

Nasus Pharma Ltd.

(NSRX: NYSE American)

NSRX: Initiating Coverage – Sniffing Out a Better Solution

Nasus' valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. Additionally, we apply a 60% probability of commercial success to the NS002 program. The adjustment recognizes regulatory and commercialization risks. The model includes contributions from the United States and the developed world.

Current Price (5/21/2026) **\$2.87**
Valuation \$19.00

INITIATION

Nasus Pharma is a clinical-stage, specialty pharmaceutical company developing powder-based formulations that are delivered intranasally. Lead product NS002 uses a dose spray unit to deliver epinephrine for anaphylaxis. It has reported positive topline data & is expected to be the subject of pivotal studies in 4Q:26. Pivotal study results are expected in early 2027 followed by a 505(b)(2) new drug application. The upcoming pivotal trial will seek to show comparability with EpiPen.

Nasus has also conducted pivotal studies for NS001, which is a powder-based formulation of naloxone for opioid overdose. Other pipeline assets use its Nasax technology for chemotherapy-induced and post-operative nausea and vomiting as well as metabolic and cardiovascular indications.

Epinephrine has been used for over a century as treatment for anaphylaxis & is the active pharmaceutical ingredient (API) used in approved therapies. Nevertheless, injectable epinephrine has notable limitations, including delayed and variable bioavailability, exposure to needles, cumbersome applicator size and short shelf life. NS002 is designed to overcome these drawbacks and has the potential to become the new standard of care for outpatient anaphylaxis management.

SUMMARY DATA

52-Week High **9.99**
 52-Week Low **1.98**
 One-Year Return (%) **N/A**
 Beta **N/A**
 Average Daily Volume (sh) **207,606**

Risk Level **Above Average**
 Type of Stock **Small-Growth**
 Industry **Med-Biomed/Gene**

Shares Outstanding (mil) **11.7**
 Market Capitalization (\$mil) **33.6**
 Short Interest Ratio (days) **1.0**
 Institutional Ownership (%) **18.6**
 Insider Ownership (%) **49.1**

Annual Cash Dividend **\$0.00**
 Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
 Sales (%) **N/A**
 Earnings Per Share (%) **N/A**
 Dividend (%) **N/A**

P/E using TTM EPS **N/A**
 P/E using 2026 Estimate **N/A**
 P/E using 2027 Estimate **N/A**

Zacks Rank **N/A**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2025	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2026	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E	\$0.0 E
2027					\$0.0 E
2028					\$3.4 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2025					-\$0.73 A
2026	-\$0.24 A	-\$0.31 E	-\$0.24 E	-\$0.20 E	-\$0.93 E
2027					-\$0.85 E
2028					-\$0.37 E

INITIATION

We are initiating coverage of Nasus Pharma Ltd. (NYSE American: NSRX) with a valuation of \$19.00 per share. This value is based on our estimates for successful development and commercialization of NS002 in patients requiring emergent care for anaphylaxis in the United States and in developed regions throughout the globe. Epidemiological estimates suggest from 14,000 to 200,000 emergency room visits for anaphylaxis and severe allergic reactions per year in the United States. However, the at-risk population is substantially larger with 1% to 3% of the population, or 3.5 to over 10 million people, susceptible to anaphylaxis due to allergies or sensitivities. The prevalence of anaphylaxis has increased over time with one source measuring a 3% increase from 2004 to 2016. The population susceptible to severe allergic reaction is much greater than the number of reported cases and many at risk fail to carry emergency epinephrine due to a variety of factors.

Emergency treatment for anaphylaxis has remained relatively constant from the late 1980s until 2024, with injectable epinephrine representing the standard of care. A liquid nasal formulation was approved in 2024, expanding the breadth of treatment modalities. However, approved approaches present a number of shortcomings. Nasus' powder-based intranasal technology is designed to address these weaknesses by eliminating needles, reducing device size, improving stability and shelf life, and enabling rapid, efficient drug delivery.

NS002 is a powder-based formulation of epinephrine engineered for broad disposition to all parts of the nasal cavity, allowing for faster delivery and greater early absorption in the plasma relative to approved methods. EpiPen has been the standard of care for anaphylaxis emergency treatment for many years. It is still used widely, despite needle injury risk, bulky form factor, dosing uncertainty, limited shelf life and limitations on speed of delivery. To address these issues, new formulations were developed including sublingual and liquid nasal delivery; however, they presented other weaknesses. NS002 seeks to address these with a powder-based formulation that provides rapid delivery, stability and an efficient form factor.

Epinephrine, also known as adrenaline, is both a natural hormone produced by the adrenal glands and a neurotransmitter. It drives the body's fight-or-flight emergency response. As a medication, it is the primary, life-saving treatment for anaphylaxis or severe allergic reactions. It reverses symptoms by relaxing airway muscles, increasing blood pressure and heart rate, and dilating airways for easier breathing. It also has an effect on metabolism by increasing blood sugar and accelerating blood supply to muscles. It helps the body respond rapidly to threats. When a person is suffering from anaphylaxis, epinephrine acts as a vasoconstrictor and bronchodilator, rapidly reversing severe allergic reactions to food, medication or insect stings. Side effects can include a racing heart, anxiety or shakiness.

Nasus has completed a Phase II pharmacokinetic (PK) and pharmacodynamic (PD) study that compared NS002 against standard of care and is expected to start a pivotal study later this year. The Phase II PK/PD study produced a faster time to target concentration of 1.69 minutes compared to 3.42 minutes for EpiPen. The study also exhibited quicker time to T_{MAX} and to target concentrations at set time points. NS002 is being readied for a pivotal study slated to begin enrollment in 4Q:26. The task will be relatively quick. 70 to 100 healthy patients will be enrolled at a single site with evaluations complete and a readout by 1Q:27. A 505(b)(2) application is expected in 2H:27 with a response expected by the FDA about one year later.

While the majority of Nasus' funding and management focus are centered on the NS002 program, the company has three preclinical products in its pipeline with identified indications. The first, designated NS003, is preparing for first in-human studies of ondansetron for nausea and vomiting later this year. NS004 is in development to evaluate an unidentified molecule for metabolic conditions and NS005 is an unidentified molecule intended for a cardiovascular indication. We do not include these assets in our valuation.

Perhaps more than 10 million individuals are at risk of anaphylaxis in the United States; however, only 10 to 15% of these individuals present at the emergency room. Many occurrences are far from emergency services and can be treated locally with epinephrine. Anaphylaxis is a severe, systemic allergic reaction that typically involves multiple organ systems simultaneously. Symptoms usually develop in a few minutes to hours after exposure to a trigger. Hives, itching and swelling occur in many cases while respiratory and cardiovascular symptoms are also common. Cardiovascular responses are a major cause of anaphylaxis death, especially cardiac arrhythmia.

Nasus' balance sheet listed cash of \$4.3 million as of December 31st, 2025 which was augmented by a \$15 million private placement executed in February. The low cost of the pivotal trial allows existing cash to support operations into the middle of 2027 and the submission of its new drug application (NDA).

Nasus has developed its supply chain so that a partner may easily absorb these operations. Nasus intends to partner with or sell to established pharmaceutical companies to commercialize NS002. Beyond the primary market in the United States, it has also identified Japan, the European Union and Brazil as attractive destinations. We believe that the management team is developing relationships with potential partners that will crystallize as more data is released and the regulatory path is closer to complete. The market size for the global epinephrine market is from \$2.5 to \$3.0 billion with about two-thirds of this total generated in the United States. We think that Nasus' intranasal powder delivery product can attract material share in this market as it addresses shortcomings present in other methods of administration and provides faster delivery and greater plasma concentrations than other products in the market.

Key reasons to own Nasus' shares:

- **Existing anaphylaxis treatment presents multiple shortcomings**
 - **Exposure to needle discomfort or phobia**
 - **Limited shelf life for liquid-based products**
 - **Existing products are too slow to achieve meaningful plasma concentration benchmarks**
 - **Form factor is large and bulky**
 - **Distribution of epinephrine not optimized**
- **NS002 approaching its pivotal trial**
 - **Forecasted trial start in 4Q:26**
 - **Trial readout expected in 1Q:27**
 - **New drug application submission anticipated in 2H:27**
- **Nasax delivery platform targets a rapid and precise delivery of drug to blood plasma and brain**
 - **Intranasal delivery**
 - **Powder formulation comprised of uniform spherical API using approved carrier**
 - **NS002 delivered using Aptar's FDA approved Unit Dose Spray device**
- **Pipeline offers other clinical indications**
 - **NS001: naloxone for opioid overdose**
 - **NS003: ondansetron for nausea & vomiting**
 - **NS004: metabolic indications**
 - **NS005: cardiovascular indications**
- **Robust intellectual property**
 - **Patent for epinephrine dry powder formulation expires in 2038**
 - **Eligible for patent term extension**

In the following sections we describe anaphylaxis, how it occurs and its implications for health and mortality. The report examines the etiology of the condition and how often it occurs in the United States and around the world. We then discuss anaphylaxis' risk factors, symptoms, diagnosis, standard of care and prognosis. We move on to describe the drug epinephrine, its chemical composition and class. We look at the approved formulations and delivery devices for the drug and identify the related shortcomings of alternate delivery approaches and how NS002 addresses them.

We summarize the company's pipeline including the lead candidate NS002 and the programs pursuing other indications. NS002 development history is presented, including a summary of pharmacokinetic and pharmacodynamic (PD) and dose finding studies along with a look ahead to the pivotal study. The next section reviews Nasus' intellectual property and summarizes several of its most important patents. The report explores peers and competitors highlighting other companies with nasal delivery technologies and anaphylaxis treatment products. This is followed by recent milestones, a brief corporate history and financial results for Nasus Pharma. We then introduce key management team members and highlight the risks faced by the company. The closing section provides our valuation discussion and details the assumptions behind our target price. Our work generates a valuation of \$19.00 per share for Nasus Pharma Ltd.

