31, 2022 include Silverback’s activity and Silverback’s assets and liabilities at their acquisition date fair value. Historical share and per share figures of ARS Pharma have been retroactively restated based on the exchange ratio in the Merger of 1.1819.

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 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 and money market and sweep accounts. mutual funds. The Company considers all highly liquid investments with original remaining maturities when purchased of three months 90 days or less at the date of purchase to be cash equivalents.

Investments

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The Company invests excess cash in investment grade intermediate-term 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 loss. (loss) gain, net. Realized gains and losses on the sale of these securities are recognized in net loss.

Fair Value of Financial Instruments

Cash, and cash equivalents, and short-term investments are carried at fair value. The carrying amounts of all 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 cash equivalents. 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.

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. Repairs Repair and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

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Long-lived assets consist primarily of property and equipment. 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. 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, 2022 December 31, 2023.

Leases

Effective January 1, 2021, the Company early adopted ASC No. 2016-02, *Leases(Topic 842)* ("ASC 842"), which supersedes the current accounting for leases, using the modified retrospective transition method. The Company has elected to apply the practical expedients allowed by the standard for existing leases. The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right-of-use ("ROU") asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense in a manner similar to current accounting, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. The Company determines the initial classification and measurement of its ROU 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 loss.

Warrant Liability

The Company has issued freestanding warrants to purchase shares of its Series C convertible preferred stock. Prior to the Merger, the Company adjusted the carrying value of such Series C convertible preferred stock warrants to the estimated fair value at each reporting date, with any related increases or decreases in the fair value being recorded within other income (expense) in the consolidated statements of operations and comprehensive loss. Pursuant to the Merger Agreement the Series C convertible preferred stock warrants became warrants to purchase shares of the combined company's common stock. As a result of the Merger, the warrants no longer meet the requirements for liability accounting, as such, the Company adjusted the value of the warrants to the estimated fair value as of the Merger date and reclassified them to equity.

Revenue Recognition

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Our revenues generally consist of licenses and research services under license and collaboration agreements. We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess 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.

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 our clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates 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.

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

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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.

The Company's equity incentive plans allow for the issuance of restricted stock awards that may be subject to vesting. The unvested shares of any restricted stock awards are held in escrow as the stock award vests or until the holder's termination of services, whichever occurs first. 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 holder's services terminate, share price of our common stock, the Company has the right of repurchase, at its option, the portion of unvested stock awards. For all early exercised unvested stock awards, a liability is established related may consider whether an adjustment to the cash received for observable market price is required when estimating the unvested portion of the stock award, which represents the Company's repurchase rights if the award holders were to be terminated and their stock repurchased. grant date fair value.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the

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year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

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

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive 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 loss was typically consists of the same as its reported net loss for all periods presented. 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.

Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without

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consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company. For purposes of this calculation, convertible preferred stock, stock options, and preferred stock warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

The following securities are excluded from the calculation of weighted-average dilutive common shares because their inclusion would have been anti-dilutive. Historical share figures have been retroactively restated based on the exchange ratio of 1.1819.

	December 31, 2022	December 31, 2021
Convertible preferred stock	—	26,473,899
Warrants to purchase convertible preferred stock	—	45,456

	As of December 31,	
	2023	2022
Warrants to purchase common stock	45,456	45,456
Common stock options granted and outstanding	11,493,481	12,063,560
Restricted stock units	4,144	10,651
Total	11,543,081	12,119,667

Recently Issued Adopted Accounting Pronouncements— Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. This update is standard was effective for the Company beginning January 1, 2023. 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 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 is effective for the Company as of January 1, 2024 for annual periods and as of January 1, 2025 for interim periods. The Company is currently evaluating the expected impact of ASU 2023-07 on the standard may have consolidated financial statements.

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In December 2023, the FASB issued ASU 2023-09, Income Taxes (ASU 2023-09), which requires issuers to make additional disclosures on its an annual basis related to specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold on an annual basis, disclose additional information about income taxes paid as well as other disaggregated disclosures. ASU 2023-09 is effective for the Company as of January 1, 2025 for annual periods. The Company is evaluating the expected impact of ASU 2023-09 on the consolidated financial statements and related disclosures.statements.

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3. Merger and Related Transactions

As described in Note 1- 1 - Nature of Business, ARS Pharma merged with Silverback on November 8, 2022. The Merger was accounted for as a reverse recapitalization under U.S. GAAP. ARS Pharma was considered the accounting acquirer for financial reporting purposes. This determination was based on the facts that, immediately following the Merger: (i) ARS Pharma stockholders own a substantial majority of the voting rights of the combined organization; (ii) ARS Pharma has designated a majority (eight of eleven) of the initial members of the board of directors of the combined organization; and (iii) ARS Pharma's senior management holds all key positions in senior management of the combined organization. The transaction was accounted for as a reverse recapitalization because on the effective date of the Merger, the pre-combination assets of Silverback were primarily cash and other non-operating assets. Additionally, the Company concluded that the in-process research and development ("("IPR&D"&D") assets that remained as of the combination were not significant when compared to the cash and investments obtained through the transaction.

Under reverse recapitalization accounting, the assets and liabilities of Silverback were recorded at their fair value, which approximated book value due to the short-term nature of the instruments. No goodwill or intangible assets were recognized. Consequently, the Company's consolidated financial statements reflect the issuance of 36,535,541 shares to the former stockholders of Silverback.

Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of ARS Pharma's preferred stock was converted into a one share of ARS Pharma's common stock.

As the accounting acquirer, ARS Pharma is deemed to have assumed all of Silverback's outstanding and unexercised stock options. The assumed options continue to be governed by the terms of the 2016 and 2020 Equity Incentive Plans of Silverback (as discussed more in Note 10- 10 - Stock-Based Compensation) under which the options were originally granted.

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As part of the reverse recapitalization, ARS Pharma obtained $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs. ARS Pharma also obtained prepaids and other current assets of approximately $4.4 0.8 million and assumed payables and accruals of approximately $12.0 million. ARS Pharma also obtained $1.1 million in IPR&D assets that have no alternative future use. The fair value attributable to these IPR&D assets was recorded as research and development expense in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2022. ARS Pharma also incurred transaction costs of approximately $2.1 million and this amount is was recorded as a reduction to additional paid-in capital.

During the fourth quarter ended December 31, 2023, the Company determined that the retrospective insurance policy that was recorded as an asset at the date of the Merger on November 8, 2022, should have been expensed by Silverback prior to the Merger. As a result, the Company has made a correction of an immaterial error during the quarter ended December 31, 2023, by reversing $0.6 million in previously recorded amortization expense incurred from the date of the Merger through September 30, 2023, removing the asset and reducing additional paid in capital in the accompanying consolidated statement amount of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2022. $3.6 million.

4. 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.

In 2021, based on the borrowing rates currently available to the Company for loans with similar terms, management believe the fair value of the note payable approximates its carrying value. In 2022, the note payable was fully paid off.

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

December 31, 2022	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair Value
Money market funds	1	$ 209,273	$ —	$ —	$ 209,273

December 31, 2023	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair Value
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

December 31, 2021	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair Value
Money market funds	1	$ 59,401	$ —	$ —	$ 59,401

December 31, 2022	Level	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair Value
Cash and cash equivalents - Money market mutual funds	1	$ 209,273	$ —	$ —	$ 209,273

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Short-term investments - U.S. Treasury securities	2	63,456	407	—	63,863
Total		$ 272,729	$ 407	$ —	$ 273,136

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, 2023, the Company purchased $272.0 million in short-term investments and there was $185.0 million in maturities of short-term investments. During the year ended December 31, 2022, the Company purchased no short-term investments and there were no 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 $0.4 million unrealized loss on available-for-sale securities for the year ended December 31, 2023 and a $0.4 million unrealized gain on available-for-sale securities for the year ended December 31, 2022. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of December 31, 2023 were primarily attributable to current economic and market conditions and not credit risk. As of December 31, 2023 and December 31, 2022, 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 $0.7 million as of December 31, 2023 and is included in prepaid expenses and other current assets in the accompanying consolidated balance sheet.

As of December 31, 2023 and December 31, 2022, the Company did not have any investments in an unrealized loss position.

As of December 31, 2022, the Company did not t have any liabilities that were measured at fair value on a recurring basis. As a result of the Merger, the preferred stock warrant liability that was outstanding was remeasured as of the Merger date and reclassified to equity. During 2022, the Company recorded total other expense relating to this warrant of $0.1 million. 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.

5. Balance Sheet Details

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

December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022

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Prepaid expenses			$ 1,124	$ 771
Prepaid insurance	$ 1,539	$ 666	904	1,539
Prepaid expenses	771	—		
Interest receivable	796	1	686	796
Prepaid development costs			380	—
Capitalized software implementation costs			163	—
Other receivables	213	—	109	213
Total	$ 3,319	$ 667	$ 3,366	$ 3,319

Property and equipment consisted of the following (in thousands):

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Equipment	$ 377	$ 86	$ 695	$ 377
Less accumulated depreciation	(48)	(14)	(121)	(48)
Total	$ 329	$ 72	$ 574	$ 329

Depreciation expense was immaterial $0.1 million for the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Capitalized software implementation costs			$ 617	$ —
Prepaid insurance	$ 2,940	$ —	—	2,940
Security deposit	21	23	21	21
Total	$ 2,961	$ 23	$ 638	$ 2,961

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Accounts payable	$ 1,659	$ 1,786	$ 759	$ 1,659

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Accrued legal and professional fees	908	53		
Accrued clinical expenses	609	477	515	609
Accrued compensation	447	660	315	447
Accrued development expenses			190	133
Accrued legal and professional fees			174	908
Accrued pre-commercialization marketing related expenses			42	—
Accrued tax expenses	174	—	4	174
Accrued development expenses	133	109		
Other	1,001	22	155	1,001
Total	$ 4,931	$ 3,107	$ 2,154	$ 4,931

6. Collaboration and Out-Licensing

The Company has entered into collaboration and licensing agreements 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. *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 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. *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

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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 transferred to the customer.

Research and Development Revenues. *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.

Clinical and Commercial Supply. *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 as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company has not earned revenues for clinical or commercial supply sales as of December 31, 2022 December 31, 2023.

Royalty/Transfer Price Revenues. *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, 2022 December 31, 2023.

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 the *neffy*technology and is responsible for completion of a certain clinical study and for the manufacturing of development and commercial drug supply. 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 is 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

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approval to commercialize *neffy*in Japan. In July 2020, the Company earned a $5.0 million milestone payment upon the completion of a clinical milestone in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy*and research and development services. The Company determined the initial transaction price to be the $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 re-assessed 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. The Company recognized revenue of less than $0.1 million and $0.2 0.1 million for the years ended December 31, 2022 December 31, 2023 and 2021, respectively and had a 2022, respectively. There was no contract liability of an immaterial amount and $0.1 million as of December 31, 2022 and 2021, respectively. December 31, 2023.

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Recordati Agreement

In September 2020, the Company entered into a License and Supply Agreement (the “Recordati Agreement”) with Recordati Ireland, Ltd. (“Recordati”) for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize *neffy* in Europe and certain European Free Trade Association, Russia/the Commonwealth of Independent States, Middle East and African countries (the “Recordati Territory”). Under the Recordati Agreement, the Company is responsible for completion of any clinical studies for *neffy* required by the European Medicines Agency (“EMA”) before granting European Union Marketing Authorization, and by the Medicines and Healthcare products Regulatory Agency (“MHRA”) prior to granting United Kingdom Marketing Authorization. The Company filed the initial regulatory submissions with the EMA in the fourth quarter of 2022 and will file the initial regulatory submissions with the MHRA for *neffy* and is responsible for the manufacturing of commercial supply. Recordati is solely responsible all regulatory activities in the region after the Company’s initial regulatory submissions to the EMA and MHRA, for any post-approval clinical studies and commercialization activities. Either party may terminate the Recordati Agreement for certain breaches. Unless terminated earlier by either or both parties, the term of the Recordati Agreement will continue as long as Recordati has commercial sales of *neffy* in the region.

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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. In addition, the Company is eligible to receive up to 90.0 million euros of milestone payments upon achievement of certain regulatory and commercial sales milestones. 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 Recordati. The per unit commercial supply costs are subject to a cap. The combined tiered royalty and supply price have a low double-digit cap.

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. These estimates will be re-assessed 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 November 2020, the Company earned a regulatory milestone of $6.0 million. The Company recognized revenue of $1.2 million and $2.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, there was a contract liability of $3.1 million and $4.4 million, respectively.

On February 22, 2023, the Company and Recordati entered into a termination agreement (the “Termination Agreement”), pursuant to which, among other things, the Company and Recordati agreed to terminate the Recordati Agreement. Pursuant to the Termination Agreement, and the Company will reacquire reacquired all of the Recordati’s Recordati rights, under paid Recordati a one-time upfront payment of €3.0 million, 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.

The Company determined that the Recordati rights at the time of entering into the 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 Termination Agreement ended the Company’s performance obligations pursuant to the Recordati Agreement as described 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. Accordingly, no revenue was recognized in the year ended December 31, 2023. The Company recognized revenue of $Note 14- Subsequent Events 1.2 million for the year ended December 31, 2022.

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,

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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. 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.

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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 would only constitute a performance obligation if they contain a material right. The Company determined the option to purchase the clinical and commercial supply was not at a significantly discounted price and does not represent a material right, therefore does not constitute a performance obligation. 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 re-assessed at each reporting period. The Company recognized revenue of the full $3.0 million during the year ended December 31, 2021.

A reconciliation of contract liability from the Alfresa, Recordati, and Pediatrix collaboration agreements was as follows (in thousands):

Balance at December 31, 2021	$	4,453		
Balance at December 31, 2022			$	3,137

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IPR&D expense related to the Termination Agreement		(3,107)
Revenue recognized	(1,316)	(30)
Balance at December 31, 2022	$ 3,137	
Balance at December 31, 2023		$ —

7. Commitments and Contingencies

Note Payable

In September 2019, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Silicon Valley Bank for working capital in the principal amount, as amended, of $10.0 million (the "Note"). The Note required interest only payments through June 30, 2021 and had a maturity date of March 1, 2024. In addition, there was a final payment ("Balloon Payment") of $0.3 million at maturity.

In connection with the Note, the lender received warrants to purchase 38,460 shares of Series C convertible preferred stock at $2.60 per share. The warrants were immediately exercisable and will expire on September 30, 2029. The estimated fair value of the warrants at issuance was $86,000, which was recorded as a debt discount. In addition, the Company recorded debt issuance costs totaling $47,000.

The debt discount, debt issuance costs and Balloon Payment were amortized to interest expense using the effective interest rate method over the loan term. The Company recognized interest expense In November 2022, as a result of the Merger, the warrants converted to warrants to purchase 45,456 shares of the Company's common stock at $0.6 2.20 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively, and debt discount amortization of $0.3 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively.per share.

