Risk Factors Comparison 2024-03-21 to 2023-03-23 Form: 10-K

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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 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** ~~our~~ **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 **. 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~~ **20** million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3. ~~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. ~~Our~~ **Following the acceptance of our** NDA ~~was accepted~~ **in October 2022** for review by **the** FDA ~~in~~ **, on May 11, 2023,** the ~~fourth~~ **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). 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 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. 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 administer; • apprehension stemming from the use of a needle that leads to approximately 40 % to 60 % of patients delaying administration by up to 18 minutes even if they are carrying the device; • a high rate of dosing errors, with meta- analyses reporting **23** ~~up to 35~~ % 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~~ **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~~ **2** million patients who currently fill their prescriptions for an epinephrine injectable device, we estimate that approximately ~~2~~ **3** . ~~5~~ **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~~ **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~~ **2** million patients who filled a prescription. Our Approach ~~neffyTM~~ -- **neffy** is an investigational drug currently in clinical trials for the emergency treatment of allergic reactions (type I) including anaphylaxis. ~~neffyTM~~ -- **neffy** is not approved by the FDA, EMA or other health authorities. 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 ~~”)~~ and ~~pharmacodynamics (“~~ 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 **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 50oC or 122oF) that allows neffy to retain potency even if accidentally left in a high temperature environment. • Combination of previously validated product components. neffy consists of a unique combination of three validated products, which we believe will significantly reduce neffy’ s 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 **its September 19,** ~~the fourth quarter of 2022 with an anticipated mid-~~ 2023 **CRL. This study assessed repeat doses of neffy compared** ~~PDUFA target action date and we believe that the completed trials are sufficient~~ 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 ”) **is under** ~~was filed and validated for~~ review **and we anticipate a regulatory decision (CHMP Opinion)** by **mid-** ~~EMA in the fourth quarter of 2022~~ **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 We were created to innovate, develop and commercialize neffy, a novel, potentially first- in- class treatment that addresses Type I allergy patients’ desire and need for a no needle, no injection, easy- to- use, portable and reliable solution for delivering epinephrine. To achieve this goal, we have assembled a management team with extensive experience in the development and commercialization of drugs, such as recently approved nasal sprays NARCAN (naloxone nasal spray) and VALTOCO (diazepam nasal spray). Our company was founded by Richard Lowenthal, M. S., MSEL, Robert Bell, Ph. D. and Sarina Tanimoto, M. D., **MBA** ~~M. B. A~~ . 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 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 ~~2~~ **FDA, on May 11, 2023, the FDA held a virtual meeting of the PADAC** . ~~0 mg~~ **At that meeting, on the question of whether the data from our** neffy ~~dose for~~ **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 **≥** ~~greater than~~ 30 kg ~~in weight to~~ **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 ~~in~~ **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 ~~third~~ **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 study requested by the FDA, and anticipate submitting our response to the FDA CRL early in the second** quarter of ~~2022~~ **2024 ,** ~~. Our NDA was accepted for review by FDA in the fourth quarter of 2022~~ with an anticipated ~~mid- 2023~~ PDUFA target action 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 **, 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 **the middle of the second half of** ~~2023~~ **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. Our Strategy Our strategy is focused on developing and commercializing neffy as a potentially first- in- class approved intranasal treatment for the approximately ~~16~~ **20** million patients in the United States **under the active care of physicians between 2020- 2022** who have been diagnosed **with** ~~and experienced~~ 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 ~~in~~ **, and anticipate submitting our response to** the ~~fourth~~ **FDA' s CRL early in the second** quarter of ~~2022~~ **2024 ,** with an anticipated ~~mid- 2023~~ PDUFA target action 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~~ **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~~ **3** . ~~5~~ **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~~ **13. 5** million patients who are diagnosed and under the care of physicians, but have not been prescribed an epinephrine intra- muscular injectable **over the last three- years** . • 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 **is under** ~~was filed and validated for~~ review **, and we anticipate a decision (CHMP Opinion)** by **mid-** ~~EMA in the fourth quarter of 2022~~ **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 The immune system plays an important role in monitoring and protecting the body against microbial threats. However, this system can lead to overstated immune and inflammatory responses that results in adverse outcomes known as hypersensitivity reactions. Type I allergic reactions are potentially life- threatening hypersensitivity reactions that can occur within minutes following exposure to an allergen and need to be treated immediately to relieve troublesome symptoms, mitigate severity and avoid a potentially fatal event. These severe reactions are caused by exposure to a specific allergen, typically foods (most commonly, nuts, eggs, shellfish), drugs and venoms and are mediated by immunoglobulin E IgE antibodies that bind to mast cells causing the release of histamines. The histamines induce smooth muscle contraction in the airways and a wheal and flare response in the skin producing swelling and inflammation. At the same time, widespread activation of mast cells leads to systemic effects of circulatory shock, hypotension or vascular collapse, and in the most severe cases respiratory arrest and death. The severity of a Type I allergic reaction is a function of the speed of onset and the number of organ systems affected by the reaction. As such, early intervention within minutes is critical in order to provide symptom relief and to prevent severe allergic reactions, known as anaphylaxis. Table 1: Symptoms of Type I Allergic Reactions including Anaphylaxis Body System Common Symptoms of Type I Allergic ReactionsRespiratory Chest tightness, wheezing, difficulty ~~breathingUpper~~ ----- **breathing ~ 50 % frequencyUpper** 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 % frequencyAngioedema including swelling of lips, tongue and mouth ~ 50 % frequency** Gastrointestinal Abdominal pain and vomiting **~ 20 % frequency** * Reprinted with permission from Dr. Pete Smith (Medical Media Kits) and Mary Johnson **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. 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 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 **1** ~~less than 5~~ % 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 ~~* Reprinted from RECAPEM (image described in the public- domain and freely available).~~ 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~~ **20** million people in the United States **under the active care of physicians between 2020- 2022** who have been diagnosed **with** ~~and experienced~~ Type I severe allergic reactions, only 3. ~~3~~ **2** million **had** ~~currently have~~ an active and filled epinephrine autoinjector 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 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. Clinical Development of neffy neffy is designed to provide injection- like absorption of epinephrine at a **2. 0 or** 1 ~~. 0 or 2~~ . 