Primary Indications

Anaphylaxis

Anaphylaxis is an acute, potentially life-threatening systemic hypersensitivity reaction characterized by rapid onset and involvement of multiple organ systems, most often skin, respiratory, cardiovascular and gastrointestinal. It occurs in developed countries at an estimated rate of 4 to 100 episodes per 100,000 person-years. Lifetime prevalence is around 0.05% to 2%¹ and possibly higher with some sources reporting prevalence of 1 in 20. Mortality is low in absolute terms, but fatal outcomes are strongly associated with delayed or absent epinephrine use and with high-risk comorbidities.²

Pathophysiology

Anaphylaxis is a serious, generalized or systemic hypersensitivity reaction with rapid onset and the potential for death. It is usually mediated by mast-cell and basophil activation with release of mediators such as histamine, tryptase, leukotrienes and platelet-activating factor. The classic mechanism involves immunoglobulin E (IgE)-mediated cross-linking on mast cells and basophils after re-exposure to a sensitizing allergen, although non-IgE-mediated pathways such as direct mast-cell activation can produce clinically indistinguishable reactions.³ Anaphylaxis usually affects cutaneous and mucosal systems, the respiratory tract, cardiovascular system and the gastrointestinal (GI) tract.⁴ Hives, shortness of breath, hypotension, nausea and vomiting may result.

Incidence and Prevalence

Population-based studies in North America and Europe estimate anaphylaxis incidence at roughly 4 to 100 cases per 100,000 person-years, with consistency over time and data sources. A meta-analysis and registry-based studies report lifetime prevalence between 0.05% and 2%, with trends indicating increasing incidence over recent decades, particularly for food-induced reactions.⁵ Other sources cite anaphylaxis occurring in one in 50 to one in 20 Americans.⁶ McLendon, 2023 estimates a prevalence of 1% to 3% for the predilection and recognizes that it is increasing.⁷ A meta-analysis published in 2023⁸ identified a worldwide incidence of 46 cases per 100,000 population. The data was confounded by the low reporting rate of anaphylaxis as many cases never reach clinics or hospitals. The organization offers other statistics finding 42% of children with food allergies experience a severe reaction and 40% of children with food allergies have experienced multiple severe reactions. The CDC estimates that 32% of adults have a diagnosed allergic condition related to seasonal allergies, eczema, food or another allergen.

Official channels underreport the true incidence of anaphylaxis, causing population-level risk estimates to appear lower than they actually are. This arises because anaphylaxis frequently occurs outside of hospital settings and only a minority of cases result in hospitalization. Many episodes are not captured by surveillance data.

In England, analysis of a national primary-care database found an age-sex standardized incidence of 6.7 per 100,000 person-years in 2001, rising by approximately 19% to 7.9 per 100,000 by 2005, with corresponding increases in recorded lifetime prevalence and prescribing of adrenaline (epinephrine).⁹ A U.S. survey-based study from the Asthma and Allergy Foundation of America estimated that about 1 in 50 Americans have experienced anaphylaxis, and suggested the true rate may be closer to 1 in 20.¹⁰ Deaths that do occur are often sudden and potentially preventable with allergen avoidance and administration of epinephrine.¹¹

¹ Wood, R.A., *et al.* [Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States](#). American Academy of Allergy, Asthma & Immunology. 2013.

² Weller, K.N., Hsieh, F.H. [Anaphylaxis: Highlights from the practice parameter update](#). Cleveland Clinic Journal of Medicine. February 2022.

³ Coop, C.A., *et al.* [Are ACE Inhibitors and Beta-blockers Dangerous in Patients at Risk for Anaphylaxis?](#) Journal of Allergy and Clinical Immunology. September 2017.

⁴ Mustafa, S.S. [Anaphylaxis](#). Medscape, August 2024.

⁵ [Emergency Department Visits for Anaphylaxis Have Increased Since 2008](#). Allergy, Asthma & Immunology. August 2019.

⁶ Wood, R.A., *et al.* [Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States](#). American Academy of Allergy, Asthma & Immunology. 2013.

⁷ McLendon, K., Sternard, B.T. [Anaphylaxis](#). Statpearls. January 2023

⁸ Pühringer, V., *et al.* [Population-based incidence of all-cause anaphylaxis and its development over time: a systematic review and meta-analysis](#). Frontiers in Allergy. December 2023.

⁹ Sheikh, A., *et al.* [Trends in national incidence, lifetime prevalence and adrenaline prescribing for anaphylaxis in England](#). Journal of the Royal Society of Medicine. March 2008

¹⁰ [Anaphylaxis in America](#). Asthma and Allergy Foundation of America. Accessed April 2026.

¹¹ Poirot, E., *et al.* [Deaths, Hospitalizations, and Emergency Department Visits From Food-Related Anaphylaxis, New York City, 2000–2014: Implications for Fatality Prevention](#). Journal of Public Health. November 2020.

While the best data for anaphylaxis comes from hospital admissions, most cases do not present at the emergency department. Anaphylaxis frequently occurs in the community or outside of hospital settings framing the need for portable, widely available, easily administered and durable epinephrine formulations. Based on a 2020 study, only 0.26% of total hospital admissions¹² and less than 20% of emergency presentations of anaphylaxis are admitted. In the United States about 5 to 6 per 100,000 population are admitted to the hospital which is lower than other countries such as the UK and Australia which exceed 10 per 100,000.¹³ We assimilate and evaluate this data to generate our estimate of a reasonable proportion of the population that is at risk of anaphylaxis of about 3%.

Fortune Business Insights quantified epinephrine's global market size at about \$2.66 billion in 2026.¹⁴ Two-thirds of the market was in the United States. Epinephrine for anaphylaxis sales are estimated at \$1.94 billion in 2026 and forecasted to grow at 9.8% over the subsequent eight years.¹⁵ Other resources estimate anywhere from 3.2¹⁶ to 3.6¹⁷ million units and prescriptions per year respectively.

Mortality

A study reviewed U.S. hospital data over the period of 1999 to 2009 and determined that the fatality rate for emergency department presentations of anaphylaxis was 0.25% to 0.33%. During the period reviewed, there were 63 to 99 deaths per year for patients who presented at the hospital. Another resource found that overall mortality was 186 to 225 deaths per year.¹⁸ Even though a very high percentage of anaphylaxis patients survive, the Allergy Asthma Network estimates that there are 225 deaths from anaphylaxis in the U.S. every year.¹⁹

Risk Factors

There are numerous triggers that can induce anaphylactic shock. They vary by age, with younger individuals reporting food, such as peanuts and shellfish as triggers and adults describing allergies to medicine, insect stings and food. Some cases have no identified source.²⁰

There are a number of characteristics that can increase the risk of anaphylaxis and its severity. Pre-existing conditions such as asthma, cardiovascular disease, mast cell disorders and a previous history of anaphylaxis are closely associated with future events.²¹ Medications can be implicated, especially beta-blockers or angiotensin-converting enzyme (ACE) inhibitors both of which may lead to more severe reactions.²² Patients at high risk for anaphylaxis should be cautious when using these agents. Other common allergens include peanuts, latex, insect stings, other foods, penicillin and radiocontrast media.²³

¹² Asai, Y., *et al.* [Rate, Triggers, Severity and Management of Anaphylaxis in Adults Treated in a Canadian Emergency Department](#). Allergy and Immunology. August 2014.

¹³ Turner, P.J. *et al.* [Global Trends in Anaphylaxis Epidemiology and Clinical Implications](#). Journal of Clinical Immunology. April 2020.

¹⁴ Fortune Business Insights. [Epinephrine Market Size, Share & Industry Analysis, By Product Type \(Auto-injectors, Pre-filled Syringes, and Ampoules & Vials\), By Application \(Anaphylaxis, Cardiac Arrest, Respiratory Disorders, and Others\), By Distribution Channel \(Hospital Pharmacy and Retail & Online Pharmacy\), and Regional Forecast, 2026-2034](#).

¹⁵ Fortune Business Insights. April 2026. [U.S. Epinephrine for Anaphylaxis Treatment Market Size, Share & Industry Analysis](#).

¹⁶ ARS Pharmaceuticals [Fourth Quarter Report](#), March 20, 2025.

¹⁷ Miyashiro, K. [Mylan's EpiPen Pricing Scandal](#). September 2017.

¹⁸ Ma, L., *et al.* [Case Fatality and Population Mortality Associated with Anaphylaxis in the United States](#). Journal of Allergy and Clinical Immunology. December 2013.

¹⁹ [Anaphylaxis Statistics](#). Allergy & Asthma Network. Accessed April 2026.

²⁰ Pflipsen, M.C., Vega Colon, K.M. [Anaphylaxis: Recognition and Management](#). American Family Physician. September 2020.

²¹ Weller, K.N., Hsieh, F.H. [Anaphylaxis: Highlights from the practice parameter update](#). Cleveland Clinic Journal of Medicine. February 2022.

²² Coop, C.A., *et al.* [Are ACE Inhibitors and Beta-blockers Dangerous in Patients at Risk for Anaphylaxis?](#) Journal of Allergy and Clinical Immunology. September 2017.

²³ Neugut, A.I., *et al.* [An Investigation Into Its Epidemiology](#). JAMA Internal Medicine. January 2001.

Diagnosis

Diagnostic criteria are provided by the National Institute of Allergy and Infectious Diseases/Food Allergy and Anaphylaxis Network (NIAID/FAAN). The institute defines anaphylaxis as highly likely when there is:²⁴

- Acute onset of illness with involvement of the skin and/or mucosal tissue and at least one of the following:
 - Respiratory compromise, such as shortness of breath
 - Reduced blood pressure or associated symptoms of end-organ dysfunction
 - Persistent GI tract symptoms such as abdominal pain

Anaphylaxis validation studies in emergency-department populations have reported sensitivity around 96.7% and specificity around 82.4% for these criteria.²⁵ Serum tryptase, a marker of mast-cell activation, can be helpful when the diagnosis is uncertain, particularly in perioperative reactions or suspected mast cell disorders. Tryptase typically peaks within about one to two hours after onset and returns toward baseline over several hours, so samples should be drawn as soon as feasible after stabilization, with a convalescent level for comparison.²⁶

Treatment

Individuals who appear to be undergoing anaphylactic shock should first be separated from the inciting agent, then placed on their back with legs elevated. First line therapy is intramuscular epinephrine administered in the thigh. It is the most critical pharmacologic treatment for anaphylaxis and should be administered as soon as possible, without waiting for progression to shock. Early epinephrine administration can reduce rates of hospital admission and improve outcomes, while failure to use epinephrine is associated with increased morbidity and mortality. Practice parameters explicitly advise against delaying epinephrine while attempting to use inhaled beta2-agonists, antihistamines or corticosteroids as initial therapy.²⁷

Other treatment beyond administration of epinephrine can include oxygen supplementation, infusion of isotonic intravenous fluids, antihistamines and corticosteroids. For subjects on beta-blockers, intravenous glucagon may be used.