On November 7, 2022, the Company paid off the remaining balance of $5.4 million on its loans with Silicon Valley Bank, including all principal and interest and the Balloon Payment. The warrants issued to Silicon Valley Bank in connection with the loans continue to be outstanding.

Leases

In October 2021, the Company entered into a 38 38-month-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

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agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. 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, 2022 December 31, 2023, the remaining lease term of the Company's operating lease was 26 14 monthsmonths, , 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 and immaterial for each of the years ended December 31, 2022 December 31, 2023 and 2021, respectively. 2022. The Company's variable lease expense was $0.1 million and immaterial for each of the years ended December 31, 2022 December 31, 2023 and 2021, respectively. 2022. Cash paid for amounts included in the measurement of lease liabilities was $0.2 million and zerofor each of the years ended December 31, 2022 December 31, 2023 and 2021, respectively.

2022.

Future As of December 31, 2023, future minimum noncancelable operating lease payments are as follows (in thousands):

Year ended December 31,	Amount	Amount
2023	$ 238	
2024	245	$ 245
2025	42	42
Total lease payments	525	287
Less imputed interest	(44)	(13)
Lease liability	481	274
Less current portion of lease liability	(230)	(237)
Lease liability, net of current portion	$ 251	$ 37

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 ("IPR") 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

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a type-1 hypersensitivity reaction, including anaphylaxis, using an aqueous nasal spray pharmaceutical formulation containing epinephrine or a salt thereof including the Company's *neffy* product candidate, 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. Both the Company and On April 12, 2023, Amphastar have the right to file a motion for reconsideration with the USPTO in addition to filed a notice of appeal with the United States Court of Appeals for the Federal Circuit. Although On May 15, 2023, the Company filed a motion to dismiss for lack of standing, which will be heard along with the merits of the case. Briefing on the merits is expected to be completed in the second quarter of 2024, and a decision from the Federal Circuit is expected by mid-2025. The results of any motion for reconsideration or notice of appeal proceedings are inherently unpredictable and uncertain, and could result in either the USPTO or the Federal Circuit finding some or all of claims 1-20 of the '414 patent to be invalid or unenforceable, the Company does not believe that an adverse outcome will have a material adverse effect on its business, operating results, cash flows or financial condition.unenforceable.

On November 5, 2021 July 24, 2023, Aera A/S, an IP consultancy firm in Denmark representing an unidentified opponent, filed a securities class action complaint was 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. We filed against Silverback a response to the notice of opposition on December 15, 2023, and certain we will continue to vigorously defend the EP '649 Patent. The results of Silverback's former officers any notice of opposition are inherently unpredictable and directors uncertain, and could result in the U.S. District for EPO finding the Western District of Washington, captioned Dresner v. Silverback Therapeutics, Inc., et al., Case No. 2:21-cv-01499 (the "Dresner Case"). The court has appointed lead plaintiff and lead plaintiff's counsel, and plaintiff's counsel then filed the amended complaint on April 11, 2022. The amended complaint alleges that between December 3, 2020 and March 31, 2022, Silverback and certain of its officers and directors violated (1) Sections 11 and 15 of the Securities Act of 1933, as amended; and (2) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, by making allegedly false and misleading statements in various SEC filings and press releases regarding the clinical and commercial prospects of its product candidate, SBT6050, which is now discontinued. The complaint seeks unspecified damages and interest, as well as attorneys' fees and other costs. Silverback and the other defendants filed a motion patent to dismiss on May 26, 2022 and lead plaintiff filed an opposition brief on July 11, 2022. On August 10, 2022, Silverback and the other defendants filed a reply brief. The court held a hearing on October 28, 2022 and issued an order granting defendants' motion to dismiss without prejudice on November 4, 2022. Plaintiffs were given leave to amend and filed a Second Amended Complaint ("SAC") on December 5, 2022, which asserted Section 11 claims only with respect to Silverback's December 3, 2020 IPO and Section 10(b) claims during a shorter class period of March 29, 2021 through March 31, 2022. Defendants filed a motion to dismiss the SAC on January 2, 2023. Lead plaintiff filed an opposition brief on January 23, 2023, and defendants filed a reply brief January 27, 2023. The court is expected to issue a ruling on the motion to dismiss in the first half of 2023.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

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its business, results of operations, and financial condition. The Company's chances of success on the merits of either 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, 2022 December 31, 2023.

Except as described above, the Company is not currently involved in any legal proceeding that it believes could have a materially adverse effect on its financial condition or results of operations. 132

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.

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8. 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 for the development of its lead product candidate, *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. The regulatory milestone payments under the Aegis Agreement will be recognized as research and development expense upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. 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 payment to Aegis upon the FDA's acceptance of the Company's New Drug Application ("NDA") NDA submission for *neffy*, which occurred in the third quarter of 2022. The Company may be required to pay royalties based on annual net product sales in the low to mid-single digits on its or its sublicensees' net sales of the Licensed Products (as defined in the Aegis Agreement) on a country-by-country and product-by-product basis.

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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, 2022 December 31, 2023 and 2021.2022.

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 "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 Supply Agreement unless this election is made. The parties may terminate the Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Supply Agreement in the event of certain breaches of the Supply Agreement or upon the earlier of the expiration or termination of the Aegis Agreement or June 2028. The Supply Agreement term may be extended by mutual written agreement. Expense recognized under Under the Supply Agreement, was $0.3 million and $1.0 million and $0.2 million for in expense was recognized in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Manufacturing Agreement with Renaissance

In September 2020, the Company entered into a manufacturing agreement (the "Renaissance Agreement") with Renaissance Lakewood, LLC ("Renaissance"), which was subsequently amended in July 2023 (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 E.U., 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.

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The initial term of the Renaissance Agreement commenced on September 9, 2020 and continues (a) for Renaissance Product designated for commercial sale in the U.S. until the earlier of the fifth anniversary of the (i) target U.S. launch date and (ii) the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the E.U. and other countries, the earlier of the fifth anniversary of (i) the target E.U. launch date and (ii) the initial E.U. launch date ("E.U. Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and E.U. 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 E.U. Renewal Term by providing the requisite prior notice to the other party. 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 Company has not submitted a regulatory filing for any Renaissance Product in the U.S. on or before June 30, 2022, (b) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before the target U.S. launch date, (c) the authorization and approval representing more than a targeted number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (d) 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. Expense recognized under the Renaissance Agreement was $2.0 million and $3.1 million for the years ended December 31, 2022 and 2021, respectively.

9. Convertible Preferred Stock and Common Stock and Stockholders' Equity (Deficit)

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.

Convertible Preferred Stock

In April 2016, the ARS Pharma issued 3,600,000 shares of Series A convertible preferred stock at $0.0833 per share for net cash proceeds of $0.3 million. Subsequently, in July 2017, an additional 1,164,000 shares of Series A convertible preferred stock were issued at $0.0833 per share for net cash proceeds of $0.1 million.

In March, June and July 2018, ARS Pharma issued a total of 606,060 shares of Series B convertible preferred stock at $1.65 per share for net cash proceeds of $1.0 million.

In September and December 2018, ARS Pharma issued 7,692,309 shares of Series C convertible preferred stock at $2.60 per share for net cash proceeds of $19.8 million.

In August 2021, ARS Pharma issued 9,337,066 shares of Series D convertible preferred stock at $5.89 per share for net cash proceeds of $54.8 million.

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Collectively, the Series A, B, C and D convertible preferred stock issuances will be referred to as “Series Convertible Preferred Stock.”

On November 8, 2022, November 2022, ARS Pharma completed the Merger with Silverback in accordance with the Merger Agreement. Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, 22,399,435 shares of ARS Pharma’s convertible preferred stock were converted into 26,473,899 shares of ARS Pharma’s common stock.

Common Stock

Upon In November 2022, upon completion of the Merger on November 8, 2022, and as the accounting acquirer, ARS Pharma is deemed to have issued 36,535,541 shares of its common stock to Silverback stockholders.

Common stock reserved for future issuance consisted of the following:

	December 31, 2022
Common stock options granted and outstanding	12,063,560
Common stock reserved for future awards or option grants	3,373,801
Total	15,437,361

	December 31, 2023	December 31, 2022
Common stock options granted and outstanding	11,493,481	12,063,560
Restricted stock units granted and outstanding	4,144	10,651
Common stock reserved for future awards or option grants	6,220,866	3,373,801
Warrants to purchase common stock	45,456	45,456
Total	17,763,947	15,493,468

10. Stock-Based Compensation

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

	Years Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Research and development expense	$ 213	$ 2,114	$ 2,274	$ 213
General and administrative expense	5,630	715	6,961	5,630

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Total stock-based compensation expense	$ 5,843	$ 2,829	$ 9,235	$ 5,843

As of December 31, 2022 December 31, 2023, the total unrecognized stock-based compensation expense related to outstanding employee options was $4.6 22.7 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.48 2.43 years.

For the year ended December 31, 2022, ARS Pharma recognized $1.3 million in stock-based compensation expense for 236,380 performance-based options that vested upon the closing of the Merger. For the year ended December 31, 2021, no performance-based stock-based compensation was recognized.

In November 2022, in connection with the Merger, the Company replaced (only for accounting purposes) 6,599,068 stock options and 493,456assumed restricted stock units held granted by Silverback, employees and directors. The replacement awards were revalued at their acquisition-date fair value and then attributed to pre and post-combination service. This resulted in $3.1 million in expense attributed to post-combination service to be recognized as compensation cost by the Company, of which $3.0 10,651 million has been recognized in general were outstanding as of December 31, 2022 and administrative expense in the accompanying consolidated statements of operations for the year ended December 31, 2022. 482,805 replaced restricted stock units vested in connection with the Merger and the remaining 10,651 4,144 are outstanding as of December 31, 2022 December 31, 2023.

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 as the accounting acquirer, is deemed to have assumed Silverback's Silverback's 2016 and 2020 Equity Incentive Plans, and Employee Stock Purchase Plan (“ESPP”). For There were 44,961 shares and an immaterial number of shares of common stock purchased under the year ESPP during the years ended December 31, 2022, ESPP activity is not material to the consolidated financial statements December 31, 2023 and 2022, respectively..

As of December 31, 2022 December 31, 2023, the 2016 and 2020 Equity Incentive Plans authorized a total of 11,321,495 16,018,660 shares, of which 3,079,688 5,923,521 shares are available for future grant, and 6,439,311 5,963,430 shares are outstanding. As of December 31, 2022 December 31, 2023, the 2018 Equity Incentive Plan authorized a total of 6,634,333 shares, of which 294,113 297,345 shares are available for future grant, and 5,634,900 5,534,195 shares are outstanding. The Company does not intend to grant future stock options or other equity awards under the 2016 or 2018 Equity Incentive Plan. Plans.

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Stock Options

Stock options granted under the Company's equity incentive plans expire no later than 10 yearsyears 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 our 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, 2022 December 31, 2023 is as follows:

	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	4,828,667	$ 16.10						
Assumed in the Merger	6,599,068	$ 14.10						
Outstanding at December 31, 2022					12,063,560	$ 6.07		
Granted	1,472,647	$ 1.50			4,749,600	$ 8.03		
Exercised	(548,768)	$ 1.04			(2,422,636)	$ 2.76		
Forfeited	(288,054)	$ 1.26			(2,897,043)	$ 15.06		
Outstanding at December 31, 2022	12,063,560	$ 7.06	5.56	$ 60,437				
Vested and expected to vest at December 31, 2022	12,063,560	$ 7.06	5.56	$ 60,437				

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Exercisable at December 31, 2022	12,03 2,474	6.0 $ 6	5.56	$ 60,336					
Outstanding at December 31, 2023					11,493,481	$ 5.32	7.89	$ 25,078	
Exercisable at December 31, 2023					7,502,931	$ 3.86	7.27	$ 25,078	

The exercisable shares subject to options outstanding at December 31, 2022 December 31, 2023 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, 2022 December 31, 2023.The aggregate intrinsic value of options exercised during the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $1.2 8.5 million and $0.1 1.2 million, respectively.

The weighted-average grant date fair value per share of option grants for the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $1.50 6.31 and $0.97 1.50, respectively. The total fair value of shares vested during the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $2.7 4.5 million and $0.4 2.7 million, respectively.

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

	Assumed on November 8, 2022	Years Ended December 31, 2022	Years Ended December 31, 2021	Year Ended December 31, 2023	Year Ended December 31, 2022
Expected term (in years)	0.8	6.1	6.0	6.0	6.1
Expected volatility	98.9%	91.3%	91.6%	95.3%	91.3%
Risk-free interest rate	4.5%	2.1%	1.2%	3.9%	2.1%
Expected dividend yield	—	—	—	—	—

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

Fair Value of Common Stock. Prior to the Merger on November 8, 2022, grant date fair market value of the shares of common stock underlying stock options was determined by ARS Pharma's Board of Directors. Following the Merger, 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. Prior to the Merger, there was no public market for the ARS Pharma's common stock, therefore the ARS Pharma Board of Directors determined the fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third-party valuations of the ARS Pharma common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, amongst other factors. Following the Merger, 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.zero.

11. Income Taxes

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,	Years Ended December 31,

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	2022	2021	2023	2022
Tax computed at federal statutory rate	$ (7,283)	$ (4,251)	$ (11,416)	$ (7,283)
State income taxes, net of federal benefit	(21)	(9)	(22)	(21)
Officers Compensation (Sec 162(m))			745	195
Equity compensation	290	562	749	290
Research and development credits	(624)	(1,120)	(1,179)	(624)
Other	452	38	(88)	257
Valuation allowance	7,186	4,780	11,211	7,186
Provision for income taxes	$ —	$ —	$ —	$ —

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

	Years Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating losses	$ 8,252	$ 5,457
Research and development credits	2,964	2,340
Intangible assets	3,746	219
Equity compensation	2,279	63
Contract liability	661	943
Other	104	257
Total deferred tax assets	18,006	9,279
Deferred tax liabilities:		
ROU asset	(94)	(131)
Other	(155)	(10)
Total deferred liabilities	(249)	(141)
Gross deferred tax assets	17,757	9,138
Valuation allowance	(17,757)	(9,138)

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Net deferred tax assets	$ —	$ —

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 16,127	$ 8,252
Research and development credits	4,143	2,964
Intangible assets	7,322	3,746
Equity compensation	1,498	2,279
Contract liability	—	661
Other	66	104
Total deferred tax assets	29,156	18,006
Deferred tax liabilities:		
ROU asset	(53)	(94)
Other	(59)	(155)
Total deferred liabilities	(112)	(249)
Gross deferred tax assets	29,044	17,757
Valuation allowance	(29,044)	(17,757)
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, 2022 December 31, 2023 was an increase of $8.6 11.3 million.