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 the fourth quarter of 2022 with an anticipated mid- 2023 PDUFA target action date~~ . 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. **The** ~~During our pre- NDA meeting in mid- 2021,~~ FDA agreed that bracketing based on the primary parameters of Cmax, tmax 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 AUC0- 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 **have completed** ~~are also conducting~~ 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. 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~~ . 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 (Cmax, tmax, early partial AUCs, AUC0- 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 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 no serious treatment- related adverse events, and adverse events reported have generally not resulted in side effects more severe than grade 1, and were comparable to injection products. Since neffy is given without **a** needle, there was also no needle- related injuries or accidental blood vessel injections. In contrast, for patients self- administering devices, which involved 132 subjects dosed **with** ~~for each of~~ 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 DataComparable PKs **to** ~~at a low dose of~~ epinephrine Cmax, tmax and AUCs were within the range of approved intra- muscular injection products with a low intranasal dose of 2. 0 mg neffy (people > 30 kg in weight) and 1. 0 mg neffy (people 15 – 30 kg weight). **Exposures with repeat doses of neffy were greater than IM to ensure efficacy, and comparable to EpiPen to ensure safety. Low dose of epinephrine avoids side- effects that can be confused with anaphylaxis symptoms Minimal to no gastrointestinal side effects with 1. 0 or 2. 0 mg neffy such as vomiting, diarrhea or abdominal pain that can occur if excess non- absorbed epinephrine is swallowed, confounding clinical monitoring since those same gastrointestinal side effects are symptoms of anaphylaxis during approximately 20 % of events.** Robust PDs within a range comparable to injection products with no risk of accidental blood vessel injections PD responses including systolic blood pressure and heart rate were within normal physiologic changes and comparable to auto-injector products, with maximum changes less ~~that~~ **than** ~~of the~~ EpiPen. neffy has no potential for the accidental blood vessel injections observed with injection products such as EpiPen, which can lead to rapid and high epinephrine exposures that cause rapid increases in systolic blood pressure and can lead to cerebral hemorrhage or other cardiovascular side effects. No meaningful pain or irritation after administration Visual analogue scale scores were an average of 5 to 8 on a 100 mm scale, and show no meaningful pain (or burning or stinging sensation) after administration, attributable to neffy being an aqueous

formulation. There is also no irritation observed based on formal scoring. Needle containing intra- muscular injection products are known to be painful and cause reluctance to dose. Easy to use No critical dosing errors during self- administration with 2. 0 mg neffy by type I allergy adult subjects (EPI- 17). Zero percent error rate in ~~two~~ human ~~factors~~ **factor validation** studies with ~~150 persons, when~~ **intended commercial instructions for** ~~used~~ **use** ~~by trained adults or trained children~~ and **quick reference guide,** when used by untrained ~~passers~~ **adults or untrained children. Ability to dose neffy is not affected by any of the frequently observed anaphylaxis** ~~byers~~ **related symptoms such as angioedema or swelling of the face, lips, tongue or larynx (~ 50 % frequency), gastrointestinal symptoms such as vomiting or dysphagia (~ 20 % frequency), or upper airway or breathing difficulty (~ 50 % frequency)** . Easy to carry neffy is comparable in size to a wireless earbud case, and multiple neffy devices can fit in a patient or parent' s pocket to satisfy guideline recommendations. High reliability neffy' s sprayer device is designed to deliver the effective dose more than 99. 999 % of the time, with no recalls or warnings among the millions of the same nasal sprayer devices sold to date. No breathing or inhalation required neffy is designed to be absorbed passively through the nasal mucosa without any inhalation, sniffing or breathing required, with its particles too large to enter the lungs. Injection- like absorption even with nasal congestion neffy reaches exposures comparable to approved injectable products even after induction of moderate to severe nasal rhinitis and / or edema (e. g., nasal congestion) Shelf- life at least comparable to injection products, but also with high temperature stability Drug stability studies show that neffy has a shelf- life at 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 50oC (122oF) for at least three months, or temperatures of 40oC (104oF) for at least six months. **Regulatory Review of neffy by the FDA 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: 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~~ , **and** we **anticipate** ~~received during EMA' s review of our prior 1. 0 mg dose neffy MAA submission, EMA required~~ a **decision (CHMP Opinion) by mid-** ~~preclinical dog anaphylaxis study, which we completed with data showing no meaningful differences in epinephrine absorption of neffy in dogs in a normal state or an anaphylactic state. In April 2022~~ **2024** ~~, 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~~ . 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 **in** ~~at end of 2023 or early~~ 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~~ **20** million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only about 3. ~~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~~ **5** million ~~devices~~ **two- pack units** . Of those 3. ~~3~~ **2** million people, roughly half don' t carry these devices due to many drawbacks that can result in patient and caregiver injury, hesitation, and delays in administration principally because of apprehension and pain of needles. In turn, the failure or delay of epinephrine delivery can allow the allergic reaction to progress in severity causing life- threatening symptoms or events that potentially require emergency services and / or hospitalization. We believe neffy could address the needs of not only the approximately 3. ~~3~~ **2** million patients in the United States who currently fill intra- muscular injectable prescriptions, but also the more than ~~22~~ **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~~ **3** . ~~5~~ **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~~ **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. 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 **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~~ **3** . ~~5~~ **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. 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~~ **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~~ **20** million patients not currently under the care of physicians. • Over time, targeting the approximately ~~11~~ **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 **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 **reported positive topline results demonstrating statistically significant** ~~are conducting a randomized, placebo- controlled proof of concept study evaluating the safety~~ and ~~efficacy of neffy~~ **clinically meaningful improvements** in **treatment- refractory chronic** ~~approximately 24 subjects with frequent~~ urticaria **patients** ~~flares. We expect to complete enrollment and report topline data from this study~~ in **February** ~~the second half of 2023~~ **2024 , and anticipate initiating a Phase 2 clinical trial in the 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~~ **300** million based on IQVIA data. In Europe and Japan, sales of epinephrine injectable devices are approximately $ ~~160~~ **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. • 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 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 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~~ **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~~ **2** million patients currently filling epinephrine injection device prescriptions, adoption by the approximately ~~2~~ **3** . ~~5~~ **3** million patient that receive, but do not fill their prescription, and the ~~11~~ **13. 