Longer term, individuals must identify the allergens that trigger the anaphylaxis and develop avoidance strategies. All patients with a history of anaphylaxis should have access to an epinephrine auto-injector. Review of medicine and food choices is important as is asthma control and cardiovascular disease management.

Prognosis

With prompt recognition and early intramuscular epinephrine, most patients recover completely, and the majority of episodes are managed without intensive care. Nevertheless, a subset of patients require hospitalization.²⁸ About 30% of individuals who have experienced anaphylaxis will have more than one episode over their lifetime, particularly when exposures continue or triggers remain unidentified. Patients with food allergy, venom allergy, or mast cell disorders have particularly high recurrence risk and may live with substantial anxiety and activity restriction.

²⁴ Manivannan, V., *et al.* [Visual representation of National Institute of Allergy and Infectious Disease and Food Allergy and Anaphylaxis Network criteria for anaphylaxis](#). International Journal of Emergency Medicine. February 2009.

²⁵ [Anaphylaxis Algorithm](#). Children's Hospital Colorado. September 2023.

²⁶ Pflipsen, M.C., Vega Colon, K.M. [Anaphylaxis: Recognition and Management](#). American Family Physician. September 2020.

²⁷ Golden, D.B.K, *et al.* [Anaphylaxis: A 2023 Practice Parameter Update](#). Annals of Allergy, Asthma & Immunology. August 2023.

²⁸ Ma, L., *et al.* [Case Fatality and Population Mortality Associated with Anaphylaxis in the United States](#). Journal of Allergy and Clinical Immunology. December 2013.

Underlying Molecule

Epinephrine

Epinephrine, also commonly called adrenaline, is both an endogenous catecholamine hormone and neurotransmitter as well as a critical emergency medicine. The word epinephrine is derived from the Ancient Greek words “epi-“ and “nephros” meaning upon the kidney. The term was introduced by American pharmacologist [John Jacob Abel](#) in 1897 to describe the location of the adrenal glands above each kidney that produce the hormone and neurotransmitter. Adrenaline is derived from Latin roots “ad-“ and “renes” meaning near the kidney. It was named by Japanese chemist [Jokichi Takamine](#) in 1901. Epinephrine is widely used in the United States while adrenaline is more commonly employed in Europe.

Adrenaline/Epinephrine History

Epinephrine was first studied in the late 19th century where experiments on adrenal gland extracts showed effects on blood pressure and the nervous system. In the early 20th century, scientists isolated, purified and commercialized the hormone for medical use. In 1906, a synthetic version of epinephrine was developed that was less expensive, shifting production away from extraction from adrenal glands. Initially the drug was used to stop bleeding and raise blood pressure but later found its calling as treatment for asthmatic attacks.²⁹ By the 1950s it was widely used in resuscitation and emergency medicine. The development of auto-injectors in the 1970s and the FDA approval of the EpiPen in 1987, made rapid self-administration possible for patients at risk of severe allergic reactions.^{30,31}

Physiologically, epinephrine is produced primarily by adrenal-medulla chromaffin cells through the catecholamine biosynthetic pathway with phenylethanolamine. The pathway is illustrated below.

tyrosine → L-DOPA → dopamine → norepinephrine → epinephrine

N-methyltransferase (PNMT) catalyzes the final step. The process is regulated by glucocorticoids and stress-associated neural inputs. Epinephrine is a nonselective agonist on α - and β -adrenergic receptors, rapidly redistributing hemodynamics and airway contraction as part of the acute stress response and as lifesaving therapy in anaphylaxis and resuscitation contexts.^{32,33}

Epinephrine Early Learnings

The discovery of epinephrine was first documented in 1894 when British physiologists George Oliver and Edward Schafer showed that injecting adrenal extract into animals caused a rise in blood pressure. The substance was not initially identified but the experiments showed that it acted upon the vascular system. In 1897, an American pharmacologist at Johns Hopkins isolated a derivative of the hormone from several animals including dogs and called it epinephrine. Adrenaline was initially sourced from animals; however, the quantity was limited. Meanwhile, chemists were identifying its therapeutic applications and characterizing its chemical structure. The product was first patented by Parke-Davis & Company in 1903. In 1904, the first synthetic formulation of epinephrine was developed and large-scale production became possible shortly thereafter. The hormone was first used to treat asthma and administered hypodermically from glass ampoules even before its mechanism of action was understood.³⁴ Other uses include resuscitation, local anesthesia and anaphylaxis.

In the 1970s, the U.S. military funded development of an auto-injector for troops to protect themselves from nerve gas exposure. Following this development, inventor Sheldon Kaplan converted the technology to civilian use in what eventually became the Epi-Pen. The Epi-Pen was approved by the FDA for immediate, emergency self-administration by those with severe allergies in 1987.^{35,36} While EpiPen was a dramatic improvement in terms of convenience

²⁹ Sneader, W. [The discovery and synthesis of epinephrine](#). Drug News & Perspectives. October 2001.

³⁰ [Epinephrine](#). Drug Bank. Accessed April 2026.

³¹ [The Evolution of Epinephrine Allergy Amulet](#). October 2024.

³² Nagatsu, T. [The catecholamine system in health and disease —Relation to tyrosine 3-monoxygenase and other catecholamine-synthesizing enzymes](#). Proceedings of the Japan Academy. January 2007.

³³ Kuhar, M.J., et al. [Biosynthesis of Catecholamines](#). Basic Neurochemistry: Molecular, Cellular and Medical Aspects. 6th edition.

³⁴ Arthur, G. [Epinephrine: A Short History](#). The Lancet. May 2015.

³⁵ Center for Drug Evaluation and Research. [Application for Epinephrine Injection](#). July 2011.

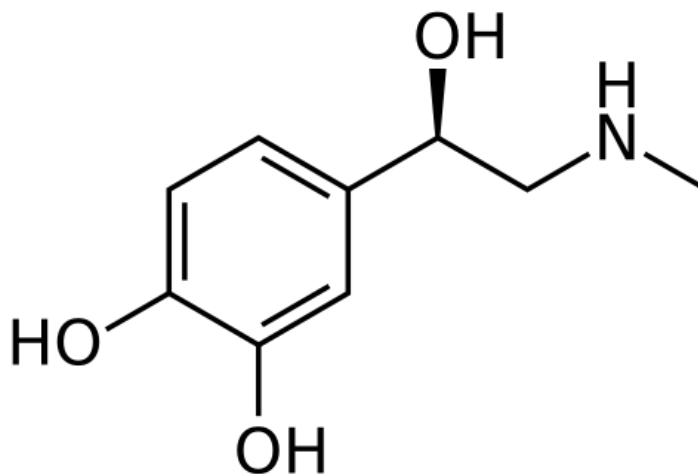
³⁶ Coady, P., et al. [Epinephrine Administered in Anaphylaxis: The Evolution of 0.3 mg Dosage](#). Therapeutic Advances in Allergy and Rhinology. March 2023.

and administration, it presented new shortcomings. Needle risk and slower than optimal delivery of epinephrine to the plasma led to work on a liquid formulation that could be sprayed into the nose. ARS Pharmaceuticals entered the field and developed an epinephrine nasal spray called neffy. The product consists of epinephrine, the absorption-enhancing agent Intravail and a Unit Dose Spray device. The product was approved by the FDA in 2024.³⁷

Epinephrine Development Timeline

- 1716 – Adrenal glands identified
- 1856 – Vital function of adrenal glands confirmed
- 1895 – Pressor Effect (blood pressure elevation through α_1 stimulation) identified (Oliver & Schafer)
- 1897 – First isolation attempt for epinephrine
- 1901 – Takamine isolates crystalline form of epinephrine
- 1904 – First synthesis of epinephrine
- 1948 – α and β receptor types classified
- 1950s – Epinephrine used in cardiac arrest
- 1973 – EpiPen invented
- 1994 – Standard dosing of 1 mg IV every 3-5 minutes codified
- 2019 – Generic epinephrine autoinjectors approved
- 2024 – Neffy nasal spray [approved](#)

Exhibit I – Epinephrine (C₉H₁₃NO₃) Chemical Composition



Source: Wikimedia Commons.[Epinephrine Structure](#). Acdx, 2009.

The chemical formula for epinephrine is C₉H₁₃NO₃. Its structure consists of a benzene ring with two hydroxyl groups, making it a catechol, and a side chain containing an amine group. Epinephrine is a chiral molecule. In the human body, it exists naturally in the L-epinephrine (or R-isomer) form, which is significantly more biologically active than the D-epinephrine form. The molecule is odorless and appears as a white to nearly-white microcrystalline powder or granules.³⁸ It is sensitive to oxidation and light; therefore, special handling and packaging are used to maintain stability.

Epinephrine Mechanism of Action for Treating Anaphylaxis

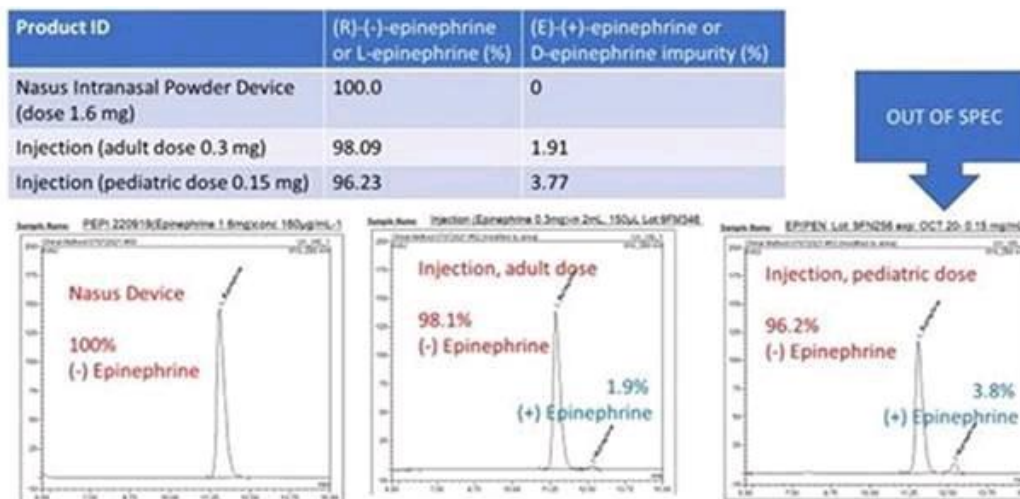
Epinephrine works through direct agonism of adrenergic receptors countering the life-threatening effects of anaphylaxis on multiple fronts. It achieves this goal through α_1 -adrenergic (vasopressor), β_1 -adrenergic (cardiac) and β_2 -adrenergic (pulmonary & mast cell) effects. Vasopressor effects cause vasoconstriction of peripheral blood vessels which reverses the vasodilation and vascular leak that causes hypotension and distributive shock. It also reduces mucosal edema in the upper airway which is critical for preventing obstruction. Cardiac effects include an increased heart rate and contractility.