At December 31, 2022 December 31, 2023, the Company had federal and state net operating loss carryforwards (“NOL”) (NOL) of $38.9 76.2 million and $7.2 2.5 million, respectively. Federal NOL carryforwards of $38.9 76.2 million, generated after 2017, may be carryforward 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 $1.6 2.0 million may be carried forward indefinitely. In addition, the Company also has federal and California research and development credit carryforwards totaling $3.4 3.8 million and $0.7 0.4 million, respectively. The federal research and development credit carryforwards will begin to expire in 2035 unless previously utilized. The California research credits do 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”) (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

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50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes have occurred or occurs 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.

Additionally, as part of the transaction with Silverback, certain deferred tax assets generated in the Silverback pre-Merger periods were acquired by the Company consisting of federal and state net operation loss carryovers, research tax credit carryovers, and other tax attributes. These deferred tax assets will be subject to limitations on future use under IRC Section 382 and some of the attributes may expire unused. The Company has not completed an analysis under IRC Section 382 to determine the amount of such tax attributes that will be available annually and how much, if any, of the tax attributes may expire unused. As a result, the Company has not included any of these deferred tax assets in its components of deferred tax asset in the table above. Once the analysis is complete, to the extent that such deferred tax assets are available for future utilization, such assets will be included in the deferred tax assets and will be fully offset by valuation allowance as of December 31, 2022 December 31, 2023.

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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.

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The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Years Ended December 31,	
	2022	2021

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Unrecognized tax benefits - beginning	$ 1,147	$ 941
Gross increase – current-period tax positions	373	206
Unrecognized tax benefits - ending	$ 1,520	$ 1,147

	Years Ended December 31,	
	2023	2022
Unrecognized tax benefits - beginning	$ 1,520	$ 1,147
Gross increases – tax positions in prior period	951	—
Gross increase – current-period tax positions	475	373
Unrecognized tax benefits - ending	$ 2,946	$ 1,520

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, within the United States, and Ireland. Due to the Company's losses incurred, the Company's 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, 2022 December 31, 2023, 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.

12. 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 contributions, pay that they contribute to the plan, subject to IRS limitations. Expense Expenses associated with the Company's matching contribution totaled $0.4 million and $0.1 million for the year years ended December 31, 2022. December 31, 2023 and 2022, respectively.

13. 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, LLC, 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 $2.1 1.9 million and $1.1 2.1 million during the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

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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. In addition, Marlinspike Group provides the use of its facilities to the Company from time to time. 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 annual expenses related to this agreement totaling $0.2 million for both of the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

In November 2018, the Company entered into a consulting agreement for commercial and marketing consulting services with Red Team Associates, LLC (“Red Team”), an entity controlled by the former Executive Vice President of Commercial Strategy of the Company. The Company incurred consulting expense related to this agreement totaling $0.2 0.4 million and $0.1 0.2 million during the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

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 its current and 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, 2022 December 31, 2023 and 2021.

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14. Subsequent Events

Termination Agreement

On February 22, 2023, the Company entered into the Termination Agreement with Recordati, pursuant to which, among other things, the Company and Recordati agreed to terminate the Recordati License and Supply Agreement. Pursuant to the Termination Agreement, the Company will reacquire all of the Recordati Rights and has agreed to pay Recordati a one-time upfront payment of €3.0 million and 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) milestone payments of up to €5.0 million in the aggregate from sales of Recordati Licensed Product(s) in the Recordati Territory. 2022.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

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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, 2022 December 31, 2023. 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, 2022 December 31, 2023, 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, 2022 December 31, 2023.

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, 2022 December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Item 9B. Other Information.

Trading Arrangements

None. During the quarter ended December 31, 2023, one of our executive officers modified an existing trading plan for the orderly disposition of the Company's securities as set forth in the table below. Such modification of the existing trading plan was treated as the termination of an existing plan and the adoption of a new plan pursuant to Rule 10b5-1(c)(iv) under the Exchange Act.

Name and Position	Action	Adoption/Termination Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1(1)	Non-Rule 10b5-1(2)		
Brian Dorsey, Chief Operating Officer	Termination(3)	December 8, 2023	X		340,000	March 31, 2025
Brian Dorsey, Chief Operating Officer	Adoption(3)	December 8, 2023	X		340,000	March 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 modification, as described in Rule 10b5-1(c)(1)(iv) under the Exchange Act, of a written plan adopted on March 31, 2023 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.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information The information required by this item and not set forth below will be set forth in the sections headed *Election of Directors* and *Executive Officers* contained in our definitive proxy statement for our 2023 2024 annual meeting of stockholders to be filed with the Securities and Exchange Commission on or before May 1, 2023 April 29, 2024 (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 section 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.

Information The information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners and Management* and Ex*Executive and Director Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information 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.

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Item 14. Principal Accountant Fees and Services.

Information The information required by this item will be set forth in the sections 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, 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:

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	116
Consolidated Balance Sheets	108 117
Consolidated Statements of Operations and Comprehensive Loss	109 118
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	110 119
Consolidated Statements of Cash Flows	111 120
Notes to Financial Statements	112 121

(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

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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. 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	Amended and Restated Investors' Rights Agreement, by and between the registrant and certain of its stockholders, dated September 22, 2020 (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
4.3	Description of Registrant's Common Stock. 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).
4.5	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 (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).

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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. 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 May 12, 2022). amended.
10.10*‡*	10.1 Termination Agreement, dated as of February 22, 2023, by and between ARS Pharmaceuticals, Inc. and Recordati Ireland, Ltd. 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*‡*	10.1 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*‡*	10.1 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*‡*	10.1 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*‡*	10.1 Manufacturing Agreement, dated as September 9, 2020, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC (incorporated by reference to Exhibit 10.4 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).

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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)

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21.1	Subsidiaries of the registrant.
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.
101.INS	Inline XBRL Instance Document 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 Document
101.CAL	Inline XBRL Taxonomy Extension Calculation With Embedded Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document Documents
104	Cover Page Interactive Data File (embedded within the page formatted as Inline XBRL document) 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.

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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 23, 2023 March 21, 2024

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

Richard Lowenthal, M.S., MBA 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 Kathy 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, M.S., MBA MSEL Richard Lowenthal, M.S., MBA MSEL	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	March 23, 2023 21, 2024
/s/ Kathy Kathleen D. Scott Kathy Kathleen D. Scott	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2023 21, 2024
/s/ Pratik Shah, Ph.D. Pratik Shah, Ph.D.	Chairman of the Board of Directors	March 23, 2023 21, 2024
/s/ Peter Kolchinsky, Ph.D.	Director	March 23, 2023 21, 2024

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Peter Kolchinsky, Ph.D.		
/s/ Rajeev Dadoo, Ph.D. Rajeev Dadoo, Ph.D.	Director	March 23, 2023 21, 2024
/s/ Brenton L. Saunders Brenton L. Saunders	Director	March 23, 2023 21, 2024
/s/ Phillip Schneider Phillip Schneider	Director	March 23, 2023 21, 2024
/s/ Michael Kelly Michael Kelly	Director	March 23, 2023 21, 2024
/s/ Jonathan S. Leff Jonathan S. Leff	Director	March 23, 2023
/s/ Laura Shawver, Ph.D. Laura Shawver, Ph.D.	Director	March 23, 2023 21, 2024
/s/ Peter A. Thompson, M.D. Peter A. Thompson, M.D.	Director	March 23, 2023 21, 2024
/s/ Saqib Islam, J.D. Saqib Islam, J.D.	Director	March 23, 2023 21, 2024

Exhibit 3.110.9

AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION OF

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SILVERBACK THERAPEUTICS, INC.

Laura Shawver, Ph.D., hereby certifies that:

ONE: She is the duly elected Chief Executive Officer of Silverback Therapeutics, ARS Pharmaceuticals, Inc., a Delaware corporation.

TWO: The date of filing the original Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware was January 4, 2016.

THREE: The Amended and Restated Certificate of Incorporation of the corporation is hereby amended and restated to read in its entirety as follows:

I.

The name of this corporation is Silverback Therapeutics, Inc. (the "***Company***").

II.

The address of the registered office of the Company in the State of Delaware is 1013 Centre Road, Suite 403-B, Wilmington, New Castle County, Delaware 19808 and the name of its registered agent at such address is Vcorp Services, LLC.

III.

The purpose of the Company is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law ("***DGCL***").

IV.

A. The Company is authorized to issue two classes of stock to be designated, respectively, "***Common Stock***" and "***Preferred Stock***." The total number of shares which the Company is authorized to issue is 210,000,000 shares. 200,000,000 shares shall be Common Stock, each having a par value of $0.0001. 10,000,000 shares shall be Preferred Stock, each having a par value of $0.0001.

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Company (the "***Board of Directors***") is hereby expressly authorized to provide for the issue of any or all of the unissued and undesignated shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the

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foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the stock of the Company entitled to vote thereon, without a separate vote of the holders of the

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Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.**Non-Employee Director Compensation Policy**

Amended Effective: December 6, 2022

C. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; *provided, however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (this "***Certificate of Incorporation***") (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other such series of Preferred Stock, to vote thereon by law or pursuant to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

V.

For the management of the business and for the conduct of the affairs of the Company, and in further definition, limitation and regulation of the powers of the Company, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A. The management of the business and the conduct of the affairs of the Company shall be vested in its Board of Directors. The number of directors that shall constitute the Board of Directors shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board of Directors.

B. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. The Board of Directors is authorized to assign members member of the Board of Directors already in office to such classes at the time the classification becomes effective. At the first annual meeting of stockholders following the initial classification of the Board of Directors, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following such initial classification, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following such initial classification, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual

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meeting. Notwithstanding the foregoing provisions of this section, each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

C. Subject to the rights of any series of Preferred Stock that may be designated from time to time to elect additional directors under specified circumstances, neither the Board of Directors nor any individual director may be removed without cause. Subject to any limitations imposed by applicable law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all then-outstanding shares of capital stock of the Company entitled to vote generally at an election of directors, voting together as a single class.

D. Subject to any limitations imposed by applicable law and subject to the rights of the holders of any series of Preferred Stock that may be designated from time to time, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by applicable law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

E. The Board of Directors is expressly empowered to adopt, amend or repeal the Amended and Restated Bylaws of the Company (the "***Bylaws Board***"). Any adoption, amendment or repeal of the Bylaws by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders shall who is not also have power to adopt, amend or repeal the Bylaws; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the Company required by law or by this Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the capital stock of the Company entitled to vote generally in the election of directors, voting together serving as a single class.

F. The directors of the Company need not be elected by written ballot unless the Bylaws so provide.

G. No action shall be taken by the stockholders of the Company except at an annual or special meeting of stockholders called in accordance with the Bylaws. No action shall be taken by the stockholders of the Company by written consent or electronic transmission.

H. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Company shall be given in the manner provided in the Bylaws.

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VI.

A. The liability of a director of the Company for monetary damages shall be eliminated to the fullest extent under applicable law.

B. To the fullest extent permitted by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Company (and any other persons to which applicable law permits the Company to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article VI to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the Company shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.

C. Any repeal or modification of this Article VI shall only be prospective and shall not affect the rights or protections or increase the liability of any director under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

A. Unless the Corporation consents 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 be the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (A) any derivative claim or cause of action brought on behalf of the Corporation; (B) any claim or cause of action for breach of a fiduciary duty owed by any current or former director, officer or other employee of the Corporation, to the Corporation or the Corporation's stockholders; (C) any claim or cause of action against the Corporation or any current or former director, officer or other employee of the Corporation, arising out of or pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws of the Corporation (as each may be amended from time to time); (D) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of this Certificate of Incorporation or the Bylaws of the Corporation (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (E) any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and (F) any claim or cause of action against the Corporation or any current or former director, officer or other employee of the Corporation, governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court

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having personal jurisdiction over the indispensable parties named as defendants. This Section A of Article VII shall not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act of 1933, as amended

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(the “1933 Act”), or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

B. Unless the Corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the 1933 Act.

C. Any person or entity holding, owning or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to the provisions of this Certificate of Incorporation.

VIII.

A. The Company reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in Section B of this Article VIII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

B. Notwithstanding any other provisions of this Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Company required by law or by this Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock that may be designated from time to time, subject to the rights of the holders of any series of Preferred Stock, the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, VII or VIII of this Certificate of Incorporation.

* * * *

FOUR: This Certificate of Incorporation has been duly adopted and approved by the Board of Directors and by written consent of the stockholders in accordance with Sections 228, 242 and 245 of the DGCL and written notice of such action has been given as provided in section 228 of the DGCL.

[Signature page follows]

IN WITNESS WHEREOF, Silverback Therapeutics, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by its Chief Executive Officer this 8th day of December, 2020.

SILVERBACK THERAPEUTICS, INC.

/s/ Laura Shawver, Ph.D.

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LAURA SHAWVER, PH.D.
Chief Executive Officer

CERTIFICATE OF AMENDMENT TO
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
SILVERBACK THERAPEUTICS, INC.

SILVERBACK THERAPEUTICS, INC. (the "***Corporation***"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "***DGCL***"), does hereby certify:

FIRST: The name of the Corporation is Silverback Therapeutics, Inc.

SECOND: The date on which the Certificate of Incorporation of the Corporation was originally filed with the Secretary of State of Delaware is January 4, 2016, under the name "Silverback Therapeutics, Inc.".

THIRD: The Board of Directors of the Corporation, acting in accordance with the provisions of Sections 141 and 242 of the DGCL, adopted resolutions amending the Corporation's Amended and Restated Certificate of Incorporation (the "***Certificate***"), as follows:

Article First of the Certificate shall be amended and restated in its entirety to read as follows:

"The name of this corporation is ARS Pharmaceuticals, Inc. (the "***Company***")."

F or any of its subsidiaries (each such member, an "*OUR Eligible Director*:") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This Certificate of Amendment to Amended and Restated Certificate of Incorporation shall become policy is effective as of November 8, 2022 at 4:02 pm Eastern Time, following the filing with the Secretary of State of the State of Delaware.

I December 6, 2022 (the "*N Effective Date* WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation as of November 7, 2022.

By: /s/ Jeffrey C. Pepe
Name: Jeffrey C. Pepe

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Title: Interim Chief Executive Officer

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of ARS Pharmaceuticals, Inc. ("we," "our" or "us") is based on the provisions of our amended and restated certificate of incorporation, as amended (our "amended and restated certificate of incorporation"), as well as our amended and restated bylaws, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our amended and restated certificate of incorporation, amended and restated bylaws, and the Delaware General Corporation Law. Our amended and restated certificate of incorporation and amended and restated bylaws have previously been filed as exhibits with the Securities and Exchange Commission.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

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Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of amended at any series of our preferred stock that we may designate and issue time in the future.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transactio that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in

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which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock o the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

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- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder’s notice;

- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, and not by our stockholders; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

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The amendment of any of these provisions would require approval by the holders of at least 662/3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation provides that 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 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 our behalf; (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 to us 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 Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law 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 will not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

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In addition, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Although we believe these provisions benefit us by providing increased consistency in the application of law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

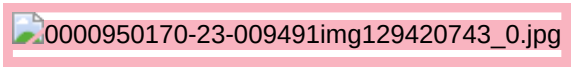
Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol “SPRY.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

Exhibit 10.8



ARS Pharmaceuticals, Inc.