5** million patients diagnosed and managed by physicians who do not currently have an epinephrine auto- injector, especially those incorrectly using antihistamines as a substitute. Other launches of intranasal products for emergency use into previously injection- only markets such as NARCAN (marketed by Emergent BioSolutions), VALTOCO (marketed by Neurelis), NAYZILAM (marketed by UCB) and BAQSIMI (marketed by Eli Lilly) have rapidly captured a significant percentage of the existing market, and also expanded their respective markets. Both products use the same device that we have chosen for neffy. We believe that NARCAN' s widespread use clearly demonstrates market uptake in response to the advantages of an intranasal product via proven device over injection, considering in particular that NARCAN is used in life threatening rescue situations where reliable administration is required for confident administration, similar to severe Type I allergic reactions. Beyond just reliability, we believe that an intranasal product has unique advantages for treating a severe Type I allergic reaction due to patient and parent fear and avoidance of injection and because time is of the essence. This perspective is distinct from other diseases with chronic use of injection products, administration by a trained professional is required, or where the injection is more manageable and tolerated. In our market research, respondents have described neffy as " game- changing " and we believe neffy, 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. 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 ~~and~~ **,** Orexo AB **and 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~~. Dodecyl maltoside or Intravail is purchased through our license agreement with Aegis Therapeutics, **LLC** ~~Inc.~~ from two manufacturers, Dr. Reddy Laboratories and Inalco, which are based in India and Italy, respectively. The unit dose sprayer device used to delivery drug product in neffy is produced by Aptar Pharma (" Aptar "). 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 **. If approved** , ~~and we plan to continue to conduct ongoing registration stability studies that~~ we anticipate **that our label** will ~~enable us to~~ indicate ~~on our label, if approved,~~ that neffy is stable at room temperature for ~~18~~ **24** months at 25oC. We have also conducted studies indicating that neffy is also stable at temperature excursions including 40oC for up to six months, and at 50oC 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~~ **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 **patents in each of** ~~Australian~~ **Australia** ~~patent~~ , ~~one granted~~ **Canada, China, Hong Kong,** ~~Japanese~~ **Japan** ~~patent~~ , **Mexico** ~~one granted Chinese patent~~ , **Singapore,** ~~one granted patent in~~ South Korea, ~~one granted European~~ **Europe** ~~patent~~ , ~~three~~ **the** ~~granted~~ United Kingdom ~~patents~~ , three pending U. S. non- provisional patent applications, and over fifteen pending foreign patent applications directed to intranasal epinephrine formulations and methods of their use **, among other things** . These issued patents and pending patent applications **provide patent protection for neffy and** are expected to expire as early as 2038, absent any patent term adjustments ~~or patent term extensions for regulatory delay~~ . In addition to patent protection, we also rely on ~~trademark~~ **trademarks** ~~registration~~ , 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~~ . 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 confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators, and other collaborators and contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see " Risk Factors — Risks Related to Our Intellectual Property. " The patent positions of specialty pharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third- party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the U. S. Patent and Trademark Office (the " USPTO ") to determine priority of invention. For more information, see " Risk Factors — Risks Related to Our Intellectual Property. " Our Collaboration and Licensing Agreements License Agreement with Aegis In June 2018, we entered into a license agreement with Aegis Therapeutics, LLC (" Aegis "), which was amended in July 2020 and January 2021. Pursuant to the agreement, Aegis granted us an exclusive, worldwide, sublicensable license under patents and know- how relating to the INTRAVAIL drug delivery technology to research, develop, make (subject to Aegis supplying the INTRAVAIL drug delivery technology to us under a supply agreement), use, sell, offer for sale, import, and otherwise commercialize products incorporating epinephrine compounds (" Aegis Licensed Compounds "), including the neffy nasal spray. During the term of the agreement, we are required to use commercially reasonable efforts to obtain regulatory approval for products containing one or more Aegis Licensed Compounds and using the excipient (including INTRAVAIL) (" Aegis Licensed Products ") and to thereafter maximize sales of the Aegis Licensed Products, and Aegis may not directly or indirectly exploit an Aegis Licensed Product or Aegis Licensed Compound or derivatives thereof without our consent. Under the agreement, Aegis received an upfront license fee of $ 50, 000 and is entitled to receive development milestone payments of up to $ 3. 95 million in aggregate and commercialization milestone payments up to $ 16. 0 million in the aggregate for each Aegis Licensed Product. We made a $ 0. 5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019, 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 studies required for approval of neffy in Japan. Additionally, Alfresa is obligated to either (i) enter into a commercial supply agreement with us pursuant to which we will supply drug product for commercial sale at an agreed upon transfer price, or (ii) if Alfresa elects to manufacture its own supply of drug product, pay us a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value we would receive by supplying drug product to Alfresa at the transfer price. The agreement will continue until the later of (i) expiration of the last- to- expire valid claim of our patents or joint patent with Alfresa covering the composition, method of manufacture or method of use in the field of any Alfresa Licensed Product in the Alfresa Territory, and (ii) 10 years after the first commercial sale of any Alfresa Licensed Product in the Alfresa Territory. Alfresa has the right to terminate the agreement (1) at any time after a specified notice period to us, or (2) upon notice to us if a binding decision is rendered invalidating any of our patents. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency- related events of the other party that are not discharged within a defined time period. Collaboration and Distribution Agreement with Pediatrix In March 2021, we entered into a collaboration and distribution agreement with Pediatrix Therapeutics (“ Pediatrix ”). Pursuant to the agreement, we granted Pediatrix (i) an exclusive, royalty- bearing, sublicensable license under our patents relating to neffy to develop, use, register and import epinephrine compositions (“ Pediatrix Licensed Compositions ”) and related products (“ Pediatrix Licensed Products ”) in China, Macau, Hong Kong and Taiwan (the “ Pediatrix Territory ”) and to promote, offer for sale and sell Pediatrix Licensed Products in the Pediatrix Territory; and (ii) an exclusive, royalty- bearing, sublicensable license to manufacture Pediatrix Licensed Compositions and Pediatrix Licensed Products solely for the purpose of exercising the license described in clause (i) in the Pediatrix Territory. We expressly reserved all rights to practice and grant licenses under our technology outside the scope of the licenses granted to Pediatrix. During the term of the agreement, Pediatrix is obligated to use commercially reasonable efforts to (1) develop the Pediatrix Licensed Products throughout the Pediatrix Territory, (2) prepare, obtain, maintain and renew all necessary regulatory approvals for the Pediatrix Licensed Products in the Pediatrix Territory, and (3) market, promote and otherwise commercialize the Pediatrix Licensed Products throughout the Pediatrix Territory. Under the agreement, we received a one- time upfront payment of $ 3. 0 million and are eligible to receive a regulatory milestone payment of $ 4. 0 million and net sales milestone payments of up to $ 80. 