³⁷ Ellis, A.K., *et al.* Development of neffy, an Epinephrine Nasal Spray, for Severe Allergic Reactions. Pharmaceuticals. June 2024.

³⁸ [Epinephrine](#). PubChem, National Library of Medicine. Accessed April 2026.

A common impurity that develops in epinephrine products is the formation of enantiomers. Enantiomers are chemical structures that represent non-superimposable mirror images of each other that have the same molecular formula and connectivity. Many enantiomeric isomers are found in both their right-handed (+) and left-handed (-) configurations. In the case of epinephrine, only the “-” configuration is active and the presence of the “+” enantiomer reflects a loss of activity in the product. Nasus tested EpiPen injectors prior to their expiration date and compared the results with samples from the epinephrine powder device. The EpiPen devices were 96.2% to 98.1% pure while Nasus’ epinephrine samples were 100%, with no detectable levels of inactive enantiomers.³⁹

Exhibit II – Enantiomeric Purity in Epinephrine Products



Source: Nasus Pharma 2025 Form 20-F

Epinephrine Side Effects

Side effects for epinephrine are usually transient and often resolve within 30 minutes of administration. Patients report feeling jittery or feel their heart racing. These include the following categories of effects:⁴⁰

- Cardiovascular
 - Rapid, pounding and irregular heartbeat (palpitations or tachycardia)
 - Hypertension
- Neurological and Central Nervous System
 - Anxiety, nervousness, restlessness, apprehension
 - Dizziness
 - Headache
 - Tremors, shakiness and weakness
- Sweating
- Pale skin (pallor)
- Nausea
- Vomiting

Some rare side effects may occur with high dose intravenous administration including arrhythmias, hypertension leading to cerebrovascular events, myocardial ischemia, pulmonary edema and tissue ischemia or necrosis if injected into hands, feet or buttocks. Patients with renal impairment should be carefully monitored. An enzyme called renalase is produced by the kidneys and is responsible for metabolizing epinephrine. Patients with chronic kidney disease (CKD) are deficient in renalase which can lead to elevated epinephrine levels.⁴¹

³⁹ Page 80 (page 71 in the printed version) of the of Nasus 2025 Form 20-F filing provides additional details on the stability and purity of NS002 compared with competing products.

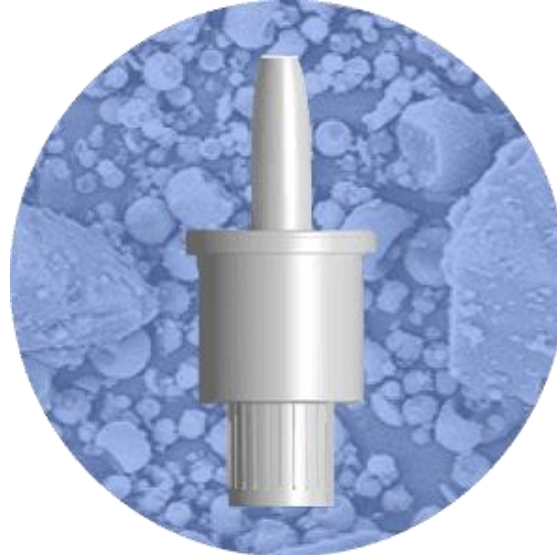
⁴⁰ [Epinephrine Injection](#). Cleveland Clinic. Accessed April 2026.

⁴¹ Dalal, R., Grujic, D. [Epinephrine](#). StatPearls, November 2024.

Epinephrine Shortcomings

While epinephrine is effective in anaphylaxis management and has a relatively benign safety profile, it is associated with practical and clinical drawbacks. The drug's effects are temporary and last about 20 to 30 minutes. Anaphylaxis symptoms may recur and then require an additional dose of epinephrine or receipt of emergency care. Auto-injectors offer fixed doses despite the recommended weight-based doses of 0.01 mg/kg. Fear of needles may prevent a patient from accepting an administration or delay administration, potentially resulting in prolonged reactions or death. The needle may become bent during use causing injury due to patient movement during administration or the needle hitting bone. Shelf life of epinephrine injection is estimated at 12 to 18 months. It must be kept at room temperature and not exposed to extreme heat or cold.

Exhibit III – NS002 Epinephrine Nasal Spray Device



Source: Nasus Pharma

Pipeline Candidates

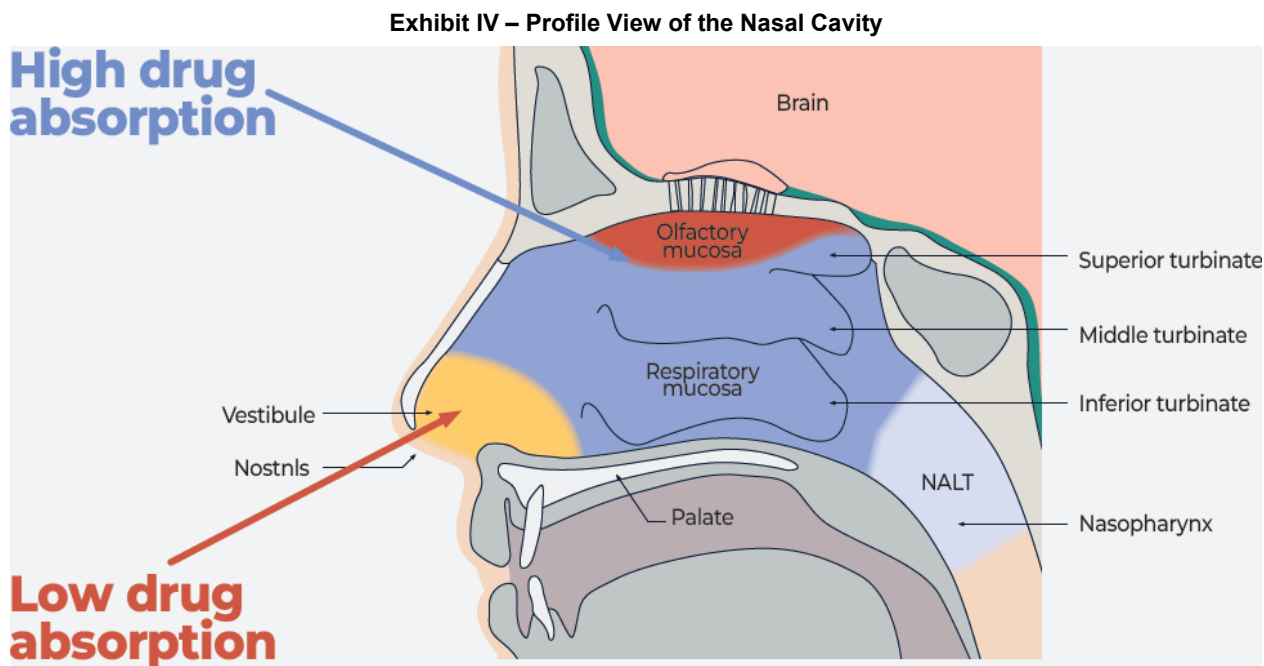
NS002: Intranasal Epinephrine

NS002 is a powder formulation of epinephrine for intranasal administration in patients suffering from anaphylaxis. Epinephrine was first widely used as an injection as rapid delivery to the bloodstream was required to quickly counteract an allergic reaction. While oral delivery is usually preferred for administration of medicines, epinephrine is not available in this form due to the harsh conditions of the gastrointestinal tract which break it down and the extended time period it would take for systemic delivery. This has led to the introduction of nasal and sublingual delivery approaches⁴² that rely upon the rapid absorption that takes place in the oral and nasal mucosa.

Epinephrine is a sympathomimetic catecholamine and a non-selective adrenergic agonist that acts on α_1 , α_2 , β_1 , β_2 and β_3 receptors. It is a hormone and neurotransmitter produced naturally, which activates the sympathetic nervous system, bringing about increased heart rate, vasoconstriction and bronchodilation.

An injectable formulation of epinephrine has been available for decades and is available worldwide. In recent years, new methods and intranasal administration have been approved and sublingual products are in development. Despite solving some of the shortcomings of the injectable version, the new methods present new challenges.

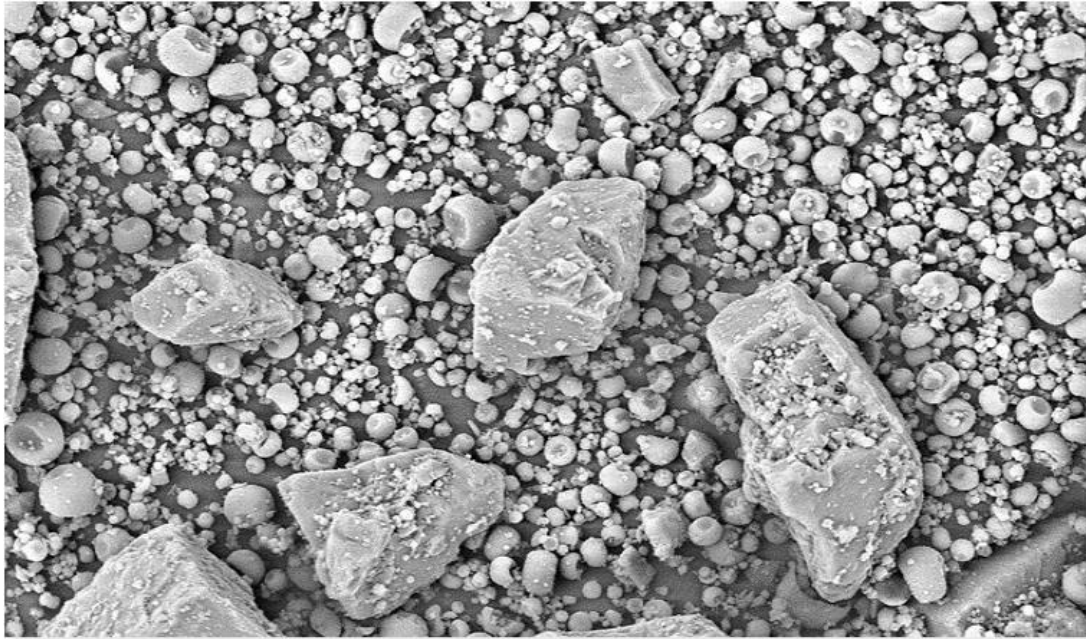
Liquid nasal spray does not cover the nasal mucosa sufficiently and does not reach the turbinates and olfactory region of the nasal cavity which offer greater drug absorption compared to the vestibule area of the nasal cavity. Nasus' poster presented at the 2026 American Academy of Allergy, Asthma & Immunology conference summarized data from a nasal cast study that demonstrated 2.7x greater powder deposition in the nasal cavity as compared to liquid spray.