Change in Control and Severance Benefit Plan

Approved by the Board of Directors: November 6, 2020

Section 1. Introduction.

The ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the “***Plan***”) was established effective upon the IPO Date. The purpose of the Plan is to provide for the payment of severance and/or change in control benefits to eligible employees of ARS Pharmaceuticals, Inc.(the “***Company***”)in the event that such employees become subject to involuntary or constructive employment terminations, including in

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connection with a Change in Control. Except as otherwise provided in an individual Participation Agreement, this Plan shall supersede any change in control or severance benefit plan, policy or practice previously maintained by the Company, including any severance benefits set forth in any individually negotiated employment contract or agreement between the Company and an employee, unless such employment contract or agreement provides for benefits that are in substance more favorable to the employee. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) "**Affiliate**" means any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(b) "**Base Salary**" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect immediately prior to a Covered Termination and prior to any reduction that would give rise to an employee's right to resign for Good Reason.

(c) "**Board**" means the Board of Directors of the Company; provided, however, that if the Board has delegated authority to administer the Plan to the Compensation Committee discretion of the Board then "**Board**" shall also mean or the Compensation Committee of the Board.

Annual Cash Compensation

(d) "**Cause**" means, with respect The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a particular employee, committee of the meaning ascribed to such term in any written agreement between such employee and Board at a time other than effective as of the Company defining such term, and, first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the absence of such agreement, means applicable fiscal quarter, with respect to such employee the occurrence of any pro-rated amount paid on the last day of the following events: (i) first fiscal quarter in which the employee's attempted commission of, or participation in, a fraud or act of dishonesty against Eligible Director provides the Company; (ii) the employee's intentional, material violation of any contract or agreement between the employee service and the Company or of any statutory duty owed to the Company; (iii) the employee's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (iv) the employee's gross or willful misconduct. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion. regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

11682 El Camino Real, Suite 120, San Diego CA 92130 1. Annual Board Service Retainer:

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a. All Eligible Directors: $40,000

b. Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

(e) 2. " Annual Committee Chair Service Retainer Change in Control :

a. Chair of the Audit Committee: $20,000

b. Chair of the Compensation Committee: $15,000

c. Chair of the Nominating and Corporate Governance Committee: $15,000

3. " shall have Annual Committee Member Service Retainer (not applicable to Committee Chairs):

a. Member of the meaning ascribed to such term in Audit Committee: $10,000

b. Member of the Compensation Committee: $7,500

c. Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2020 Equity Incentive Plan.

(f) "**Change in Control Period**" means the period commencing three (3) months prior to the Closing of a Change in Control and ending twelve (12) months following such Closing.

(g) "**Change in Control Termination**" means an Involuntary Termination that occurs within the Change in Control Period. For such purposes, if the events giving rise to an employee's right to resign for Good Reason arise within the Change in Control Period, and the employee's resignation occurs not later than thirty (30) days after the expiration of the Cure Period (as defined below), such termination shall be a Change in Control Termination.

(h)"Closing" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(i) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985.

(j) "**Code**" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(k) "**Company**" means ARS Pharmaceuticals, Inc. or, following a Change in Control, the surviving entity resulting from such event.

(l) "**Covered Termination**" means a Regular Termination or a Change in Control Termination.

(m)"Director" means a member of the Board.

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(n) "**Disability**" means any physical or mental condition which renders an employee incapable of performing the work for which he or she was employed by the Company or similar work offered by the Company. The Disability of an employee shall be established if (i) the employee satisfies the requirements for benefits under the Company's long-term disability plan or (ii) if no long-term disability plan, the employee satisfies the requirements for Social Security disability benefits.

(o) "**Eligible Employee**" means an employee of the Company who meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

(p)"Entity" means a corporation, partnership, limited liability company or other entity.

(q) "**Good Reason**" for an employee's resignation means the occurrence of any of the following events, conditions or actions taken by the Company without Cause and without such employee's consent: (i) a material reduction of such employee's annual base salary, which is a reduction of at least 10% of such employee's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); (ii) a material reduction in such employee's authority, duties or responsibilities; (iii) in the case of employees reporting to the Board or the Company's Chief Executive Officer, a material adverse change in such reporting level requiring that employee to report to a corporate officer or executive other than the Board or the Company's Chief Executive Officer, as the case may be; (iv) a relocation of such employee's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases such employee's one-way commute by more than fifty (50) miles as compared to such employee's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business); provided that if such employee's principal place of employment is his or her personal residence, this clause (iv) shall not apply; or (v) a material breach by the Company of any material agreement between you and the Company; provided, however, that in each case above, in order for the employee's resignation to be deemed to have been for Good Reason, the employee must first give the Company written notice of the action or omission giving rise to "Good

Reason" within ninety (90) days after the first occurrence thereof; the Company must fail to reasonably cure such action or omission within thirty (30) days after receipt of such notice (the "**Cure Period**"), and the employee's resignation must be effective not later than thirty (30) days after the expiration of such Cure Period.

(r) "**Involuntary Termination**" means a termination of employment that is due to: (1) a termination by the Company without Cause (and other than as a result of the employee's death or Disability) or (2) an employee's resignation for Good Reason.

(s) "**IPO Date**" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the common stock, of the Company pursuant to which the

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common stock of the Company is priced for the initial public offering, which occurred on December 3, 2020.

(t) "**Participation Agreement**" means an agreement between an employee and the Company in substantially the form of Appendix A attached hereto, which may include such other terms as the Plan Administrator deems necessary or advisable in the administration of the Plan.

(u) "**Plan Administrator**" means the Board, or a duly authorized committee thereof, prior to the Closing and the Representative upon and following the Closing.

(v)"Representative" means one or more members of the Board or other persons or entities designated by the Board prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 10(a).

(w) "**Regular Termination**" means an Involuntary Termination that is not a Change in Control Termination.

(x) "**Section 409A**" means Section 409A of the Code and the treasury regulations and other guidance thereunder and any state law of similar effect.

(y) "**Target Bonus**" means with respect to an Eligible Employee, if there is a cash bonus plan applicable to such Eligible Employee for the year in which such Covered Termination occurs ("**Cash Bonus Plan**"), the cash bonus payable to such Eligible Employee under such Cash Bonus Plan as if all the applicable performance goals for such year were attained at a level of 100%. If no Cash Bonus Plan is in effect for the year in which such Covered Termination occurs, the Target Bonus Amount will be the target bonus, if any, in such Eligible Employee's then-effective employment agreement or offer letter with the Company, as if all of the applicable performance goals for such year were attained at a level of 100%.

SECTION 2. ELIGIBILITY FOR BENEFITS.

(a)Eligible Employee. An employee of the Company is eligible to participate in the Plan if (i) the Plan Administrator has designated such employee as eligible to participate in the Plan by providing such person with a Participation Agreement (the initial list of such employees designated by the Plan Administrator to participate in the Plan is set forth in Appendix B hereto); (ii) such employee has signed and returned such Participation Agreement to the Company within the period specified therein; (iii) such employee's employment with the Company terminates due to a Covered Termination; and (iv) such employee meets the other Plan eligibility requirements set forth in this Section 2. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

(b)Release Requirement. In order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release in substantially the form attached hereto as Exhibit A, Exhibit B or

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Exhibit C, as appropriate (the "**Release**"), within the applicable time period set forth therein, but in no event more than sixty (60) days following the date of the applicable Covered Termination, and such Release must become effective in accordance with its terms. The Company, in its sole discretion, may modify the form of the Release to comply with applicable law and may elect to incorporate it into a more fulsome separation and release agreement.

(c)Plan Benefits Provided in Lieu of Individual Agreement Severance Benefits. Unless otherwise determined by the Plan Administrator in its discretion, if an employee is an Eligible Employee and eligible to receive severance benefits under this Plan and otherwise eligible to receive severance benefits under the terms of an individually negotiated employment contract or agreement with the Company or any other severance arrangement with the Company that are of the same category and would otherwise duplicate the severance benefits available under this Plan ("**Duplicative Benefits**") such Eligible Employee will receive severance benefits under this Plan in lieu of, and not additional to, such Duplicative Benefits. If an Eligible Employee is eligible to receive Plan benefits, such Eligible Employee will receive severance benefits under any individually negotiated employment contract or agreement only to the extent that such benefits have not been waived or terminated and are not Duplicative Benefits.

(d)Exceptions to Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee is terminated by the Company for any reason or voluntarily terminates employment with the Company in any manner (including due to the employee's death or Disability), and in either case, such termination does not constitute a Covered Termination. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date.

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

(3) The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation and would not give rise to the employee's right to resign for Good Reason.

(4) The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control and the terms of such reemployment would not give rise to the employee's right to resign for Good Reason. For purposes of the

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foregoing, “immediate reemployment” means that the employee’s employment with the successor to the Company or an Affiliateor the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets. An employee who becomes immediately reemployed as described in this Section 2(d)(4) by a successor to the Company or an Affiliate or by a purchaser of the Company’s assets, as the case may be, following a Change in Control shall continue to be an Eligible Employee following the date of such reemployment.

(5) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date benefits under the Plan are scheduled to commence.

(e)Termination of Severance Benefits. An Eligible Employee’s right to receive severance benefits under this Plan shall terminate immediately if, at any time prior to or during the period for which the Eligible Employee is receiving severance benefits under the Plan, the Eligible Employee, without the prior written approval of the Plan Administrator, engages in a Prohibited Action (as defined below). In addition, if benefits under the Plan have already been paid to the Eligible Employee and the Eligible Employee subsequently engages in a Prohibited Action during the Prohibited Period (or it is determined that an Eligible Employee engaged in a Prohibited Action prior to receipt of such benefits), any benefits previously paid to the Eligible Employee shall be subject to recoupment by the Company on such terms and conditions as shall be determined by the Plan Administrator, in its sole discretion. The “**Prohibited Period**” shall commence on the date of the Eligible Employee’s Covered Termination and continue for the number of months corresponding to the Severance Period set forth in such Eligible Employee’s Participation Agreement. A “**Prohibited Action**” shall occur if the Eligible Employee: (i) breaches any material statutory, common law, or contractual obligation to the Company or an Affiliate (including, without limitation, the contractual obligations set forth in the Company’s standard employee confidentiality agreement, the Release and/or any other obligations of confidentiality, non-solicitation, non-disparagement, no conflicts or non-competition set forth in the Eligible Employee’s employment agreement, offer letter, any other written agreement between the Eligible Employee and the Company, or under applicable law); (ii) encourages or solicits any of the Company’s

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then current employees to leave the Company’s employ for any reason or interferes in any other manner with employment relationships at the time existing between the Company and its then current employees; or (iii) induces any of the Company’s then current clients, customers, suppliers, vendors, distributors, licensors, licensees, or other third parties to terminate their existing business relationship with the Company or interferes in any other manner with any existing business relationship between the Company and any then current client, customer, supplier, vendor, distributor, licensor, licensee, or other third parties.

SECTION 3. AMOUNT OF BENEFIT.

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(a)Severance Benefit. Benefits under the Plan shall be provided to an Eligible Employee as set forth in the Participation Agreement.

(b)Additional Benefits. Notwithstanding the foregoing, the Company may, in its sole discretion, provide benefits to employees or consultants who are not Eligible Employees ("**Non-Eligible Employees**") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other Non-Eligible Employee, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(c)Certain Reductions. The Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance benefits, in whole or in part, by any other severance benefits, pay and benefits provided during a period following written notice of a plant closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law, (ii) any individually negotiated employment contract or agreement or any other written employment or severance agreement with the Company, or (iii) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time (not to exceed sixty (60) days) after being given notice of the termination of the Eligible Employee's employment, and the Plan Administrator shall so construe and implement the terms of the Plan. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (i.e., any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice, and any continued insurance benefits under the Plan shall be reduced solely by any continued insurance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Eligible Employee, even if similarly situated. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(d)Parachute Payments.

(1) Except as otherwise provided in an individual Participation Agreement, if any payment or benefit an Eligible Employee will or may receive from the Company or otherwise (a "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such Payment shall be

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equal to the Reduced Amount. The "**Reduced Amount**" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for the Eligible

Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

(2) Notwithstanding any provisions in this Section above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Eligible Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(3) The Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section 3(d). The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. If the Eligible Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) above and the U.S. Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) above) so that no portion of the remaining Payment is subject to the Excise Tax. If the Reduced Amount was determined pursuant to clause (y) above, the Eligible Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

SECTION 4. RETURN OF COMPANY PROPERTY.

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An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "Company Property" means all Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part).

SECTION 5. TIME OF PAYMENT AND FORM OF BENEFIT.

The Company reserves the right in the Participation Agreement to specify whether severance payments under the Plan will be paid in a single sum, in installments, or in any other form and to determine the timing of such payments. All severance payments under the Plan will be subject to applicable withholding for federal, state and local taxes. If an Eligible Employee is indebted to the Company on his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness. All severance benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; provided, however, that to the extent such an exemption is not available, the severance benefits provided under the Plan are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly.

Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under the Plan that constitute "deferred compensation" within the meaning of Section 409A shall not commence in connection with an Eligible Employee's termination of employment unless and until the Eligible Employee has also incurred a "separation from service," as such term is defined in Treasury Regulations Section 1.409A-1(h) ("Separation from Service"), unless the Company reasonably determines that such amounts may be provided to the Eligible Employee without causing the Eligible Employee to incur the adverse personal tax consequences under Section 409A.

It is intended that (i) each installment of any benefits payable under the Plan to an Eligible Employee be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the

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exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any such benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Eligible Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such benefit payments shall be delayed until the earlier of (1) the date that is six (6) months and one (1) day after the Eligible Employee's Separation from Service and (2) the date of the Eligible Employee's death (such applicable date, the "Delayed Initial Payment Date"), and (B) the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the benefit payments that the Eligible Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

In no event shall payment of any benefits under the Plan be made prior to an Eligible Employee's termination date or prior to the effective date of the Release. If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Eligible Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Eligible Employee's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective any earlier than the latest permitted effective date (the "***Release Deadline***"). If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, then except to the extent that payments may be delayed until the Delayed Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll date following the effective date of an Eligible Employee's Release, the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the benefit payments that the Eligible Employee would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

All severance payments under the Plan shall be subject to applicable withholding for federal, state and local taxes. If an Eligible Employee is indebted to the Company at his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness.