0 million in the aggregate. We will receive a per unit supply price for any sale of commercial supply to Pediatrix. Additionally, we are eligible to receive a tiered royalty on the net sales of all Pediatrix Licensed Products during the applicable royalty term, which is less than one percent below a minimum annual sales threshold, and increasing to low- to- mid double- digit percentages above the minimum annual sales threshold, subject to reductions under certain conditions including due to generic competition. Pediatrix’ s obligation to pay us royalties continues on a Pediatrix Licensed Product- by- Pediatrix Licensed Product and region- by- region basis in the Pediatrix Territory, until the latest of (i) expiration of the last- to- expire valid claim of our patents covering such Licensed Product in such region; (ii) the expiration of all regulatory exclusivities that cover such Licensed Product in such region; or (iii) ten years after the first commercial sale of such Pediatrix Licensed Product in such region (the “ Pediatrix Royalty Term ”). The agreement will continue until the expiration of the last- to- expire Pediatrix Royalty Term. Pediatrix has the right to terminate the agreement at any time after a specified notice period to us. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency- related events of the other party that are not discharged within a defined time period. Manufacturing Agreement with Renaissance In September 2020, we entered into a manufacturing agreement with Renaissance Lakewood, LLC (“ Renaissance ”) **, which was subsequently amended in July 2023** . 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 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. U. S. Drug Development Process In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U. S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following: • completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA' s Good Laboratory Practice (" GLP ") regulations and other applicable regulations; • submission to the FDA of an investigational new drug (" IND "), which must become effective before human clinical trials may begin; • approval by an independent institutional review board (" IRB ") at each clinical site before each trial may be initiated; • performance of adequate and well- controlled human clinical trials in accordance with applicable regulations, including the FDA' s good clinical practice (" GCP ") regulations to establish the safety and efficacy of the proposed drug for its proposed indication; • submission to the FDA of an NDA after completion of all pivotal trials; • a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review; • satisfactory completion of an FDA pre- approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug' s identity, strength, quality and purity; • potential FDA audit of the preclinical and / or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP regulations; • satisfactory completion of an FDA **PADAC** ~~advisory committee~~ review, if applicable; and • FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States. Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP requirements. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol (s) for human trials. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30- day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non- compliance. Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor' s control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any

subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined: • Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life- threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. • Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. • Phase 3. The drug is administered to an expanded patient population to further evaluate dosage and clinical efficacy at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit / risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well- controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. Post- approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 trials. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA. During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. U. S. Review and Approval Processes Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. In addition, the Pediatric Research Equity Act (" PREA ") requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. The FDA must send a non- compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric

assessment may still be required for any applications to market that same product for the non- orphan indication (s). The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in- depth review of the NDA. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months from the date of " filing " of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a " filing " decision after it the application is submitted The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification. After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product' s identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows **such** ~~the advisory~~ committee' s recommendations. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a **CRL** ~~Complete Response Letter~~. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A **CRL** ~~Complete Response Letter~~ indicates that the review cycle of the application is complete and the application will not be approved in its present form. A **CRL** ~~Complete Response Letter~~ usually describes all of the specific deficiencies in the NDA identified by the FDA. The **CRL** ~~Complete Response Letter~~ may require additional clinical data and / or (an) additional pivotal Phase 3 clinical trial (s), and / or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a **CRL** ~~Complete Response Letter~~ is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post- market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a risk evaluation and mitigation strategy (" REMS ") is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Fast Track Designation The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, the FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life- threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals. Fast track designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, such designations or shortened review periods may not provide a material commercial advantage. Post- Approval Requirements Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record- keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and

distribution requirements, and complying with FDA promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long- term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post- market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; • fines, warning letters, or untitled letters; • clinical holds on clinical studies; • refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals; • product seizure or detention, or refusal to permit the import or export of products; • consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; • mandated modification of promotional materials and labeling and the issuance of corrective information; • the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or • injunctions or the imposition of civil or criminal penalties. The FDA also may require post- marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product' s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product' s labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off- label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer' s communications on the subject of off- label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined companies from engaging in off- label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA- approved labelling. **Hatch- Waxman Act** Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505 (b) (1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505 (b) (2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA' s prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505 (j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application (" ANDA "). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed " abbreviated " because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject' s bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant' s drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs

listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505 (b) (2) NDA. Upon submission of an ANDA or a 505 (b) (2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505 (b) (2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505 (b) (2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505 (b) (2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505 (b) (2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner (s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant' s favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30- month stay. In instances where an ANDA or 505 (b) (2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner (s) regularly take action to trigger the 30- month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505 (b) (2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor' s decision to initiate patent litigation. The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505 (b) (2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505 (b) (2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505 (b) (2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505 (b) (2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Hatch- Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505 (b) (2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted / sponsored by the applicant. This three- year exclusivity period protects against FDA approval of ANDAs and 505 (b) (2) NDAs for the condition of the new drug' s approval. As a general matter, the three year exclusivity does not prohibit the FDA from approving ANDAs or 505 (b) (2) NDAs for generic versions of the original, unmodified drug product. Five- year and three- year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well- controlled clinical trials necessary to demonstrate safety and efficacy. Pediatric exclusivity is another type of non- patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six- month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA- issued " Written Request " for such a trial. Other Healthcare Laws In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti- kickback laws, false claims laws, data privacy and security laws, and other healthcare fraud and abuse laws, such as transparency laws regarding payments or other items of value provided to healthcare providers. The U. S. federal Anti- Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term " remuneration " has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case- by- case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute' s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal healthcare program anti- kickback statute has been violated. Additionally, the intent standard under the federal anti- kickback statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the " ACA ") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program anti- kickback statute

constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. A claim includes " any request or demand " for money or property presented to the U. S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, the federal civil monetary penalties law, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program. Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to **the Centers for Medicare & Medicaid Services (" CMS ")** information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti- kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives. Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including significant fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies. Coverage and Reimbursement Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third- party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third- party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third- party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan- by- plan basis. The process for determining whether a third- party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Some third- party payors require pre- approval of coverage for new drugs before they will reimburse healthcare providers who use such therapies. Generally, third- party payors limit coverage and reimbursement for new medication prior to a formal review by the payors' pharmacy and therapeutics committees. As such, several third- party payors have indicated that our products may be subject to denial or limited coverage prior to formal review. There may be significant delays in obtaining reimbursement for newly- approved drugs, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. 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. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the **EU** ~~European Union~~ 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 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 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 **. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ **the** ~~may be~~ **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~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report **outlining** ~~on how the~~ **three** ~~Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for **testing by the CMS Innovation Center which will be evaluated on their ability to** ~~lowering~~ **lower** ~~drug~~ **the** ~~costs~~ **cost** ~~for Medicare~~ **of drugs, promote accessibility,** and ~~Medicaid beneficiaries~~ **improve quality of care** . It is unclear whether **the models** ~~this executive order or similar policy initiatives~~ 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 Numerous state, local, federal and foreign laws, including consumer protection laws and regulations related to data privacy, security, and protection, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health- related information. Such obligations may include, without limitation, HIPAA, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 (" CCPA "), the Canadian Personal Information Protection and Electronic Documents Act, Canada' s Anti- Spam Legislation, the **EU** ~~European Union~~ ' s General Data Protection Regulation 2016 / 679 (" EU GDPR "), and the EU GDPR as it forms part of United Kingdom (" UK ") law by virtue of section 3 of the **EU** ~~European Union~~ (Withdrawal) Act 2018 (" UK GDPR "). HIPAA, as amended by HITECH, imposes obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, certain state and non- U. S. laws, such as the CCPA, the CPRA and the GDPR, govern the privacy and security of personal information, including health- related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and / or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing. In addition, Congress and various other states have enacted or are considering new laws and regulations regarding the privacy and security of ~~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. The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information, including requiring covered companies to provide new disclosures to California residents, and affords such residents new abilities to opt- out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. Moreover, the California Privacy Rights Act, or the CPRA, – a consumer privacy ballot initiative that amends and expands the CCPA became effective on January 1, 2023, and expands the CCPA. The CPRA affords California residents significantly more control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcement agency dedicated to consumer privacy. While aspects of the CCPA and CPRA and its interpretation remain to be determined in practice, they create further uncertainty and may result in additional costs and expenses in an effort to comply. Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority (ies) and affected individuals; and mandating the appointment of representatives in the UK and / or the EU in certain circumstances. The U. S. Foreign Corrupt Practices Act The U. S. Foreign Corrupt Practices Act of 1977 (“ FCPA ”) prohibits any U. S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Europe / Rest of World Government Regulation In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of an application for a clinical trial authorization (“ CTA ”) much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to each country’ s national health authority and an application made to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country’ s requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed. 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. 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. 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 **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~~ Our corporate headquarters are located at 11682 El Camino Real, Suite 120, San Diego, California 92130, and our telephone number is (858) 771- 9307. Our corporate website address is www. ars- pharma. com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10- K. Our periodic and current reports are available on our website, free of charge, as soon as reasonably practicable after filing. We have included our website in this Annual Report on Form 10- K solely as an inactive textual reference. **Employees As** ~~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..... our financial statements for the year ended December 31, ~~2022~~ **2023** ~~included in Item 8 of this Annual Report for more information regarding the Merger. Employees As of December 31, 2022~~, 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 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, **2023 and** 2022 ~~and 2021~~, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~76~~ **131**. ~~9~~ **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. 