Source: Nasus Poster: Nasal Epinephrine Spray for Anaphylaxis.

⁴² As of May 2026, no sublingual epinephrine product is FDA approved. Aquestive Therapeutics had submitted an NDA for Anaphylm, a dibutepinephrine sublingual film, in June 2025; however, the FDA issued a Complete Response Letter in January 2026. Aquestive expects to re-submit the NDA later in 2026.

Exhibit V – NS002 Nasax Powder Formulation (Magnified)



Source: Nasus Pharma Corporate Presentation

NS002 Clinical Trials

Pharmacokinetic and Pharmacodynamic Study

In 2021 Nasus launched a pharmacokinetic (PK) and pharmacodynamic (PD) study evaluating NS002 to compare the bioavailability of epinephrine following a single nasal dose of microspheres powder. The study was entitled Bioavailability of Nasal Epinephrine and listed on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04696822) under the designator [NCT04696822](https://clinicaltrials.gov/ct2/show/study/NCT04696822). An open label trial was performed in 12 adults with seasonal allergic rhinitis without asthma. PK, PD and safety were compared with 1.6 mg and 3.2 mg doses of NS002 and intramuscular EpiPen (0.3 mg). The drug was administered with and without a nasal allergen challenge.

The 3.2 mg administration produced a shorter T_{MAX} compared with EpiPen when administered after a nasal allergen challenge. Furthermore, the 3.2 mg dosage of epinephrine microsphere powder administered after the challenge test resulted in a doubling of the maximal measured plasma analyte concentration over the sampling period. No serious adverse events (AEs) were reported during the study and none of the participants withdrew due to an AE. 15 AEs were reported in 11 subjects during the study and no AEs were reported after the administration of EpiPen. Twelve events in nine subjects were considered to be related to the study treatment and were classified as mild. Most frequent AEs included application site erythema, headache and nasal congestion.

The journal article published after the PK/PD study explained that powder-based products are better distributed in the nasal cavity and reach the optimal absorbing area of the mucosa more efficiently than water soluble liquid-based alternatives. This powder's unique particle distribution profile allows a more efficient absorption of epinephrine to the plasma, as compared with solution-based products. Unlike solution-based formulations and due to the unique structure of the powder particle, no absorption enhancers are required to achieve significant plasma levels of endogenous epinephrine and no stabilizers are needed to extend product shelf life.⁴³

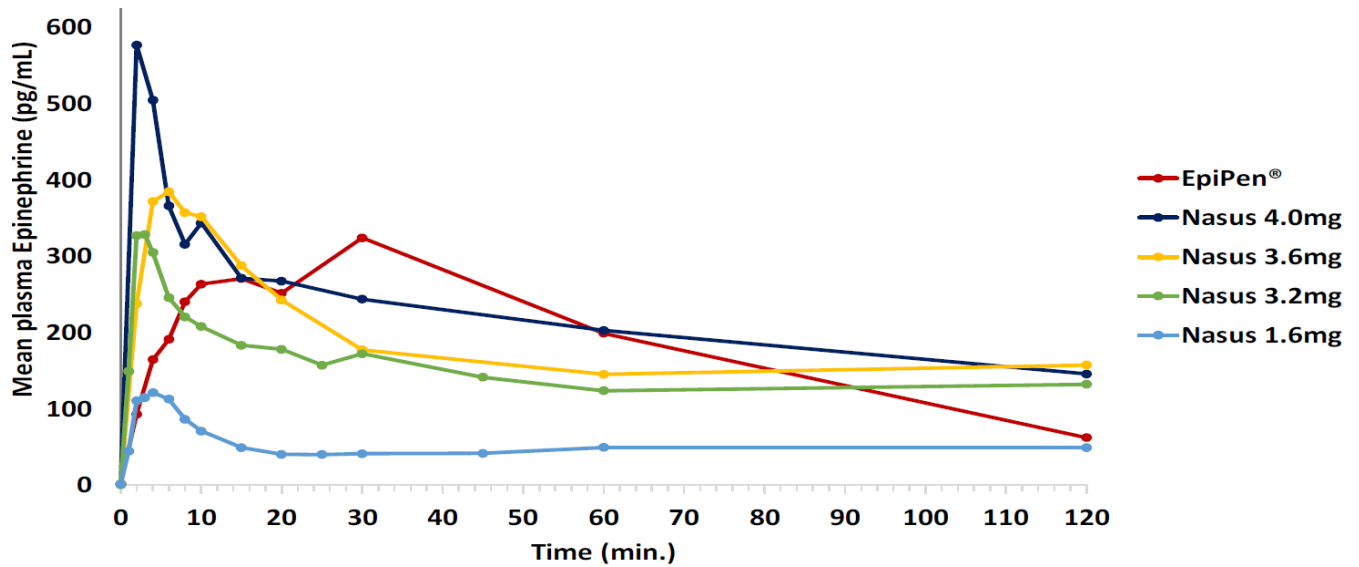
Dose Finding Clinical Study (NP006)

In 2023, Nasus began its study to compare NS002 bioavailability to EpiPen using a 3.6 mg and 4 mg dose of epinephrine microspheres powder to EpiPen 0.3 mg intramuscular injection. 12 healthy adults were enrolled in this study entitled Comparative Bioavailability of Intranasal Epinephrine and listed on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT06205134) under the designator [NCT06205134](https://clinicaltrials.gov/ct2/show/study/NCT06205134). This study selected a higher dose than that used in the PK/PD study in order to achieve adequate plasma epinephrine levels in all participants, including those who may not experience nasal congestion during a severe allergic reaction. NS002 4.0 mg was absorbed faster and more efficiently than EpiPen, demonstrating a higher C_{MAX} and higher mean Area Under the Curve (AUC) during the first 30 minutes after treatment. The propor-

⁴³ Tal, Y., *et al.* Fast Acting, Dry Powder, Needle-Free, Intranasal Epinephrine Spray: A Promising Future Treatment for Anaphylaxis. American Academy of Allergy Asthma & Immunology. June 2023.

tion of subjects that achieved the clinical threshold of 100 pg/mL was higher for the nasal powder. 10 of 12 subjects achieved the threshold at the six-minute time point for 4.0 mg of NS002 compared with 8 of 12 subjects for EpiPen 0.3 mg. This work provided the necessary support for using the 4.0 mg dose in later trials.

Exhibit VI – Mean Plasma Epinephrine in Healthy Volunteers



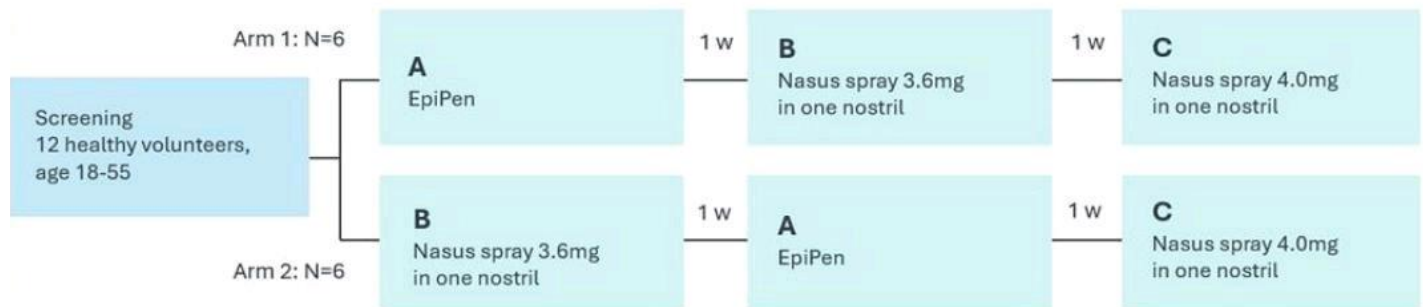
Source: Nasus Pharma Corporate Presentation

In the dose finding study 24 AEs were reported by nine subjects. 18 events in six subjects were considered related to the study treatment. All events were mild, transient and self-resolved. No serious AEs occurred. None of the subjects withdrew from the study due to an AE. More events related to epinephrine effect (palpitations, headache) were reported after the nasal administration; however, there were no statistically significant differences in the rates of AEs (overall and treatment-related) among the treatment groups. No clinically significant abnormal physical examination results, including nasal cavity examination findings, were reported. No clinically significant changes in laboratory test values were observed between screening and the end of the study. No clinically significant abnormal findings were noted in physical examination, vital signs or ECG results. The most common symptoms after administration were runny nose and sneezing. All symptoms were transient and resolved without treatment. There were no reports of anosmia (loss of sense of smell).

NP006 Trial Design

NP006 sought to define the final clinical dose to be used in the subsequent trial. It compared the bioavailability of epinephrine following a single nasal dose of NS002 Microspheres Epinephrine Powder at either 3.6 mg, or 4 mg with EpiPen 0.3 mg intramuscular injection in healthy adult volunteers.

Exhibit VII – NP006 Clinical Trial Design



Source: Nasus Pharma 2025 Form 20-F

NP006 was an open-label, single-dose, three-treatment, randomized, three-sequence, comparative bioavailability study. Twelve healthy volunteers were randomized to receive intranasal epinephrine of 3.6 mg, 4.0 mg and intramuscular (IM) of 0.3 mg at weekly intervals. Epinephrine pharmacokinetics (PKs) were evaluated based on 13 plasma samples of the first two hours after administration from each subject on each dosing day. Clinical and safety assessments were conducted at screening, on dosing days and at the end of the study visit. The study was per-

formed at Hadassah Medical Center, Jerusalem, and approved by the hospital ethics committee, in accordance with good clinical practices (GCP).