SECTION 6. TRANSFER AND ASSIGNMENT.

The rights and obligations of an Eligible Employee under this Plan may not be transferred or assigned without the prior written consent of the Company. This Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs.

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Section 7. Mitigation.

Except as otherwise specifically provided in the Plan, an Eligible Employee will not be required to mitigate damages or the amount of any payment provided under the Plan by seeking other employment or otherwise, nor will the amount of any payment provided for under the Plan be reduced by any compensation earned by an Eligible Employee as a result of employment by another employer or any retirement benefits received by such Eligible Employee after the date of the Eligible Employee's termination of employment with the Company.

Section 8. Clawback; Recovery.

All payments and severance benefits provided under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange

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or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Plan Administrator may impose such other clawback, recovery or recoupment provisions as the Plan Administrator determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of common stock of the Company or other cash or property upon the occurrence of a termination of employment for Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for Good Reason, constructive termination, or any similar term under any plan of or agreement with the Company.

Section 9. Reemployment.

In the event of an Eligible Employee's reemployment by the Company during the period of time in respect of which severance benefits pursuant to the Plan have been paid, the Company, in its sole and absolute discretion, may require such Eligible Employee to repay to the Company all or a portion of such severance benefits as a condition of reemployment.

Section 10. Right to Interpret and Administer Plan; Amendment or Termination.

(a)Interpretation and Administration. Prior to the Closing, the Board, or a duly authorized committee thereof, shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Board shall be

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binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Board" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

(b)Amendment or Termination. The Plan Administrator reserves the right to amend or terminate this Plan at any time, without advance notice to any Eligible Employee and without regard to the effect of the amendment or termination on any Eligible Employee or on any other individual, except as otherwise provided herein or in an individual Participation Agreement. Any amendment or termination of the Plan will be in writing. Notwithstanding the foregoing, an Eligible Employee's rights to receive payments and benefits pursuant to the Plan under an effective Participation Agreement may not be adversely affected, without the Eligible Employee's written consent, by an amendment or termination of the Plan.

Section 11. No Implied Employment Contract.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved.

Section 12. Legal Construction.

This Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("**ERISA**") and, to the extent not preempted by ERISA, the laws of the State of Washington.

Section 13. Claims, Inquiries and Appeals.

(a)Applications for Benefits and Inquiries. Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

ARS Pharmaceuticals, Inc.
Board of Directors or Representative
11682 El Camino Real, Suite 120
San Diego, CA 92130

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of

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the applicant's right to review the denial. Any electronic notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

(4) an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 13(d) below.

This notice of denial will be given to the applicant within ninety (90) days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional ninety (90) days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial ninety (90) day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

(c)Request for a Review. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within sixty (60) days after the application is denied. A request for a review shall be in writing and shall be addressed to:

ARS Pharmaceuticals, Inc.
Board of Directors or Representative
11682 El Camino Real, Suite 120
San Diego, CA 92130

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative)

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relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(d)Decision on Review. The Plan Administrator will act on each request for review within sixty (60) days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional sixty (60) days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial sixty (60) day period. This notice of extension will describe the special

circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

(4) a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

(e)Rules and Procedures. The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

(f)Exhaustion of Remedies. No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 13(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 13(c) above, and (iv) has been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an Eligible Employee's claim or appeal within the relevant time limits specified in this Section 13, the Eligible Employee may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA.

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Section 14. Basis of Payments to and from Plan.

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

Section 15. Other Plan Information.

(a)Employer and Plan Identification Numbers. The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by the Internal Revenue Service is 81-1489190. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is 410.

(b)Ending Date for Plan's Fiscal Year. The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

(c)Agent for the Service of Legal Process. The agent for the service of legal process with respect to the Plan is:

ARS Pharmaceuticals, Inc.
Board of Directors or Representative
11682 El Camino Real, Suite 120
San Diego, CA 92130

In addition, service of legal process may be made upon the Plan Administrator.

(d)Plan Sponsor. The "Plan Sponsor" is:

ARS Pharmaceuticals, Inc.
Board of Directors or Representative
11682 El Camino Real, Suite 120
San Diego, CA 92130
(858) 771-9307

(e)Plan Administrator. The Plan Administrator is the Board prior to the Closing and the Representative upon and following the Closing. The Plan Administrator's contact information is:

ARS Pharmaceuticals, Inc.
Board of Directors or Representative
11682 El Camino Real, Suite 120
San Diego, CA 92130
(858) 771-9307

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The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

SECTION 16. STATEMENT OF ERISA RIGHTS.

Participants in this Plan (which is a welfare benefit plan sponsored by ARS Pharmaceuticals, Inc.) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a participant in the Plan and, under ERISA, you are entitled to:

(a)Receive Information About Your Plan and Benefits.

(1) Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration;

(2) Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series), if applicable, and an updated (as necessary) Summary Plan Description. The Administrator may make a reasonable charge for the copies; and

(3) Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

(b)Prudent Actions by Plan Fiduciaries. In addition to creating rights for Plan Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Eligible Employees and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

(c)Enforce Your Rights. If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within thirty (30) days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

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If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court.

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

(d) Assistance with Your Questions. If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

APPENDIX A

ARS PHARMACEUTICALS, INC.

CHANGE IN CONTROL AND SEVERANCE BENEFIT PLAN

PARTICIPATION AGREEMENT

Name: _____

SECTION 1. ELIGIBILITY.

You have been designated as eligible to participate in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the "***Plan***"), a copy subject to the approval of which is attached as Annex I the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise

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price per share equal to this Participation Agreement 100% of the Fair Market Value (as defined in the Plan) of the underlying shares of the Company's common stock (the "***Agreement Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 80,000 shares of Common Stock (the "***Initial Grant***"). Capitalized terms not explicitly defined One-third of the shares subject to each Initial Grant will vest twelve months after the date of grant and the remaining shares will vest in this Agreement but equal monthly installments over the following two-year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan shall have the same definitions as Plan) through each such vesting date and will vest in the Plan.

SECTION 2. SEVERANCE BENEFITS.

Subject to the terms of the Plan and Section 3 of this Agreement, if you are terminated in a Covered Termination, and meet all the other eligibility requirements set forth in the Plan, including, without limitation, executing the required Release within the applicable time period set forth therein and provided that such Release becomes effective in accordance with its terms, you will receive the applicable severance benefits set forth in this Section 2. Notwithstanding the schedule for provision of severance benefit as set forth below, the provision of any severance benefits under this Section 2 is subject to any delay in payment that may be required under Section 5 of the Plan.

(a)Regular Termination. Upon a Regular Termination, you shall be eligible to receive the following severance benefits.

(1)*Cash Severance Benefit*. You will be entitled to continue to receive your then-current Base Salary for [twelve (12) / nine (9) / six (6)][1] months (such period of months, the "***Severance Period***"), commencing on the first payroll period following the effective date of your Release.

(2)*Payment of Continued Group Health Plan Benefits.*

(i) If you timely elect continued group health plan continuation coverage under COBRA following your termination date, the Company shall pay directly to the carrier the full amount of your COBRA premiums, or

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shall provide coverage under any self-funded plan, on behalf of you for your continued coverage under the Company's group health plans, including coverage for your eligible dependents, until the earliest of (A) the end of the Severance Period following the date of your termination, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment (such period from your termination date through the earliest of (A) through (C), the "***COBRA Payment Period***"). Upon the conclusion of such period of insurance premium payments made by the Company, or the provision of coverage under a self-funded group health plan, you will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under COBRA for the duration of your eligible COBRA coverage period. For purposes of this Section, (x) references to COBRA shall be deemed to refer also to analogous provisions of state law and (y) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by

[1] NTD: Insert 12 months for the CEO, 9 months for other C-Suite and ExVP, and 6 months for SVP/VP-level executives.

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you under an Internal Revenue Code Section 125 health care reimbursement plan, which amounts, if any, are your sole responsibility. You agree to promptly notify the Company as soon as you become eligible for health insurance coverage in connection with new employment or self-employment.

(ii) Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums directly to the carrier on your behalf, the Company will instead pay you on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "***Special Severance Payment***"), such Special Severance Payment to be made without regard to your election of COBRA coverage or payment of COBRA premiums and without regard to your continued eligibility for COBRA coverage during the COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the COBRA Payment Period.

(b)Change in Control Termination. Upon a Change in Control Termination, you shall be eligible to receive (as defined in the following severance benefits. In no event shall you be entitled to benefits under both Section 2(a) and this Section 2(b). If you are eligible for severance benefits under both Section 2(a) and this Section 2(b), you shall receive the benefits set forth in this Section 2(b) and such benefits shall be reduced by any benefits previously provided to you under Section 2(a) Plan).

(1)*Cash Severance Benefits*. You will receive the cash severance benefit described in Section 2(a)(1) above, except that:

(i) 2. your Severance Period will be [twenty-four (24) / eighteen (18) / twelve (12)] Annual Grant2 months and Base Salary payments will be paid in a lump sum within ten (10) business days following the later of

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(A) the effective date of your Release, or (B) the Closing of the Change in Control;

(ii) you will additionally be entitled to an amount equal to [200% / 150 / 100%][3] of your Target Bonus for the year in which your Change in Control Termination occurs, payable in a lump sum payment within ten (10) business days following the later of (A) the effective date of your Release, or (B) the Closing of the Change in Control; and

(iii) you will additionally be entitled to an amount equal to a prorated portion of your Target Bonus for the year in which your Change in Control Termination occurs (with such prorated amount calculated by reference to the number of days that elapsed in the year of your termination of employment between the first day of such year and: On the date of your termination each annual stockholder meeting of employment divided the Company held after the Effective Date (an "***Annual Meeting***"), each Eligible Director who continues to serve as a non-employee member of the Board following such Annual Meeting will be automatically, and without further action by 365), payable in the Board or the Compensation Committee of the Board, granted a lump sum payment within ten (10) business days following stock option to purchase 40,000 shares of Common Stock (the "***Annual Grant***"). If an Eligible Director was elected or appointed for the later of (A) first time to be an Eligible Director after the effective Effective Date and prior to an Annual Meeting, then the Eligible Director will be granted a prorated Annual Grant on the date of your Release, the Eligible Director's election or (B) the Closing of the Change in Control.

(2)*Accelerated Vesting of Stock Awards* *appointment (the "***.**

(i) Prorated Annual Grant Effective as of the later of the effective date of your Release or the Closing of the Change in Control, to the extent not previously vested: (A) the vesting and exercisability of all outstanding stock options to purchase the Company's common stock held by you on such date shall be accelerated in full, (B) any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to any other stock award granted to you by the Company shall lapse in full,

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2 NTD: Insert 24 months for the CEO, 18 months for other C-Suite and ExVP-level executives, and 12 months for SVP/VP-level executives.

[3] NTD: Insert 200% for the CEO, 150% for other C-Suite and ExVP-level executives, and 100% for SVP/VP-level executives.

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and (C) the vesting of any other stock awards granted to you by the Company, and any issuance of shares triggered by the vesting of such stock awards, shall be accelerated in full. For purposes of determining the number of shares") that will vest pursuant to the foregoing provision with respect to any performance based vesting award that has multiple vesting levels depending upon the level of performance, vesting acceleration shall occur with respect be subject to the number of shares of Common Stock equal to 40,000 multiplied by a

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fraction (the numerator of which is equal to (i) 12 *minus* (ii) the number of completed months since the most recent Annual Meeting as of the Eligible Director's date of election or appointment, and the denominator of which is 12), with the resulting number of shares rounded down to the nearest whole share. The shares subject to the award as if Annual Grant or Prorated Annual Grant will vest in full on the applicable performance criteria had been attained at a 100% level.

(ii) In order to give effect to the intent sooner of the foregoing provision, notwithstanding anything to first anniversary of the contrary set forth in date of grant or on the date of Company's applicable equity incentive plan or the applicable stock award agreements that provides that any then unvested portion of your award will immediately expire upon your termination of service, your stock awards shall remain outstanding following your Change in Control Termination to give effect to such acceleration as necessary.

(iii) Notwithstanding anything to the contrary set forth herein, your stock awards shall remain next Annual Meeting, subject to the terms of Eligible Director's Continuous Service (as defined in the Company's applicable equity incentive plan, including Plan) through such vesting date; provided, further, that the stock award agreement governing your stock award, that may apply shares subject to the Annual Grant or Prorated Annual Grant will vest in full upon a Change in Control and or/termination (as defined in the Plan).

Non-Employee Director Compensation Limit

Notwithstanding the foregoing, the aggregate value of your service and no provision of the Plan all compensation granted or this Agreement shall be construed paid, as to limit the actions that may be taken, or to violate the terms, thereunder.

(3)*Payment of Continued Group Health Plan Benefits*. You will receive the payment for continued group health plan benefits described in Section 2(a)(2) above, except that the COBRA Payment Period will be equal to [the Severance Period applicable, to any individual for service as a Change Non-Employee Director (as defined in Control Termination as the Plan) shall in no event exceed the limits set forth in Section 2(b)(1)(i) above][4] / [eighteen 18 months. In addition to payment for continued group health plan benefits, within ten (10) business days following the later of (i) the effective date of your Release or (ii) the Closing of the Change in Control, you will receive a lump sum cash payment equal to the amount of your monthly COBRA premiums for six months, subject to applicable tax withholding, such additional payment to be made without regard to your election of COBRA coverage.][5]

SECTION 3. REQUIREMENTS DURING SEVERANCE PERIOD.

Your eligibility for and receipt of any severance benefits to which you may become entitled as described in Section 2 above is expressly contingent upon your timely execution of an effective Release and your compliance with the terms and conditions oftheprovisions of the Proprietary Information and Invention

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Assignment Agreement between you and the Company, as may be amended from time to time (the "***PIIAA***"). Severance benefits under this Agreement shall immediately cease in the event of your violation of the provisions in this section.

SECTION 4. ACKNOWLEDGEMENTS.

As a condition to participation in the Plan, you hereby acknowledge each of the following: Plan.

(a) The severance benefits that may be provided to you under this Agreement are subject to all of the terms of the Plan which is incorporated into and becomes part of this Agreement, including but not limited to the reductions under Section 3 of the Plan.

[4] NTD: For all participants other than CEO.

[5] NTD: For CEO only. 2.

Exhibit 21.1

(b) Except as provided herein, this Agreement and the Plan supersede and replace any severance or change in control benefit previously provided to you by the Company. This Agreement and the Plan do not supersede, replace or otherwise alter the PIIAA.ARS PHARMACEUTICALS, INC.

(c) You may not sell, transfer, or otherwise assign or pledge your right to benefits under this Agreement and the Plan to either your creditors or to your beneficiary, except to the extent permitted by the Plan Administrator if such action would not result in adverse tax consequences under Section 409A.