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; • 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; • initiate and continue research, preclinical and clinical development efforts for any future product candidates; • experience any delays or encounter any issues with any of the above, including but not limited to failed studies, negative or mixed clinical trial results, safety issues or other regulatory challenges, the risk of which in each case may be exacerbated by **a** ~~COVID- 19 or other~~ health epidemic or pandemic; • add clinical, scientific, operational, financial and management information systems and 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; • 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 • 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. 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' s commercial 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 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. 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. 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. 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 candidates that we may pursue and their development requirements, if any; • if approved, the costs of commercialization activities for neffy for any approved indications, or the similar cost of any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any current or future licensing and collaboration partners, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; • subject to receipt of regulatory approval, revenue received from commercial sales of neffy for any approved indications or from future product candidates, if any; • the amount and timing of potential royalty and milestone payments to our current or future licensing and collaboration partners; • the receipt of licensing fees, royalties and potential milestone payments under our current or future out-licensing arrangements; • the extent to which we in- ~~licenses~~ **license** or acquire rights to other products, product candidates or technologies; • our headcount growth and associated costs as we expand our personnel, including personnel to support our product candidate development and potential future commercialization efforts and help us comply with our obligations as a public company; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and • the ongoing costs of operating as a public company. We cannot be certain that additional funding will be available on acceptable terms, or at all. The global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, 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. 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. Risks Related to the Development of neffy or Any Future Product Candidates We ~~currently depend on the success of~~ **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** , ~~which~~ **or commercialized, a pharmaceutical product. It** is **possible that the FDA and the EMA may refuse to accept any** ~~our~~ **or** ~~only current product candidate. If we are unable~~ **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 ~~, and successfully commercialize,~~ neffy **or any future product candidates. As we announced on September 19** , **2023, the FDA issued a CRL** ~~or~~ **for** ~~experiences significant delays in~~ **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** ~~doing~~ **dosing** ~~so~~ **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 ~~business~~ **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** ~~.We have never commercialized a product and~~ **an** ~~may experience~~ **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 ~~or unexpected costs or difficulties~~ in **the** ~~obtaining regulatory~~ approval **of** ~~for neffy for its initial indication or~~ **our** ~~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~~ **resubmitted** ~~or planned NDAs~~ **NDA** ~~and MAAs for~~ **or** ~~substantive review~~ **the issuance by the FDA of another CRL,would likely cause a material adverse effect to** ~~or~~ **our business** ~~may conclude after review of our data that an application is insufficient to obtain regulatory approval for neffy or any future product candidates~~ . **Additionally** ~~For example~~ ,the EMA required us to submit our preclinical ~~dog~~ **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 ~~costly~~ 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** ~~1mg~~ **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 ~~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~~ materially ~~harmed~~ **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** . 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; • 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; • entry into collaborations to further the development of neffy or any future product candidates; • establishing sales, marketing and distribution capabilities and launching commercial sales of any approved products, whether alone or in collaboration with others; • successfully launching commercial sales of neffy or any future product candidates, if and when approved; • acceptance of neffy or any future product candidates, if and when approved, by patients, the medical community and third- party payors; • obtaining and maintaining third- party coverage and adequate reimbursement; • products, following approval, maintaining a continued acceptable safety profile; • effectively competing with other therapies; • ensuring that we promote and distribute our products consistent with all applicable healthcare laws; and • enforcing and defending intellectual property rights and claims. Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission and review process, 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; • our inability to gain agreement from applicable foreign regulatory authorities that neffy is appropriate for approval under applicable regulatory pathways; • 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 neffy outweigh any safety or other perceived risks; • 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; • 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, the EMA' s or any other applicable foreign regulatory agency' s having differing requirements for the trial protocols used in our clinical trials; • 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..... 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 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: • 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 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; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • 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; • 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; • 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 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 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~~ . 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 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. 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, or to conduct or continue a clinical trial at a prospective or specific trial site; • we may not reach an agreement on acceptable terms with prospective 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, 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 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. 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. 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. 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; • 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; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. 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. 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 **, 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 **, 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 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. 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 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 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. 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. 