Phase II Pharmacokinetic and Pharmacodynamic Trial (NP007)

Nasus reported topline results from its pharmacokinetic (PK) and pharmacodynamic (PD) Phase II study of NS002 on March 16th, 2026. The study compared Nasus' intranasal epinephrine powder product with the intramuscular EpiPen autoinjector. The open-label Phase II study enrolled 50 healthy adults with a history of allergic rhinitis. Each received a single and repeat dose of NS002 and intramuscular EpiPen with and without a nasal allergic challenge (NAC). The study provided comprehensive data supporting NS002's clinical utility across multiple administration scenarios that patients may encounter during actual anaphylactic emergencies.

Results from the study demonstrated a faster time to target concentration of 1.69 minutes for NS002 vs. 3.42 minutes for EpiPen. Time to peak concentration for NS002 was 15 minutes compared to 19.8 minutes for EpiPen.

Exhibit VIII – Summary of NP007 Phase II Clinical Trial Topline Results

Metric	NS002, Normal*	EpiPen	p value =
Time to 100 pm/mL	1.69 min	3.42 min	0.033
Time to T _{max}	15.0 min	19.8 min	
C _{MAX} (pg/mL) geometric mean	513.7	539.3	
Reached 100 pg/mL @			
2.5 minutes	67.4%	27.1%	0.0001
5 minutes	88.4%	64.6%	0.0081
10 minutes	95.0%	89.6%	
30 minutes	95.3%	95.8%	
60 minutes	95.3%	100%	

Source: Compiled by Zacks' Analyst from Nasus Pharma March 16th, 2026 Press Release *Normal excludes the allergic challenge

NS002 was well tolerated by all 50 subjects in the trial. No serious adverse events (SAEs) were reported and there were no cardiovascular AEs.⁴⁴ Most of the AEs were local and self-resolving and were 95% mild and 5% moderate. Investigators note vomiting adverse events occurred only after a double dose. (see slide 18)

Exhibit IX – Summary of NS002 Adverse Events

Adverse Events			
Local		Systemic	
Runny Nose	Nasal Itching	Headache	Lightheadedness
Administration Site Discomfort	Nasal Congestion	Nausea	Vomiting
		Shakiness	Stomach Discomfort

Source: Compiled by Zacks' Analyst from Nasus Pharma March 16th, 2026 Presentation

Background for NP007 Study

Nasus launched its Phase II PK and PD clinical study to evaluate intranasal epinephrine powder compared with EpiPen intramuscular autoinjector in 2025. The study was entitled Comparative PK/PD of FMXIN002 and EpiPen, in Healthy Adults With Allergic Rhinitis. It was given the abbreviated designator NP007 and the Clinical Trials identification code [NCT07228325](#). NP007 evaluated a group of 50 healthy adults who received single and repeat doses of both intranasal epinephrine powder and EpiPen under normal and nasal congestion conditions induced by nasal allergen challenge.

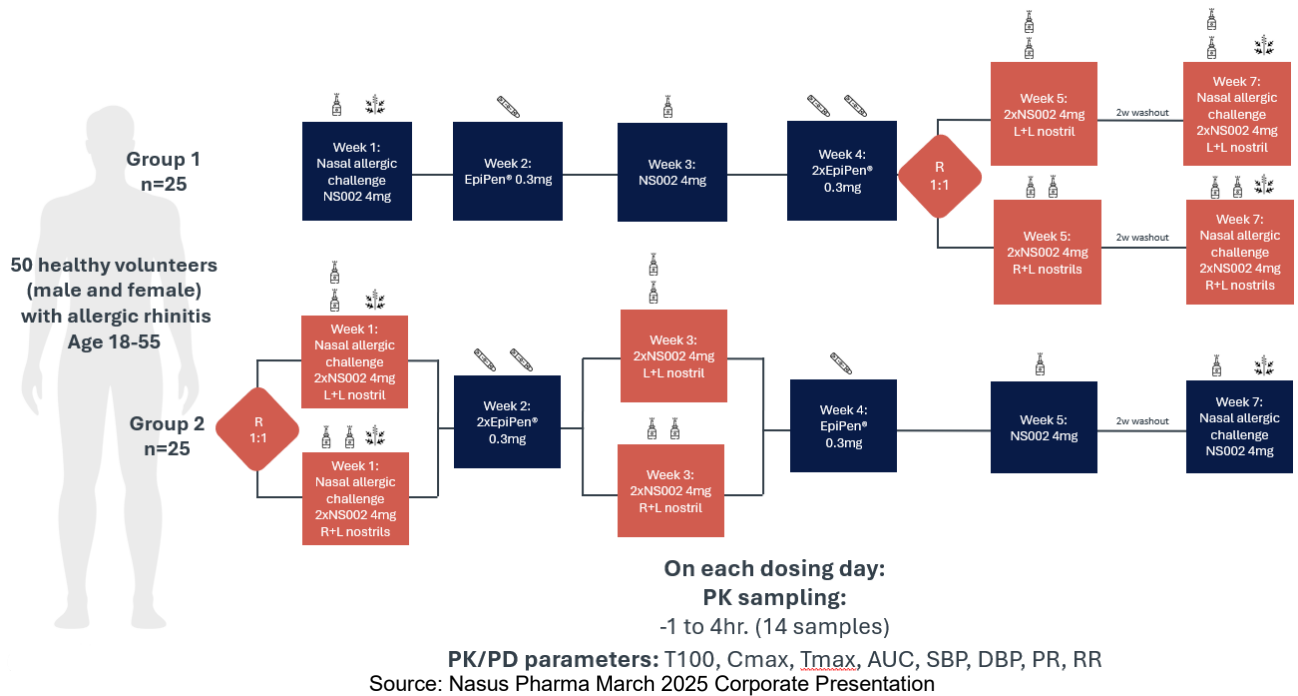
⁴⁴ EpiPen's label discusses cardiovascular reactions including arrhythmias, including fatal ventricular fibrillation in patients with underlying cardiac disease or those receiving certain drugs. Other events include rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease and angina may occur in patients with coronary artery disease. Investigators have reported rare cases of stress cardiomyopathy in patients treated with epinephrine.

Inclusion criteria allowed enrollment of non-smoking adults with documented positive skin allergy tests and a history of hay fever, seasonal allergies or allergic rhinitis over the year prior to enrollment. The trial offered six interventions that were performed either in the same nostril or opposite nostrils:

- One 4.0 mg dose of NS002
- One 0.3 mg EpiPen autoinjector dose
- One 4.0 mg dose of NS002 after nasal allergenic challenge (NAC)
- Two 0.3 mg EpiPen autoinjector doses, 10 minutes apart
- Two 4.0 mg doses of NS002, 10 minutes apart
- Two 4.0 mg doses of NS002 after NAC 10 minutes apart

Endpoints included epinephrine level in plasma over time, T_{MAX} , Time to 100 pg/mL, C_{MAX} , Area Under the Curve (AUC), blood pressure, heart rate and respiratory rate. Safety measures included adverse event rate at each treatment and severity. All subjects were evaluated at Pharma Medica Research Inc. in Mississauga, Canada.

Exhibit X – NP007 Clinical Trial Design



NP007 Summary and Conclusions

NS002 achieved the epinephrine therapeutic plasma threshold significantly faster than the EpiPen under all conditions. Furthermore, a higher proportion of participants achieved the therapeutic epinephrine threshold of 100 pg/mL in the blood plasma at the critical 2.5-, 5- and 10-minute time points in the NS002 group compared to EpiPen. NS002 was further well tolerated with transient mild symptoms, no serious adverse events and no cardiovascular AEs. Nasus plans to launch its pivotal study in 4Q:26 and is expected to pursue the 505(b)(2) regulatory pathway with the FDA.

NS001

NS001 is an intranasal naloxone powder spray which was being developed to rapidly reverse opioid overdoses. The program successfully advanced through both pilot and pivotal Phase III studies, proving its efficacy in delivering faster systemic drug levels; however, further work was suspended. Nasus plans to pursue partnering for further development of NS001. Future development under partnership would require several tasks to be completed.

- Stability study with reliability study;
- Usability study; and
- A two-week preclinical safety study in rats to study the histology of the product.

NS001 was being developed with the intent to follow the section 505(b)(2) application pathway which allows the sponsor to rely in part on studies conducted by others. Based on our discussions with management and review of the competitive environment, we believe that the availability of a generic, over the counter, intranasal naloxone product reduced the attractiveness of this market and led to the subsequent pause. In its filings, Nasus provides a thorough discussion of necessary and remaining work required prior to developing a supplemental NDA.

The NS001 pivotal study demonstrated superior absorption compared with liquid Narcan. In Lapidot 2022,⁴⁵ Nasus intranasal powder-based naloxone formulation produced significantly higher exposure at the initial time points of 4, 10, and 30 min, post-administration, compared to Narcan. The paper concluded that NS001 is expected to have a shorter onset of action for a more effective therapeutic intervention to manage opioid overdose. The performance of the formulation in the pivotal study validates the mechanism of delivery and supports further investigation into delivery of other medicines where rapidity of action is critical.

As illustrated in the company's pipeline graphic, there are three additional preclinical programs planned to advance into the clinic. These include the following assets and indications:

- NS003: an intranasal ondansetron powder nasal spray for the treatment of intractable vomiting;
- NS004: an undisclosed molecule for metabolic indication; and
- NS005: an undisclosed molecule for a cardiovascular indication.

We intend to revisit these programs as they enter the clinic. Nasus has indicated that NS003 and NS004 are moving towards in-human studies expected to start in the second half of 2026.

Recent and Future Milestones:

- NP007 Phase II Topline Readout – March 2026
- NS002 Investigational New Drug (IND) submission – 3Q:26
- NS003 initiation of first in-human studies – 3Q:26
- Launch NS002 pivotal study – 4Q:26
- Pivotal study readout – 1Q:27
- NS002 New Drug Application (NDA) submission to the FDA – 2H:27

⁴⁵ Lapidot, T., *et al.* [A Novel Faster-Acting, Dry Powder-Based, Naloxone Intranasal Formulation for Opioid Overdose](#). Pharmaceutical Research. March 2022.

Nasus Pipeline

Nasus offers five programs in its development pipeline. This includes lead candidate NS002, which is indicated for anaphylaxis and other assets which we have previously reviewed.