(d) Notwithstanding anything to the contrary in the Plan or this Agreement, your rights under this Agreement may not be adversely affected by an amendment or termination of the Plan without your written consent.

To accept the terms of this Agreement and participate in the Plan, please sign and date this Agreement in the space provided below and return it to Lynda Harris, no later than ten (10) days from the date first set forth below.

[signature page to follow]

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ARS Pharmaceuticals, Inc.

By:

Name:

Title:

Date:

_____ _____

[Eligible Employee] Date

Annex I

ARS Pharmaceuticals, Inc.

Change in Control and Severance Benefit Plan

(see attached)

Appendix B

Initial Designated Employees under the Plan

Name	Title of Subsidiary
Laura Shawver	Chief Executive Officer
Valerie Odegard	President & Chief Scientific Officer
Naomi Hunder	Chief Medical Officer
Jonathan Piazza	Chief Financial Officer
Jeff Pepe	SVP & General Counsel
Scott Moorefield	SVP of Business Development
Russ Hawkinson	SVP of Finance

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Sateesh Natarajan	SVP of CMC Development
Graham Jang	VP of Development Sciences
Jill Herendeen	VP, Regulatory
Katie Carrigan	VP of Human Resources
Patricia Leith	VP of Program Management and Operations
Peter Baum	VP of Immunology
Sue Hamke	VP of Clinical Operations

For Eligible Employees Age 40 or Older
Individual Termination

EXHIBIT A

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the "*Plan*").

I understand that this Release Agreement (the "***Release***"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an affiliate of the Companythat is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act (if applicable), or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby acknowledge and agree to abide by my continuing obligations under my confidential information and invention assignment agreement with the Company and/or an affiliate of the Company.

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I hereby confirm that, except for materials the Company has expressly authorized me to retain in writing, I have returned to the Company all Company property, including, but not limited to, all equipment, vehicles, product samples, computers, pass codes, keys, swipe cards, credit cards, documents, or other materials, in whatever form or format that I received, prepared, or helped prepare them; and that I have not retained, whether in hard copy or electronic form, any copies, duplicates, reproductions, computer disks, or excerpts thereof.

If I am an officer or director of the Company or any of its affiliated entities, effective as of the date my employment with the Company ends, I agree to (and hereby do) resign from any and all offices and directorships with any such entities, and agree to execute all documents reasonably requested by the Company to effectuate such resignation(s).

I understand that I may apply for unemployment insurance benefits after my employment with the Company ends and that the Company will not contest my eligibility for such benefits; *provided*, *however*, that I understand that the state agency responsible for administering unemployment insurance benefits, and not the Company, is ultimately responsible for determining my eligibility for such benefits. I further understand that, in response to any request for references from a prospective employer, the Company will only confirm my dates of employment and last job title.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its affiliates and assigns, and their parents, subsidiaries, successors, predecessors and affiliates, and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns (collectively, the "***Releasees***"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a)

---

all claims arising out of or in any way related to my employment with the Company and any other Releasees, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and any other Releasees; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, penalties, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act (as amended) ("***ADEA***"), the federal Employee Retirement Income Security Act of 1974, the Washington Industrial Welfare Act, the Washington Law Against Discrimination, the Washington Family Leave

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Act, the Washington Leave Law, the Washington Minimum Wage Requirements and Labor Standards Act, Title 49 of the Revised Code of Washington, the Washington Equal Pay Opportunity Act, the Washington Fair Chance Act, Unfair employment practices (Seattle Mun. Code 14.04); Minimum wage (Seattle Mun. Code 14.19); Wage theft (Seattle Mun. Code 14.20); Paid sick and safe time (Seattle Mun. Code 14.16); Fair chance employment (Seattle Mun. Code 14.17), all including any amendments and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, or otherwise) that may be legally waived and released

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or any other Releasees to which I am a party, the charter, bylaws, or operating agreements of the Company or any other Releasees, or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the Washington State Department of Labor and Industries, or any other government agency (each a "***Government Agency***"), except that I hereby waive my right to any monetary benefits in connection with any claim, charge or proceeding arising from or relating to any of the Released Claims. In addition, nothing herein shall be interpreted or applied in a manner that limits my ability to challenge, under the Older Workers Benefit Protection Act ("***OWBPA***") (29 U.S.C. § 626), the knowing and voluntary nature of my release of any claims under the ADEA. I hereby represent and warrant that, other than the foregoing excluded claims I am not aware of any claims I have or might have that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA and the OWBPA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not do so); (c) I have twenty-one (21) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice of such revocation to the Company's Human Resources department or the Company's General Counsel; and (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release, provided I have not earlier revoked it.

I represent that I have no lawsuits, claims, or actions pending in my name, or on behalf of any other person or entity, against the Company or any other Releasees. Employee also represents that Employee does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any other Releasees.

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I understand and agree that nothing in this Release or in the Plan is to be construed as an admission of liability or wrongdoing by the Company or any other Releasees, and that the Company and other Releasees disclaim any such liability or wrongdoing.

I understand and agree that while the I may apply for future employment with the Company or its successor, I have no right to such future employment, and the Company or its successor may, in its sole discretion, deny my employment application. I further understand and agree that in the event I obtain employment with the Company or its successor, the Company or its successor may, in its sole discretion, terminate my employment. I also acknowledge and agree that my rehire may affect the amount of severance pay and benefits to which I am entitled under the Plan (as provided in Section 2 of the Plan).

I agree that except for disclosures made (i) in confidence to my attorneys, financial advisors, accountants, spouse, or registered domestic partner, or (ii) to a Government Agency, I will keep this Release and its terms confidential and will not reveal its contents to anyone, unless necessary to enforce my rights hereunder or as other otherwise required by law.

I further agree not to, at any time, take any action through any medium or in any forum, to directly or indirectly disparage the employees, products, business reputation, abilities, or capabilities of the Company or any other Releasees. This provision includes, without limitation, email, any electronic media, and any postings to the Internet. Notwithstanding the foregoing, it shall not be a breach of this paragraph for me to comply with the lawful orders or processes of any court, including the obligation to testify truthfully in any legal proceeding. Additionally, this paragraph does not apply to communications between me and any Government Agency, or between me and the Company or any other Releasee.

This Release, together with the Plan, constitutes the entire understanding and agreement with respect to the subject matter hereof. The provisions of this Release and the Plan are severable and if any part is found to be unenforceable, the other portions shall remain fully valid and enforceable. Additionally, if any of the waivers and releases set forth in this Release are held to be invalid, illegal, void and/or unenforceable: (i) the remaining waivers and releases shall remain fully valid and enforceable; and (ii) upon request by the Company, I shall immediately execute and deliver to the Company a release and waiver that is legal and enforceable to the fullest extent of the law. The construction and interpretation of this Release shall be subject to the terms and conditions of the Plan, and no ambiguity in this Release or the Plan shall be construed against any party as the drafter. I acknowledge that I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me or such other date as specified by the Company. By signing below, I represent that: I have read this Release and the Plan; I have had adequate time to consider them; I have been advised to consult with an attorney before signing this Release; I understand the meaning and application of this Release and the Plan; and that I sign this Release knowingly and voluntarily and with the intent of being bound by it.

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[signature page to follow]

ELIGIBLE EMPLOYEE

Printed Name:

Signature: _____

Date: _____

For Eligible Employees Age 40 or Older
Group Termination

EXHIBIT B

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the *"Plan"*).

I understand that this Release Agreement (the "***Release***"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an affiliate of the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act (if applicable) or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby acknowledge and agree to abide by my continuing obligations under my confidential information and invention assignment agreement with the Company and/or an affiliate of the Company.

I hereby confirm that, except for materials the Company has expressly authorized me to retain in writing, I have returned to the Company all Company property, including, but not limited to, all equipment, vehicles, product samples, computers, pass codes, keys, swipe cards, credit cards, documents, or other materials, in

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whatever form or format that I received, prepared, or helped prepare them; and that I have not retained, whether in hard copy or electronic form, any copies, duplicates, reproductions, computer disks, or excerpts thereof.

If I am an officer or director of the Company or any of its affiliated entities, effective as of the date my employment with the Company terminates, I agree to (and hereby do) resign from any and all offices and directorships with any such entities, and agree to execute all documents reasonably requested by the Company to effectuate such resignation(s).

I understand that I may apply for unemployment insurance benefits after my employment with the Company ends and that the Company will not contest my eligibility for such benefits; *provided*, *however*, that I understand that the state agency responsible for administering unemployment insurance benefits, and not the Company, is ultimately responsible for determining my eligibility for such benefits. I further understand that, in response to any request for references from a prospective employer, the Company will confirm only my dates of employment and last job title.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its affiliates and assigns, and their parents, subsidiaries, successors, predecessors and affiliates, and its and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns (collectively, the "***Releasees***"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and any other

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Releasees, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and any other Releasees; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, penalties or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act ("***ADEA***"), the federal Employee Retirement Income Security Act of 1974, the Washington Industrial Welfare Act, the Washington Law Against Discrimination, the Washington Family Leave Act, the Washington Leave Law, the Washington Minimum Wage Requirements and Labor Standards Act, Title 49 of the Revised Code of Washington, the Washington Equal Pay Opportunity Act, the Washington Fair Chance Act, Unfair employment practices (Seattle Mun. Code 14.04); Minimum wage (Seattle Mun. Code 14.19); Wage theft

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(Seattle Mun. Code 14.20); Paid sick and safe time (Seattle Mun. Code 14.16); Fair chance employment (Seattle Mun. Code 14.17), all including any amendments and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, or otherwise) that may be legally waived and released.

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or any other Releasees to which I am a party, the charter, bylaws, or operating agreements of the Company or any other Releasees, or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the Washington State Department of Labor and Industries, or any other government agency (each a "***Government Agency***"), except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding arising from or relating to any of the Released Claims. In addition, nothing herein shall be interpreted or applied in a manner that limits my ability to challenge, under the Older Workers Benefit Protection Act ("***OWBPA***") (29 U.S.C. § 626), the knowing and voluntary nature of my release of any claims under the ADEA. I hereby represent and warrant that, other than the foregoing excluded claims, I am not aware of any claims I have or might have that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA and the OWBPA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have forty-five (45) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an employee in the Company's Human Resources department or the Company's General Counsel; (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release provided I have not revoked it; and (f) I have received with this Release, enclosed as **Attachment 1**, all of the information required by the ADEA and the OWBPA, including without limitation a detailed list of the job titles and ages of all employees who were terminated in this group termination and the ages of all employees of the Company in the same job classification or organizational unit who were not terminated.

I represent that I have no lawsuits, claims, or actions pending in my name, or on behalf of any other person or entity, against the Company or any other Releasees. Employee also represents that Employee

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does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any other Releasees.

I understand and agree that nothing in this Release or in the Plan is to be construed as an admission of liability or wrongdoing by the Company any other Releasees, and that the Company and the other Releasees disclaim any such liability or wrongdoing.

I understand and agree that while the I may apply for future employment with the Company or its successor, I have no right to such future employment, and the Company or its successor may, in its sole discretion, deny my employment application. I further understand and agree that in the event I obtain employment with the Company or its successor, the Company or its successor may, in its sole discretion, terminate my employment. I also acknowledge and agree that my rehire may affect the amount of severance pay and benefits to which I am entitled under the Plan (as provided in Section 2 of the Plan).

I agree that except for disclosures made (i) in confidence to my attorneys, financial advisors, accountants, spouse, or registered domestic partner, or (ii) to a Government Agency, I will keep this Release and its terms confidential and will not reveal its contents to anyone, unless necessary to enforce my rights hereunder or as other otherwise required by law.

I further agree not to, at any time, take any action through any medium or in any forum, to directly or indirectly disparage the employees, products, business reputation, abilities, or capabilities of the Company or any other Releasees. This provision includes, without limitation, email, any electronic media, and any postings to the Internet. Notwithstanding the foregoing, it shall not be a breach of this paragraph for me to comply with the lawful orders or processes of any court, including the obligation to testify truthfully in any legal proceeding. Additionally, this paragraph does not apply to communications between me and any Government Agency, or between me and the Company or any other Releasees.

This Release, together with the Plan, constitutes the entire understanding and agreement with respect to the subject matter hereof. The provisions of this Release and the Plan are severable and if any part is found to be unenforceable, the other portions shall remain fully valid and enforceable. Additionally, if any of the waivers and releases set forth herein are held to be invalid, illegal, void and/or unenforceable: (i) the remaining waivers and releases shall remain fully valid and enforceable; and (ii) upon request by the Company, I shall immediately execute and deliver to the Company a release and waiver that is legal and enforceable to the fullest extent of the law. The construction and interpretation of this Release shall be subject to the terms and conditions of the Plan, and no ambiguity in this Release or the Plan shall be construed against any party as the drafter. I acknowledge that I must sign and return this Release to the Company so that it is received not later than forty-five (45) days following the date it is provided to me or such other date as specified by the Company. By signing below, I represent that: I have read this Release and the Plan; I have had adequate time to consider them; I have been advised to consult with an attorney before signing this Release; I understand the meaning and

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application of this Release and the Plan; and that I sign this Release knowingly and voluntarily and with the intent of being bound by it.

[signature page to follow]

ELIGIBLE EMPLOYEE

Printed Name:

Signature: _____

Date: _____

ATTACHMENT 1 TO
EXHIBIT B RELEASE AGREEMENT

ADEA DISCLOSURE
(UNDER TITLE 29 U.S. CODE SECTION 626(f)(1)(H))

***Confidentiality Provision**: The information contained in this document is private and confidential. You may not disclose this information to anyone except your professional advisors.*

1. The following ARS Pharmaceuticals, Inc. (the "***Company***") decisional unit(s) were selected for the termination program: [_____]

2. Within the departments listed above, the following criteria were used to select employees who are eligible for the termination program: [_____]

3. All eligible employees who have attained the age of forty (40) years or older will have up to forty-five (45) calendar days to review, consider, and accept the terms and conditions of the Company's termination program, and seven (7) calendar days to revoke their acceptance of the such program, pursuant to the Age Discrimination in Employment Act of 1967, as amended.

EMPLOYEES ELIGIBLE FOR THE TERMINATION PROGRAM	
Job Title / Department	AGE

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[ ]	[ ] Jurisdiction
ARS Pharmaceuticals Operations, Inc.	Delaware
ARS Pharmaceuticals IRL, Limited	Ireland

EMPLOYEES NOT ELIGIBLE FOR THE TERMINATION PROGRAM (RETAINED EMPLOYEES)	
Job Title / Department	AGE
[ ]	[ ]

For Eligible Employees Under 40 Years of Age
Individual and Group Termination

EXHIBIT C

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the *"Plan"*).

I understand that this Release Agreement (the "***Release***"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an affiliate of the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act (if applicable), or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

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I hereby acknowledge and agree to abide by my continuing obligations under my confidential information and invention assignment agreement with the Company and/or an affiliate of the Company.