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. 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 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 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 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. 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 our product candidates according to our specifications; • the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified; • clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and • the misappropriation of our proprietary information, including our trade secrets and know- how. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications 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 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 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. 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. 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 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 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. 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 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~~ **our failure to educate** adequate numbers of allergists, pediatricians and other physicians ~~to prescribe any~~ **on the benefits of our** future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • the availability of adequate coverage by and reimbursement from third- party payors; and • 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. 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 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. 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; • 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. 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. 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 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 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. Any failure by neffy 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. 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 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 **. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ - **the ~~may be~~ 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~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report **outlining** ~~on how the~~ **three** ~~Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for ~~lowering drug costs~~ **testing by the Centers** for Medicare ~~and~~ **&** Medicaid ~~beneficiaries~~ **Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care** . It is unclear whether **the models** ~~this executive order or similar policy initiatives~~ 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 successfully develop and commercialize neffy or any future product candidates. Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any. In some countries, including certain Member States of the EU, the pricing of prescription drugs is, in part, subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. The EU provides options for the EU Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low- priced and high- priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of 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. 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 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 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; • 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; • federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts on approved products; • federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and • analogous state laws and regulations, such as state anti- kickback and false claims laws, that

may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; some state laws that require biotechnology companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives. Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities after neffy or any future product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, **disgorgement,** exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non- compliance, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. We are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third- party data, business plans, transactions, and financial information (collectively, " sensitive data "). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, the California Consumer Privacy Act 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 **EU** ~~European Union~~ ' 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. 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 **. 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 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 **; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations** . Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. 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 ~~)~~ **attacks** , credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. 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. 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. 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** ~~our~~ **or any of our future** product candidates. If we are unable to obtain or maintain patent protection with respect to **neffy** ~~our~~ **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** ~~our~~ **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. 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 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~~ **Canada, China, Hong Kong,** ~~Japanese~~ **Japan** ~~patent~~, **Mexico** ~~one granted Chinese patent~~, ~~one granted~~ **Singapore,** South Korea ~~patent~~, ~~one granted European~~ **Europe** ~~patent~~, and ~~three~~ **the** ~~granted~~ 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 **over fifteen pending foreign patent applications directed to neffy and its uses, among** other **things** ~~foreign jurisdictions for neffy~~, 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. 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** ~~our~~ **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** ~~our~~ **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. 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~~ **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, 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** ~~our~~ **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. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce the existing patents we own, co- own or license and patents that we or our licensors might obtain in the future. **As an example, beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the " UPC "). Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. In 2012, the European Union Patent Package (the " EU Patent Package ") regulations were passed with the goal of providing a single pan- European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. During the first seven years of the UPC' s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt- out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan- European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.** Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or patent applications will be due to be paid to the USPTO and various foreign patent agencies at various stages over the lifetime of our patents and / or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we or our licensors fail to maintain the patents and patent applications covering our product 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** ~~our~~ **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. 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 **neffy** ~~our product candidates~~ that are pending at the patent offices in the United States, Europe, Japan, and other foreign jurisdictions, however, we cannot predict: • if and when patents may issue based on the patent applications we own, co- own or exclusively license; • the scope of protection of any patent issuing based on the patent applications we own, co- own or exclusively license; • whether the claims of any patent issuing based on the patent applications we own, co- own or exclusively license will provide protection against competitors, • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those covered by the patent applications we own, co- own or exclusively license; • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • whether the patent applications that we own, co- own or exclusively license will result in issued patents with claims that cover **neffy** ~~our~~ **or any of our future** product candidates or uses thereof; and / or • whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates. We cannot be certain that the claims in our pending patent applications directed to **neffy** ~~our~~ **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** ~~our~~ **or any of our future** ~~products~~ **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. 