Exhibit XI – Nasus Pharma Pipeline

Drug Candidate	Molecule	Indication	Preclinical	Phase 1	Phase 2	Pivotal Trial	Next Milestone
NS002	Epinephrine	Anaphylaxis	Phase 2 repeat dose PK study interim results reported				Pivotal study expected to initiate Q4 2026
NS003	Ondansetron	Nausea and Vomiting	Preclinical				FIH study H2/26
NS004	Undisclosed	Metabolic	Preclinical				FIH study H2/26
NS005	Undisclosed	Cardiovascular	Preclinical				TBD
NS001*	Naloxone	Opioid overdose	Pivotal Phase 3 completed (n=42)				Available for partnering

Source: Nasus Corporate Presentation, March 2026

Intellectual Property

Nasus intellectual property consists of two patent families. The first family relates to dry powder formulations for intranasal delivery and covers Nasus' basic powder formulation for intranasal administration of Active Pharmaceutical Ingredients (APIs). Nasus has been granted four patents in the U.S. (one of which is specifically covering Naloxone), one patent in India, one patent in Japan and one patent in Israel. The company has pending applications under examination in Europe by the European Patent Office (EPO), Australia, Canada and China.

The second family of patents relates to dry powder formulations for intranasal delivery of epinephrine. In this family Nasus has one granted patent in the U.S., and pending applications in the U.S., Argentina, Taiwan, Australia, Brazil, Canada, China, Europe, India, Israel, Japan, Mexico, New Zealand and South Korea. The first patent related to NS002 is expected to expire in 2038 while a second should expire in 2040. We expect Nasus to take advantage of patent term extension provisions of about three years.

Exhibit XII – Nasus' Primary U.S. Patents

Compound	Title	Patent #	Filed	Region	Expiry
NS001	Dry powder compositions for intranasal delivery	11.202.757	12/1/2020	US	8/19/2038
Platform	Dry powder compositions for intranasal delivery	11.331.270	5/17/2022	US	8/19/2038
NS001	Dry powder compositions for intranasal delivery	11.844.859	12/19/2023	US	8/19/2038
Platform	Dry powder compositions for intranasal delivery	11.116.723	8/19/2019	US	8/19/2038
NS002	Treatment with powdered intranasal Epinephrine	11.400.045	8/2/2022	US	12/28/2040
Platform	Sustained-release intranasal pharmaceutical composition	Exam in Process	4/15/2024	US	4/15/2045

Source: Analyst work drawn from Nasus Corporate Filings

Peers and Competitors

There are numerous companies operating across the nasal drug delivery, powder formulation and epinephrine markets. Several of them overlap with Nasus' strategic focus on needle-free emergency therapies for anaphylaxis and severe allergic reactions. Among the closest comparators are Orexo AB and ARS Pharmaceuticals, both of which have developed intranasal epinephrine products utilizing advanced absorption and delivery technologies. In addition, AptarGroup is important due to its role as a leading supplier of nasal drug delivery devices used in multiple FDA-approved products, including Narcan, Baqsimi, and neffy. Collectively, these companies illustrate the growing commercial and clinical interest in needle-free emergency therapies and intranasal systemic drug delivery.

Orexo AB is a Swedish pharmaceutical company specializing in drug delivery technologies. It is developing OX640, a needle-free intranasal epinephrine candidate intended for the treatment of severe allergic reactions and anaphylaxis. OX640 successfully completed Phase I clinical studies demonstrating rapid systemic epinephrine exposure comparable to injectable products. However, Orexo has publicly indicated that the program is available for partnering, suggesting that internal development activities are on hold pending an external collaboration.

ARS Pharmaceuticals is the most advanced pure-play competitor in the nasal epinephrine market following FDA approval of neffy, the first approved needle-free epinephrine nasal spray for type I allergic reactions, including anaphylaxis. Neffy delivers 2 mg of epinephrine intranasally and incorporates the proprietary Intravail absorption-enhancing technology licensed from Aegis Therapeutics to facilitate rapid systemic uptake. Neffy's approval is a significant validation of nasal epinephrine delivery and could accelerate broader adoption of non-injectable emergency allergy treatments.

Kindeva Drug Delivery is a contract development and manufacturing organization (CDMO) focused on inhalation and nasal drug delivery technologies. The company supports development programs spanning local nasal delivery, systemic administration, nose-to-brain therapeutics, and pulmonary delivery systems. Although Kindeva does not market or develop a dedicated anaphylaxis therapy, its formulation expertise and manufacturing capabilities position it as a potential enabling partner for future intranasal epinephrine products.

Optinose is another notable participant in the nasal drug delivery field. The company specializes in enhanced intranasal delivery technologies utilizing its proprietary Exhalation Delivery System (EDS), which improves deposition into the upper posterior nasal cavity. While Optinose's commercial focus is on chronic sinus and neurological indications rather than anaphylaxis, its technology platform demonstrates the broader innovation occurring within advanced nasal delivery systems.

Aquestive Therapeutics is a specialty pharmaceutical company developing needle-free emergency allergy treatments through its proprietary PharmFilm oral dissolving film technology. Its lead anaphylaxis-focused product candidate, Anaphylm, is a sublingual epinephrine film intended for the emergency treatment of type I allergic reactions, including anaphylaxis. The company submitted an NDA to the FDA in 2025; however, the agency subsequently issued a Complete Response Letter (CRL) in early 2026 related primarily to product usability in emergency situations. Aquestive has stated that it intends to modify the packaging and resubmit the NDA later in 2026. Although Anaphylm is not a nasal product, it competes directly in the broader needle-free epinephrine market.

Viatrix is a dominant incumbent in the epinephrine market through its EpiPen franchise, which was originally commercialized by Mylan prior to the company's merger with Upjohn. Viatrix markets EpiPen, EpiPen Jr., and authorized generic equivalents. Historically, EpiPen represented approximately 90% of the epinephrine auto-injector market, though its market share has declined substantially following the introduction of generic competitors and newer alternative delivery platforms, including nasal sprays and other needle-free products.

Several large pharmaceutical and medical device companies also participate in adjacent markets relevant to Nasus' areas of interest. AstraZeneca markets multiple nasal spray therapies for respiratory and inflammatory conditions. Becton, Dickinson and Company offers the Accuspray Nasal Spray System for vaccine and biologic delivery applications. GSK is a major supplier of dry powder inhalation products across respiratory and immunology indications. In the epinephrine market specifically, Teva Pharmaceuticals markets generic versions of EpiPen and EpiPen Jr., while Amneal Pharmaceuticals manufactures generic Adrenaclick epinephrine auto-injectors in addition to injectable epinephrine products for hospital settings. Other established suppliers of injectable epinephrine formulations include Dr. Reddy's Laboratories, Bausch Health Companies, Pfizer, and Merck KGaA.

Among all participants, AptarGroup is a strategically important infrastructure provider within the nasal delivery ecosystem. Aptar develops and commercializes a broad portfolio of drug delivery devices and systems, including its widely adopted Unidose Liquid Nasal Spray System, which is utilized in several FDA-approved products such as Narcan, Baqsimi, and neffy. The company also offers the Unidose Powder Nasal Spray System, which supports dry-powder intranasal formulations and has been associated with development programs including Nasus' product candidates and Orexo's OX640. Aptar's established regulatory track record and commercial manufacturing capabilities provide an important competitive advantage for companies seeking to develop intranasal therapeutics.

Exhibit XIII – Peers and Competitors

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
AKBLF	ALK-Abelló	\$38.89	\$8,617	\$8,870	Jext autoinjector in UK for severe allergic reactions
AMRX	Amneal Pharma	\$12.42	\$3,962	\$6,381	Generic epi injection (AdrenaClick) & epi injection for hospital use
AQST	Aquestive Tx	\$4.23	\$531	\$445	Needle free epi using sublingual/oral dissolving film (Anaphylm)
ATR	Aptargroup	\$115.51	\$7,372	\$8,286	Drug delivery systems & devices including powder delivery device
AZN	AstraZeneca	\$189.75	\$294,285	\$311,036	Diversified biopharma: nasal spray products & injected adrenaline
BDX	Becton Dickinson	\$146.25	\$40,298	\$54,357	Drug delivery devices & systems, nasal spray system
BHC	Bausch Health	\$5.45	\$2,037	\$20,620	Emerade epi injection (Canada) & non-epi nasal spray products
ZYDUSLI	Zydus Lifesciences	₹1,038.95	₹1,045,000	₹1,090,000	Injectable epi for hospital use
GSK	GlaxoSmithKline	\$51.53	\$104,565	\$118,690	Diversified biopharma offering dry powder inhalers.
JNJ	J&J	\$231.73	\$557,824	\$573,300	Diversified biopharma w/ multiple nasal spray products
MKKGY	Merck KGaA	\$29.69	\$19,186	\$27,447	Epinephrine powder sold by subsidiaries
ORXOF	Orexo AB	\$2.10	\$74	\$31	Ph1 OX640 intranasal epi for anaphylaxis
PFE	Pfizer	\$25.95	\$147,901	\$195,391	Diversified biopharma with epi injection solution for hospital use
RDY	Dr. Reddy's Labs	\$13.55	\$11,309	\$10,453	Generic/specialty pharma with nasal spray product for migraine
SPRY	ARS Pharma	\$8.23	\$817	\$743	Approved intranasal Neffy + Ph2 for urticaria
TEVA	Teva	\$34.16	\$39,278	\$49,552	Generics including epinephrine auto-injector
VTRS	Viatis	\$16.46	\$19,169	\$29,778	Generics including EpiPen & authorized generics
pvt	Flo Nasal Products				Nasal & sinus care products including sprays
pvt	Kaléo Pharma				Auvi-Q epi autoinjector
pvt	Kindeva Drug				CDMO focused on inhalation & nasal products
pvt	Neurelis				Diazepam nasal spray for epilepsy/Licensed Intravail to ARS
pvt	Paratek Pharma				Bought OptiNose's nasal spray & powder drug delivery system
NSRX	Nasus Pharma	\$2.87	\$33.61	\$32.32	Nasal powder delivery for anaphylaxis & other indications

Compiled by Zacks' analysts as of May 21, 2026

Corporate Milestones, History and Financial Results

Milestones

- Pilot trial [results](#) for intranasal epinephrine powder delivery (PK) – June 2021
- Phase II trial [results](#) for intranasal epinephrine powder (NP006) – December 2023
- Five-year stability [achieved](#) for NS002 (FMXIN002) – August 2024
- NS002 [presentation](#) at AAAAI Annual Scientific Meeting – March 2025
- [Closing](#) of IPO – August 2025
- [Agreement](#) with AptarGroup for supply of Unit Dose System technology – October 2025
- NS002 [regulatory clearance](#) for and [start](#) of Phase II study by Health Canada – November 2025
- Eyal Rubin [appointed](#) as Chief Financial Officer – November 2025
- CEO [Letter to Shareholders](#) – December 2025
- NS002 Phase II interim results [reported](#) – January 2026
- [Private placement](#) of \$15 million – February 2026
- [Announcement](#) of topline results from Phase II study – March 2026
- Launch of pivotal NS002 study – 4Q:26

Origin of Nasus Pharma

Nasus was founded in 2019 by Dr. Dalia Megiddo and Udi Gilboa. The two entrepreneurs recognized the value of a powder-based, nasal delivery product that was presented to them by a drug formulation company. They acquired the technology from this company and began to develop a powder formulation of naloxone (NS001) for opioid overdose. Nasus advanced the NS001 program to a late stage of development; however, during this period the competitive environment had changed and advancing NS001 was no longer attractive. Despite the commercial setback, the clinical work demonstrated that the product was able to successfully deliver drug to sites in the nasal cavity with high absorption and into areas where liquid sprays could not reach. In clinical trials, Nasus' powder-delivered naloxone generated higher absorption rates and produced faster therapeutic levels of drug in the bloodstream compared with Narcan.