I hereby confirm that, except for materials the Company has expressly authorized me to retain in writing, I have returned to the Company all Company property, including, but not limited to, all equipment, vehicles, product samples, computers, pass codes, keys, swipe cards, credit cards, documents, or other materials, in whatever form or format that I received, prepared, or helped prepare them; and that I have not retained, whether in hard copy or electronic form, any copies, duplicates, reproductions, computer disks, or excerpts thereof.

If I am an officer or director of the Company or any of its affiliated entities, effective as of the date my employment with the Company terminates, I agree to (and hereby do) resign from any and all offices and directorships with any such entities, and agree to execute all documents reasonably requested by the Company to effectuate such resignation(s).

I understand that I may apply for unemployment insurance benefits after my employment with the Company ends and that the Company will not contest my eligibility for such benefits; *provided*, *however*, that I understand that the state agency responsible for administering unemployment insurance benefits, and not the Company, is ultimately responsible for determining my eligibility for such benefits. I further understand that, in response to any request for references from a prospective employer, the Company will confirm only my dates of employment and last job title.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its affiliates and assigns, and their parents, subsidiaries, successors, predecessors and affiliates, and its and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns (collectively, the "***Releasees***"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited

to: (a) all claims arising out of or in any way related to my employment with the Company and any other Releasees, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and any other Releasees; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, penalties or other claims arising under the federal Civil

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Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Employee Retirement Income Security Act of 1974, the Washington Industrial Welfare Act, the Washington Law Against Discrimination, the Washington Family Leave Act, the Washington Leave Law, the Washington Minimum Wage Requirements and Labor Standards Act, Title 49 of the Revised Code of Washington, the Washington Equal Pay Opportunity Act, the Washington Fair Chance Act, Unfair employment practices (Seattle Mun. Code 14.04); Minimum wage (Seattle Mun. Code 14.19); Wage theft (Seattle Mun. Code 14.20); Paid sick and safe time (Seattle Mun. Code 14.16); Fair chance employment (Seattle Mun. Code 14.17), all including any amendments and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, or otherwise) that may be legally waived and released.

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or any other Releasee to which I am a party, the charter, bylaws, or operating agreements of the Company or any other Releasee, or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the Washington State Department of Labor and Industries, or any other government agency (each a "***Government Agency***"), except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding arising from or related to any of the Released Claims. I hereby represent and warrant that, other than the claims identified in this paragraph, I am not aware of any claims I have or might have that are not included in the Released Claims.

I understand and agree that nothing in this Release or in the Plan is to be construed as an admission of liability or wrongdoing by the Company or any other Releasees, and that the Company and the Releasees disclaim any such liability or wrongdoing.

I represent that I have no lawsuits, claims, or actions pending in my name, or on behalf of any other person or entity, against the Company or any other Releasees. Employee also represents that Employee does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any other Releasees.

I understand and agree that while the I may apply for future employment with the Company or its successor, I have no right to such future employment, and the Company or its successor may, in its sole discretion, deny my employment application. I further understand and agree that in the event I obtain employment with the Company or its successor, the Company or its successor may, in its sole discretion, terminate my employment. I also acknowledge and agree that my rehire may affect the amount of severance pay and benefits to which I am entitled under the Plan (as provided in Section 2 of the Plan).

I agree that except for disclosures made (i) in confidence to my attorneys, financial advisors, accountants, spouse, or registered domestic partner, or (ii) to a Government Agency, I will keep this Release

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and its terms confidential and will not reveal its contents to anyone, unless necessary to enforce my rights hereunder or as other otherwise required by law.

I further agree not to, at any time, take any action through any medium or in any forum, to directly or indirectly disparage the employees, products, business reputation, abilities, or capabilities of the Company or any other Releasees. This provision includes, without limitation, email, any electronic media, and any postings to the Internet. Notwithstanding the foregoing, it shall not be a breach of this paragraph for me to comply with the lawful orders or processes of any court, including the obligation to testify truthfully in any legal proceeding. Additionally, this paragraph does not apply to communications between me and any Government Agency, or between me and the Company or any other Releasee.

This Release, together with the Plan, constitutes the entire understanding and agreement with respect to the subject matter hereof. The provisions of this Release and the Plan are severable and if any part is found to be unenforceable, the other portions shall remain fully valid and enforceable. Additionally, if any of the waivers and releases set forth herein are held to be invalid, illegal, void and/or unenforceable: (i) the remaining waivers and releases shall remain fully valid and enforceable; and (ii) upon request by the Company, I shall immediately execute and deliver to the Company a release and waiver that is legal and enforceable to the fullest extent of the law. The construction and interpretation of this Release shall be subject to the terms and conditions of the Plan, and no ambiguity in this Release or the Plan shall be construed against any party as the drafter.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than fourteen (14) days following the date it is provided to me or such other date as specified by the Company. By signing below, I represent that: I have read this Release and the Plan; I have had adequate time to consider them; I understand the meaning and application of this Release and the Plan; and that I sign this Release knowingly and voluntarily and with the intent of being bound by it.

[signature page to follow]

ELIGIBLE EMPLOYEE

Printed Name:

Signature: _____

Date: _____

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Exhibit 10.10

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

TERMINATION AGREEMENT

THIS TERMINATION AGREEMENT (the "**Agreement**") is entered into as of February 22, 2023 (the "**Termination Agreement Effective Date**"), by and between **ARS PHARMACEUTICALS, INC.**, a company incorporated and existing under the laws of Delaware, having its registered office at 1682 El Camino Real, Suite 120. San Diego, CA 92130, U.S. (hereinafter "**ARS**"), and **RECORDATI IRELAND, LTD**, a company incorporated and existing under the laws of Ireland, having its registered office at Raheens East, Ringaskiddy, Co Cork, P43 KD30, Republic of Ireland (hereinafter "**Recordati**"). Recordati and ARS are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**."

WHEREAS, the Parties entered into that certain License and Supply Agreement dated September 21, 2020 (the "**License and Supply Agreement**") pursuant to which, inter alia, ARS granted to Recordati, and Recordati obtained from ARS, an exclusive license to Commercialize the Product in the Territory;

WHEREAS, the Parties now desire to terminate the License and Supply Agreement in its entirety by mutual written agreement of the Parties; and

WHEREAS, the Parties desire to document this mutual agreement as to termination of the License and Supply Agreement and to address and settle other matters relating thereto pursuant to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing and the premises and conditions set forth herein, the Parties agree as follows:

1. **Defined Terms**. Capitalized terms that are used in this Agreement have the meaning set forth in the License and Supply Agreement, unless otherwise defined in this Agreement.

(a) **"Business Partner"** means any Third Party appointed by ARS or any of its Affiliates to perform one or more activities in connection with the Commercialization of the Product, within one or more countries in the Territory.

(b) "**First Commercial Sale**" means, the first sale for monetary value of the Product in a country of the Territory to a Third Party after all Regulatory Approvals for the Product has been obtained in such country. Sales prior to receipt of all Regulatory Approvals for the Product in such country, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

(c) "**Net Sales**" means [***].

(d) "**Product**" means ARS-1 (- (epinephrine nasal spray)).

(e) "**Reseller**" means a third party wholesaler or distributor that (i) has no significant responsibility for marketing and promotion of the Product within its distribution territory or field, and (ii) does not pay any consideration to ARS, its Affiliates or their respective licensees for wholesale or distributor rights.

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2. **Termination; Effects of Termination**.

(a) The Parties hereby agree to terminate the License and Supply Agreement in its entirety as of the Termination Agreement Effective Date. As of the Termination Agreement Effective Date, all rights and obligations of the Parties under the License and Supply Agreement, and all sublicenses under the ARS Intellectual Property Rights granted by Recordati (if any), shall be, and hereby are, automatically terminated. For clarity, on execution of this Agreement, unless otherwise specified in this Agreement, all provisions of the License and Supply Agreement, including any which are expressly stated in the License and Supply Agreement as surviving its termination, or which might otherwise have done so by implication, are terminated.

(b) The Parties acknowledge that Recordati and/or one or more of its Affiliates is currently designated as the contact for pharmacovigilance (QPPV) and quality person responsibilities in the applicable for the EU Marketing Authorization submitted by ARS for the Product. Promptly following the Termination Agreement Effective Date, Recordati and ARS shall cooperate to take all necessary actions and execute such other instruments, assignments and documents as may be necessary to, transfer such responsibility in the above mentioned application for the EU Marketing Authorization to one or more persons designated by ARS. ARS shall be responsible for all associated expenses to transfer such responsibilities and shall not commercialize the Product in the EU Territory prior to the completion of such transfer. ARS undertakes to proceed promptly with all the activities needed to transfer such responsibility, it being understood that the Product will not be commercialized in the EU Territory without the finalization of the transfer of such responsibilities.

(c) For the avoidance of doubt and as more fully set forth in Section 6(a), no payment whatsoever shall be due by Recordati to ARS in connection with anything done (or omitted) until the Termination Agreement Effective Date by Recordati pursuant to the License and Supply Agreement, nor its termination hereunder.

3. **Financial Provisions**.

(a) Upfront Payment. As partial consideration for Recordati's agreements set forth in this Agreement, ARS will pay Recordati a one-time non-refundable upfront payment in the amount of Euro 3,000,000 (three million) (the "Upfront Payment"). Recordati will issue an invoice for the Upfront Payment on or after the Termination Agreement Effective Date, and ARS will pay the Upfront Payment no later than thirty (30) days following ARS' receipt of such invoice.

(b) Milestone Payments. As partial consideration for Recordati's agreements set forth in this Agreement, following achievement by ARS, its Affiliates or its Business Partner, as applicable, of any of the milestone events described below with respect to the first time (and only the first time) the Product achieves such milestone event (each, a "Milestone Event"), ARS will pay Recordati the corresponding milestone payment (a "**Milestone Payment**") as follows:

(i) a one-time and non-refundable payment in the amount of Euro 2,000,000 (two million) upon recommendation by European Medicines Agency to the European Commission to grant the EU Marketing Authorization of the Product; and

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(ii) a one-time and non-refundable payment in the amount of Euro 5,000,000 (five million) upon the First Commercial Sale of the Product in the Territory.

For clarity, each Milestone Payment is payable only upon the first achievement of the corresponding Milestone Event, and none of the Milestone Payments will be payable more than once regardless of how many times such Milestone Event is achieved. ARS will notify Recordati in writing no later than [***] following achievement of a Milestone Event. Following Recordati's receipt of such notice from ARS, Recordati shall invoice ARS for the applicable Milestone Payment, and ARS will pay such Milestone Payment no later than [***] after receipt of such invoice.

(c) Sales-Based Payments.

(i) As partial consideration for Recordati's agreements set forth in this Agreement, following the First Commercial Sale of a Product in the Territory, ARS will pay to Recordati [***] payments based on the aggregate Net Sales of all Products in the Territory, as calculated by multiplying [***] percent ([***]%) by the amount of Net Sales of all Products in the Territory ("Sales-Based Payments"); provided that in no event shall the total amount of Sales-Based Payments payable to Recordati under Section 3(c) of this Agreement exceed Euro 5,000,000 (five million) (the "Payment Cap") and no further Sales-Based Payments shall be due once ARS has paid Recordati Sales-Based Payments in an amount equal to the amount of the Payment Cap.

(ii) Within [***] after the end of each Calendar [***] with respect to which Sales-Based Payments are payable under Section 3(c) of this Agreement, ARS shall furnish to Recordati a written report showing in reasonable detail: (w) the gross sale of the Product during such Calendar [***] and the calculation of the Net Sales from such gross sales during such Calendar [***], (x) based upon such Net Sales, the calculation of the Sales-Based Payments applicable during the relevant Calendar [***] (for any foreign currency conversion to Euro required for the calculation of the relevant Sales-Based Payments, such conversion shall be made at the average of such Calendar [***] rates reported by the European Central Bank); (y) the withholding taxes, if any, required by the Applicable Laws to be deducted with respect to such Net Sales; and (z) the exchange rates, if any, used to determine the amount of local currency transformed in Euro. Following Recordati's receipt of such report from ARS, Recordati shall invoice ARS for the applicable Sales-Based Payments, and ARS will pay such Sales-Based Payments no later than [***] after receipt of such invoice.

(d) Currency. All payments owed under this Agreement shall be paid in Euro in immediately available funds and shall be made by wire transfer to a bank account held in the name of Recordati (details of which will be set out in the relevant invoice).

(e) Taxes. Paragraph 32.02 of the License and Supply Agreement shall apply to this Agreement, mutatis mutandis (with the references to "ARS" and "Recordati" switched), and is hereby incorporated into this Agreement by reference.

(f) Status Updates. ARS acknowledges Recordati's desire to be informed about the evolution of activities triggering the payment obligations provided under this Section 3 in support of Recordati's financial and

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budgeting planning needs, and, subject to Recoradti's confidentiality obligations under this Agreement, in the event ARS is no longer subject to the United States Securities Exchange Act of 1934 and if Recordati has reasonable inquiries regarding the status of such activities, ARS undertakes to provide Recordati from time to time with reasonable level of information thereof (but in any event no more frequently than [***]).

4. **Confidentiality; Publicity**.

(a) Each Party (the receiving Party) shall keep confidential, shall not disclose to third persons and shall not use for any purpose any Confidential Information of the other Party (the disclosing Party) without the prior written consent of the disclosing Party, except to its employees, officers, representatives or advisers to the extent necessary to exercise its rights or perform its obligations under this Agreement. The receiving Party shall ensure that its employees, officers, representatives or advisers to whom it discloses the Confidential Information of the other Party comply with Section 4 of this Agreement. Paragraphs 47.02, 47.03 and 47.05 of the License and Supply Agreement shall apply to this Agreement, mutatis mutandis (except that, for clarity, the exceptions set forth in Paragraphs 47.03(i) and 47.03(ii) shall not apply to Recordati as the receiving Party), and are hereby incorporated into this Agreement by reference. For purposes of Section 4 of this Agreement: (a) "Confidential Information" means all Know-How and other proprietary scientific, marketing, financial or commercial information or data that is not publicly available, and which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates under this Agreement, whether made available orally, in writing, or in electronic or visual form; and (b) the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties (and both Parties shall be deemed the receiving Party and the disclosing Party with respect thereto). The obligations with respect to any Confidential Information under Section 4 of this Agreement shall remain valid and in force for so long as such information remain confidential and not in the public domain.