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** ~~our~~ **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** ~~our~~ **or any of our future** ~~products~~ **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** ~~our~~ **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** ~~our~~ **or any of our future** ~~products~~ **product candidates**. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. If we are sued for infringing 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** ~~our~~ **or any of our future** product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell **neffy** ~~our~~ **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** ~~our~~ **or any of our future** ~~products~~ **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. 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 **appeal from a Final Written Decision in an** ~~inter~~ **Inter** ~~partes~~ **Partes** ~~review~~ **Review** of U. S. Patent No. 10, 682, 414 B2 **and to** ~~that was instituted on February 14, 2022, and~~ **an opposition proceeding with the European Patent Office with respect to EP 3678649. We** may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time- consuming and could interfere with our ability to sell and market our products. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company. In an infringement proceeding, even one initiated by us, there is a risk that a court will decide that our patents are not valid and that we do not have the right to stop the other party from

using the inventions they describe. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party' s activities do not infringe our rights to these patents. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our research programs and product candidates, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own or have licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of our patents is upheld, the court will construe the claims of our patents narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are ~~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 **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** ~~our~~ **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 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 regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We have registered **and pending** trademarks in the United States, as well as in **several** foreign jurisdictions, including the United Kingdom, **EU** ~~European Union~~, 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. 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; • we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own, co- own or exclusively license; • we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we may own or co- own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • third parties performing manufacturing or testing for us using 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 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. 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 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; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; • a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; • 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 intellectual property or proprietary information or expose us to potential liability; • 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; • 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; • 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 • 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 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 enrolling patients in our clinical trials; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism that reduces site resources; • interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; • risk that participants enrolled in our clinical trials will acquire a virus or illness while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials; • limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; • delays in receiving authorizations from regulatory authorities to initiate our future clinical trials; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; • interruption in global shipping that may affect the transport of clinical trial materials, such as neffy used in our clinical trials; • changes in local regulations as part of a response to the public health crisis which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether; • interruptions or delays in nonclinical studies due to restricted or limited operations at research and development laboratory facilities; • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and • refusal of the FDA, the EMA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States, the EU or other relevant local geographies. Any negative impact a ~~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 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. We only have a limited number of employees to manage and operate our business. As of December 31, ~~2022~~ **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; • manufacturing standards; • federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non- U. S. regulatory authorities; and • laws that require the reporting of financial information or data accurately. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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 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; • 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 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; • adverse regulatory authority decisions; • introduction of new products, services or technologies by our competitors; • failure to meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our product candidates; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity generally, including with respect to other products and potential products in such markets; • the introduction of technological innovations or new therapies that compete with potential products of ours; • changes in the structure of health care payment systems; and • period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. ~~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 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. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Our status as a Delaware corporation and the anti- takeover provisions of the Delaware General Corporation Law (" DGCL ") may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of us more difficult, including the following: • a classified board of directors with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority

of our board of directors; • the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; • the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chair of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • the requirement for the affirmative vote of holders of at least 66- 2 / 3 % of the voting power of all of the then- outstanding shares of our voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and • advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of us. In addition, as a Delaware corporation, we will be subject to Section 203 of the DGCL. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then- current board of directors, including delay or impede a merger, tender offer or proxy contest involving us. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction. Our amended and restated certificate of incorporation designates the state courts **of** the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. These exclusive forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. We do not anticipate paying any cash dividends in the foreseeable future. We plan to retain our future earnings, if

any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future. ~~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. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. 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 **use** ~~avail ourself of~~ this **extended transition period under** ~~exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other~~ -- **the JOBS Act** ~~public companies that are not " emerging growth companies~~ . ~~"~~ 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 ~~")~~ 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.