(b) On the Termination Agreement Effective Date or such later date as mutually agreed to by the Parties, ARS shall issue a press release regarding the execution of this Agreement, as set forth in Exhibit A hereto (the "Press Release"). Thereafter, neither Party shall issue (and each Party shall cause its Affiliates not to issue) any press release or public disclosure relating to the subject matter of this without the prior written approval of the other Party, other than for any press release or public disclosure that is consistent with the Press Release and does not reveal any Confidential Information of the other Party. For clarity, ARS shall have the right to issue any press release or other public disclosure regarding the development, Regulatory Approval status or the commercialization of the Product by ARS, its Affiliates and/or licenses that does not reveal any Confidential Information of Recordati without prior written approval of Recordati.

5. **Survival**. The following provisions of the License and Supply Agreement will survive termination of the License and Supply Agreement: Paragraphs 2, 40, 43.01 (other than clauses (iii) and (iv) thereof), 46.03(iv), and 47, as well as Section XVI and Section XVII.

6. **Mutual Release of Claims**.

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(a) **Release by ARS**. Notwithstanding any provision to the contrary set forth in the License and Supply Agreement, from and after the Termination Agreement Effective Date: ARS, on behalf of itself and each of its Affiliates and each of their respective successors and assigns (collectively, the "**ARS Releasors**"), do hereby now and forever release, remise, hold harmless and forever discharge Recordati, its Affiliates, its Sublicensees and each of their respective sublicensees, officers, directors, employees, consultants, contractors and agents, and its and any and all of the foregoing Persons' respective successors and assigns (collectively, the "**Recordati Releasees**") of and from any and all claims, actions, causes of action, choses in action, or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversies, assessments, arbitration, examinations, audits, investigations, hearings, charges, complaints, demands, or proceedings to, from, by or before any governmental authority (collectively, "**Actions**"), losses, liabilities, damages, judgments, rights, debts, dues, sums of money, accounts, reckonings, obligations, costs, expenses, liens, bonds, bills, specialties, covenants, contracts, controversies, agreements, promises, variances, trespasses, of every kind and nature whatsoever, whether now known or unknown, foreseen or unforeseen, matured or unmatured, suspected or unsuspected, in law, admiralty or equity (collectively, "**Liabilities**"), whether known or unknown, suspected or unsuspected and that arose at any time on or prior to the Termination Agreement Effective Date, or that thereafter could arise based on any act, fact, transaction, matter, or cause that occurred on or prior to the Termination Agreement Effective Date arising from, under or otherwise in connection with the License and Supply Agreement, in each case, except to the extent arising after the Termination Agreement Effective Date from (i) a Recordati Releasee's violation of its obligations under the License and Supply Agreement that survive termination as provided in Section 5 (Survival) of this Agreement, or (ii) a breach of this Agreement by Recordati. The ARS Releasors agree that they will (i) forbear from exercising any rights or remedies against any Recordati Releasee in respect of any or all Actions or Liabilities in connection with the License and Supply Agreement and (ii) not commence any lawsuit or bring any legal or equitable action against any Recordati Releasee in respect of any or all Actions or Liabilities in connection with the License and Supply Agreement; in each case, except to the extent arising after the Termination Agreement Effective Date (i) from a Recordati Releasee's violation of its obligations under the License and Supply Agreement that survive termination as provided in Section 5 (Survival) of this Agreement or (ii) a breach of this Agreement by Recordati.

(b) Release by Recordati. Notwithstanding any provision to the contrary set forth in the License and Supply Agreement, from and after the Termination Agreement Effective Date: Recordati, on behalf of itself and each of its Affiliates and each of their respective successors and assigns (collectively, the "Recordati Releasors"), do hereby now and forever release, remise, hold harmless and forever discharge ARS, its Affiliates, its licensees and each of their respective sublicensees, officers, directors, employees, consultants, contractors and agents, and its and any and all of the foregoing Persons' respective successors and assigns (collectively, the "ARS Releasees") of and from any and all Actions and Liabilities, whether known or unknown, suspected or unsuspected and that arose at any time on or prior to the Termination Agreement Effective Date, or that thereafter could arise based on any act, fact,

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transaction, matter, or cause that occurred on or prior to the Termination Agreement Effective Date arising from, under or otherwise in connection with the License and Supply Agreement, in each case, except to the extent arising after the Termination Agreement Effective Date from (i) a ARS Releasee's violation of its obligations under the

License and Supply Agreement that survive termination as provided in Section 5 (Survival) of this Agreement or (ii) a breach of this Agreement by ARS. The Recordati Releasors agree that they will (i) forbear from exercising any rights or remedies against any ARS Releasee in respect of any or all Actions or Liabilities in connection with the License and Supply Agreement and (ii) not commence any lawsuit or bring any legal or equitable action against any ARS Releasee in respect of any or all Actions or Liabilities in connection with the License and Supply Agreement; in each case, except to the extent arising after the Termination Agreement Effective Date from (i) an ARS Releasee's violation of its obligations under the License and Supply Agreement that survive termination as provided in Section 5 (Survival) of this Agreement or (ii) a breach of this Agreement by ARS.

(c) Third Party Beneficiaries. Each Recordati Releasee and each ARS Releasee will be an express beneficiary of the rights and releases granted under this Section 6 (Mutual Release of Claims) and will be entitled to rely on the same as a defense to any suit brought against such Recordati Releasee or ARS Releasee, as applicable, in contravention of the provisions of this Section 6 (Mutual Release of Claims), without regard to the fact that such Recordati Releasee or ARS Releasee, as applicable, may not be a party to this Agreement.

7. **Representations and Warranties**.

(a) **Mutual Representations and Warranties**. Each of the Parties hereby represents and warrants to the other Party as of the Termination Agreement Effective Date that: (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and it has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement; (ii) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency or other Applicable Law of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity), (iii) the execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party, (iv) it is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith,

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or for the performance by it of its obligations under this Agreement and such other agreements, and (v) neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

(b) Additional Representations. Each Party represents and warrants to the other Party and the ARS Releasees or Recordati Releasees, as applicable, as of the Termination Agreement Effective Date that (i) it has all requisite legal capacity to grant the rights and releases set forth in Section 6 (Mutual Release of Claims) on behalf of itself and its respective ARS Releasors or Recordati Releasors, as applicable and (ii) neither it nor any of the other ARS Releasors or Recordati Releasors, as applicable, have assigned, transferred or granted to any Person that is not a ARS Releasors or Recordati Releasors, as applicable, any Action or Liability intended to be covered or released pursuant to Section 6 (Mutual Release of Claims).

8. **Miscellaneous**. The provisions of this Agreement supersede all provisions of the License and Supply Agreement that are inconsistent with the provisions of this Agreement. The provisions of Paragraphs 50 through 61 (other than Paragraphs 50.02 and 59) of the License and Supply Agreement shall apply to this Agreement, *mutatis mutandis*, and are hereby incorporated into this Agreement by reference.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to sign this Agreement effective as of the Termination Agreement Effective Date.

RECORDATI IRELAND, LTD

By: /s/ Kevin Buckley

Name: Kevin Buckley

Title: Chairman

Date: 22 February 2023

By: /s/ Cédric Ripert

Name: Cédric Ripert

Title: Managing Director

Date: 22 February 2023

ARS PHARMACEUTICALS, INC.

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By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Title: Chief Executive Officer and President

Date: 22 February 2023

[Signature Page to the Termination Agreement]

Exhibit 10.21

ARSPHARMACEUTICALS,INC.
EXECUTIVEEMPLOYMENT AGREEMENT
for
ALEXANDER A. FITZPATRICK

This Executive Employment Agreement (this "**Agreement**") is made and entered into effective as of December 1, 2022 (the "**Effective Date**"), by and between Alexander A. Fitzpatrick ("**Executive**") and ARS Pharmaceuticals, Inc. (the "**Company**").

1. Employment by the Company.

1.1 Position. Executive's employment with the Company shall begin on the Effective Date (the "**Start Date**"). Executive shall serve as the Company's Chief Legal Officer & General Counsel (subject to approval of the Board of Directors), reporting to the Company's Chief Executive Officer. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and full-time attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company's policies applicable to senior executives and general employment policies.

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1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of Chief Legal Officer & General Counsel and such other duties as are assigned to Executive by the Company's Chief Executive Officer. Executive will primarily work from the Company's offices in San Diego, California; provided that Executive shall be expected to engage in other travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable law, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of $515,000, less standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Annual Bonus. During Executive's employment, Executive will be eligible for an annual discretionary bonus, subject to applicable payroll deductions and withholdings, and prorated for the number of days Executive remains continuously employed in a calendar year (the **"Annual Bonus"**). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors (the "**Board**") and/or the Compensation Committee thereof in its discretion based upon the achievement of Company corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board. Executive

must continue to be employed through the date the Annual Bonus is paid in order to earn such bonus.

2.3 Equity Grant. Subject to approval by the Board, and pursuant to the Company's 2020 Equity Incentive Plan (the "**Plan**"), the Company shall grant Executive an option to purchase 700,000 shares of the Company's common stock at the fair market value as determined by the Board as of the date of grant (the "**Option**"). The Option will be subject to the terms and conditions of the Plan and

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Executive's grant agreement. Executive's grant agreement will include a four-year vesting schedule, under which 25 percent of Executive's shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either the Option is fully vested or Executive's Continuous Service ends (as defined in the Plan), whichever occurs first.

2.4 Indemnification. Executive shall be entitled to indemnification with respect to Executive's services provided hereunder pursuant to Delaware law, the terms and conditions of the Company's certificate of incorporation and/or by-laws, and the Company's standard indemnification agreement for directors and officers as executed by the Company and Executive. The Executive shall be entitled to coverage under the Company's Directors' and Officers' ("**D&O**") insurance policies that it may hold now or in the future to the same extent and in the same manner (i.e., subject to the same terms and conditions) to which the Company's other executive officers are entitled to coverage under any of the Company's D&O insurance policies.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional, professional and other expenses incurred by Executive in the performance of Executive's business-related obligations under this Agreement (collectively "**Expenses**"). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than 30 days after Executive submits an expense report in accordance with the preceding sentence.

5.Confidential Information Obligations.

5.1Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to execute and abide by the Company's Employee Confidential Information and

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Inventions Assignment Agreement (the "**Confidential Information Agreement**") attached hereto as **Exhibit A**. In addition, Executive agrees to abide by the Company's policies and procedures, as may be modified from time to time within the Company's discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information that is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

6.Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Except with the prior written consent of the Company's Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for- profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Chief Executive Officer, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venture, associate, representative or consultant of any person or entity engaged in, or planning or

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preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7.Termination of Employment; Severance Benefits.

7.1At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2Severance Benefits. Executive will be eligible to participate in the Company's Change in Control and Severance Benefit Plan (the "**CIC Plan**"),as amended and restated from time to time, pursuant to the terms and conditions therein.

8.Section 409A. It is intended that all of the benefits and payments payable under this Agreement and the CIC Plan to satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent

possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service (as defined under Treasury Regulation Section 1.409A-1(h)) to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed

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commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 8 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits constitute "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the applicable separation and release agreement will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the separation and release agreement actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable separation and release agreement spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

9.Section 280G. If any payment or benefit Executive will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment pursuant to this Agreement or otherwise (a "**Payment**") shall be equal to the Reduced Amount. The "**Reduced Amount**" shall

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be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount

determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally

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recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within 15 calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other reasonable time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax). For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence

---

10.Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise between Executive and the Company, both Executive and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16 (the "**FAA**"), and to the fullest extent permitted by applicable law, Executive and the Company will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: **(i)** the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or **(ii)** Executive's employment with the Company (including but not limited to all statutory claims); or **(iii)** the termination of Executive's employment with the Company (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATIONPROCEDURE, BOTH EXECUTIVE AND THE COMPANY WAIVE THE RIGHT TORESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE ORTHROUGH AN ADMINISTRATIVE PROCEEDING.** The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Section and to determine any procedural questions which grow out of such disputes, claims or causes of action

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and bear on their final disposition. All claims, disputes, or causes of action under this Section, whether by Executive or the Company, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this Section are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. Any arbitration proceeding under this Section shall be presided over by a single arbitrator and conducted by JAMS, Inc. ("**JAMS**") in San Diego, California, or as otherwise agreed to by Executive and the Company, under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). Executive and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the amount of court fees that would be required of Executive if the dispute were decided in a court of law. This Section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, sexual assault disputes and sexual harassment disputes as defined in the FAA, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the FAA or otherwise invalid (collectively, the "**Excluded Claims**"). In the event Executive intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Nothing in this Section is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

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11.General Provisions.

11.1Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

11.2Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

11.3Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

11.4Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

11.5Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

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11.6Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

11.7Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

11.8Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made

pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

11.9Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date.

ARSPHARMACEUTICALS,INC.

By: /s/ Richard Lowenthal

Richard Lowenthal

Chief Executive Officer

EXECUTIVE

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/s/ Alexander A. Fitzpatrick

Alexander A. Fitzpatrick

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

Exhibit A

Employee Confidential Information and Inventions Assignment Agreement

(separately attached)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-271359) of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.)

(2) Registration Statement (Form S-8 No. 333-269262) pertaining to the 2018 Equity Incentive Plan, the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.)

(2) Registration Statement (Form S-8 No. 333-261980) pertaining to the 2020 Equity Incentive Plan and
(3) the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.)

(3) Registration Statement (Form S-3 No. 333-261979) of ARS Pharmaceuticals, Inc. (formerly
(4) Silverback Therapeutics, Inc.)

(4) Registration Statement (Form S-8 No. 333-254827) pertaining to the 2020 Equity Incentive Plan and
(5) the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.)

(5) Registration Statement (Form S-8 No. 333-251143) pertaining to the 2016 Equity Incentive Plan, the
(6) 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.)

of our report dated March 23, 2023 March 21, 2024, with respect to the consolidated financial statements of ARS Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of ARS Pharmaceuticals, Inc. for the

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year ended December 31, 2022 December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California
March 23, 2023 21, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Lowenthal, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of ARS Pharmaceuticals, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2023 March 21, 2024

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

Richard Lowenthal, M.S., MSEL

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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I, Kathleen Scott, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of ARS Pharmaceuticals, Inc. ("the registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2023 March 21, 2024

By: /s/ Kathleen D. Scott

Kathleen D. Scott

Chief Financial Officer

(Principal Financial Officer)

">

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ARS Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2022 December 31, 2023, to which this Certification is attached, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company herby hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2023 March 21, 2024

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

Richard Lowenthal, M.S., MSEL

Chief Executive Officer

(Principal Executive Officer)

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Date: March 23,
2023 March 21, 2024

By: /s/ Kathleen D. Scott

Kathleen D. Scott

Chief Financial Officer

(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 97.1

ARS PHARMACEUTICALS, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing***

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Standards").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

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"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

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"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a)Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b)Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c)Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d)Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation

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hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e)No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g)No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

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5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

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8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

ARS Pharmaceuticals, Inc.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the ARS Pharmaceuticals, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with ARS Pharmaceuticals, Inc. (the

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"***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

Name: _____

Title: _____

Date: _____

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