As the attraction to the naloxone market waned, COVID was emerging. Nasus management realized that the powder technology could produce a prophylactic product that may block the SARS-CoV-2 virus from binding to surface proteins in the nasal cavity. The product, dubbed Taffix, was first available in July 2020 and generated near \$10 million in revenues for the company. Taffix forms a protective gel barrier in the nasal cavity that lasts for several hours, with clinical studies indicating it can help protect against infection. Despite market interest in the product, it was never approved and Nasus ended production after several quarters due to insufficient sales.

Following the wind down of Taffix, Nasus conducted a pilot study evaluating a fast-acting, dry powder, needle-free epinephrine spray. Results from the trial were published in 2023 and found that the dry powder version was able to produce faster absorption versus EpiPen. Results supported further work and later in 2023, Nasus conducted a Phase II trial that explored the safety and efficacy of the product in 12 healthy volunteers. Results were announced in December 2023. This supported yet further work including stability studies and conference presentations featuring generated data. The results stimulated investor interest and Nasus conducted an initial public offering in August 2025, raising \$10 million.

Another Phase II study was subsequently announced to be run at a single site in Canada. It started in November 2025 and was designed to address regulatory approval considerations by comparing bioavailability and pharmacokinetics of NS002 vs. EpiPen. Following a \$15 million private placement in February, positive results from the study were presented in March. The data from the Phase II supported the launch of a pivotal trial, which is planned to start in the fourth quarter of 2026.

Fiscal Year 2025 Financial Results

Nasus provided fiscal year 2025 results in a [press release](#) and its [Form 20-F](#) filing on March 25th, 2026. The company reviewed previously released topline results from its Phase II study for NS002, provided an update on the status of its NS003 program and confirmed its plans to launch a pivotal study for NS002 in 4Q:26. The company asserts that it is well funded through the planned pivotal study. For the year ending December 31st, 2025 and versus the comparable prior year, no revenues were reported. The 2025 operational loss was \$4.9 million compared to \$1.5 million with increased research activity for NS002 and expenses related to becoming a public company the primary drivers for the year over year change.

- Research and development expenses totaled \$2.2 million, up more than fivefold from \$335,000 attributable to a substantial increase in expenses related to the development of NS002, including greater expenses for payroll, share-based compensation and clinical research expenses;
- General and Administrative expenses were \$2.7 million, up 260% from \$743,000. Recognition of costs related to Nasus becoming a public company were the primary driver. Higher payroll stemming from new hires and payment of bonuses, along with greater business consultant expenses and share-based compensation expenses also contributed to the increase;
- Interest income of \$78,000 compares to interest expense of \$29,000 due to higher net cash balances;
- Total other expense of \$1.0 million was related to the change in value of convertible securities and a small expense related to undisclosed items;
- Net loss was \$5.9 million vs. \$1.5 million or \$0.73 and \$0.22 per share, respectively.

As of December 31st, 2025 cash and equivalents totaled \$4.3 million. This amount compares to the \$311,000 balance held at the end of fiscal year 2024. Cash burn for 2025 was \$4.9 million versus \$665,000 for the same prior year period. In February 2026, Nasus executed a \$15 million private placement which is expected to be sufficient to support the company's operations until its anticipated NDA submission in 2H:27.

Management Profiles

Dan Teleman, Director and CEO

Mr. Dan Teleman has served as Nasus' Chief Executive Officer (CEO) since January 2025 and has served as a Director since September 2025. Prior to this appointment, Mr. Teleman served as Pharma Two B's CEO from May 2023 to January 2025 and as its President from October 2022 to May 2023. Mr. Teleman brings over 20 years of experience in the biotechnology industry. From May 2022 to May 2023, Mr. Teleman was an Executive Partner at Israel Biotech Fund, a life science venture capital firm. From January 2023 to November 2023, Mr. Teleman also served as a board member of 4C Biomed, an early-stage immune-oncology company developing a novel antibody. From July 2021 to May 2023, Mr. Teleman served as the chairman of Tamarix Pharma, an early-stage ophthalmology company developing novel anti-apoptotic molecules. From January 2010 to May 2022, Mr. Teleman was the chief executive officer of Atox Bio, where he led the company through an NDA submission for Reltecimod, the first immunomodulator developed for NSTI. Previously, Mr. Teleman was the co-founder and chief executive officer of PainReform, head of business development for Pharmos Corporation and held marketing and sales roles at Amgen. Mr. Teleman holds an MBA from the Fuqua School of Business at Duke University and an MSc in Biochemical engineering from Ben-Gurion University in Israel.

Eyal Rubin, Chief Financial Officer and Executive Vice President

Mr. Eyal Rubin has served as Nasus' Chief Financial Officer (CFO) and Executive Vice President since November 2025. Prior to this appointment, Mr. Rubin served as the Senior Vice President and CFO of Protalix Biotherapeutics since September 2019. Prior to joining Protalix, he served as Executive Vice President and Chief Financial Officer of BrainStorm Cell Therapeutics, a publicly traded biotechnology company, where he was responsible for corporate finance, accounting and investor relations activities. Prior to his role at BrainStorm, Mr. Rubin served at Teva in several roles, most recently as Vice President, Head of Corporate Treasury. Mr. Rubin holds a BA in Financing and IT Systems from the College of Management, Israel, where he graduated Summa Cum Laude with a specialization in Financing and IT Systems, and an MBA from Bar-Ilan University, Israel, where he graduated Summa Cum Laude with a specialization in finance.

Udi Gilboa, Co-Founder and Executive Chairman

Mr. Udi Gilboa has served as Nasus' Co-Founder and Executive Chairman since 2019. Since January 2012, Mr. Gilboa has been serving as a director, Senior Vice President of Operations and the Chief Financial Officer of Bioblast Pharma. Mr. Gilboa is the founder and managing partner of TopNotch Capital, a prominent Israeli life sciences investment bank. He is also the founder of a number of medical device and pharmaceutical companies. Mr. Gilboa is Chairman of the Board of Samson NeuroSciences. Mr. Gilboa has served as a director of InsuLine Medical until 2014 and served, until 2010 as a director and chairman of the board of directors of Topspin Medical. Mr. Gilboa holds a Bachelor's degree and MBA from Tel Aviv University.

Dr. Dalia Megiddo, Co-Founder, Director, Chief Development Officer and Chief Medical Officer

Dr. Dalia Megiddo is a Co-Founder of Nasus and served as a director of the company since May 2019. She has served as Nasus' Chief Development Officer and Chief Medical Officer since June 2019. Dr. Megiddo also served as the Chief Executive Officer from March 2020 to January 2025. She has founded and served as management or a director for multiple biopharma and medtech companies, including Chiasma from 2002 to 2008 as co-founder and director; Medingo (sold to Roche Holding AG) from 2005 to 2007 as co-founder and director; Alcobra Pharmaceuticals from 2008 to 2013 as co-founder and director; and Bioblast Pharma from February 2012 through its public offering in February 2015 as CEO and director from February 2012 to March 2019. Dr. Megiddo managed two venture capital funds: 7 Health Ventures from 2006 through 2010 and InnoMed Ventures, since 2000. Dr. Megiddo has been involved in the Life Science Venture Capital Industry since 1999 and is well recognized as one of the leaders in the healthcare investment and entrepreneurial community both in Israel and internationally. She is a frequent speaker at local and international meetings and served as a board member at Given Imaging, Elron Ventures, Alcobra and Bioblast. Dr. Megiddo is a member of the scientific-investment advisory boards to several academic institutes in Israel including the Technion and Tel Aviv University. Dr. Megiddo holds an MBA from Kellogg-Recanati School of Business and teaches at various entrepreneurial programs in Israeli universities. She completed her medical studies at the Hebrew University's Hadassah Medical School and a specialty program in Family Medicine. After spending a few years as a faculty member in the Family Medicine department at the Hebrew University in Jerusalem, Dr. Megiddo founded and sold two successful businesses in the medical field: The Journal Club, Israel's leading provider of Continuing Medical Education for physicians and Academia Medica, a medical multimedia developer and worldwide distributor for Continuing Medical Education programs for physicians.

RISKS

All investments contain an element of risk that reflects the uncertainty of a business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk.

The pharmaceutical space includes companies at both ends of the spectrum, from mega-cap pharmaceutical titans that have multiple products generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, some hazards are particular to smaller companies that have not yet established themselves or their products.

For smaller, early-stage companies, investing in drug development is a lengthy process. The timeframe for conducting preclinical research to eventually commercializing a drug can take from 12 to 15 years or even longer given market and company-specific conditions. And with, on average, only one in one thousand compounds eventually making it to the market from the discovery stage, the risks are substantial.

Financing

Even if a company has a strong, experienced team that is developing a therapy with a high likelihood of success and a large addressable market, securing funding may be difficult. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to suspend research and development activities, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route to progress or force a company to accept onerous terms.

Increases in cost of capital can make previously attractive investments less so. Interest rates have stabilized, but remain elevated relative to the past 15 years. Higher interest rates can materially change the perceived net present value and reward to risk ratio for many investments, especially those in higher risk categories such as drug development. Early-stage life sciences companies are dependent on a steady flow of capital to support their research and development activities. As capital becomes more dear, formerly attractive projects may become less so, making access to critical capital inflows less certain. As of December 31st, 2025, Nasus held \$4.3 million in cash on its balance sheet. Following the end of the year, the company raised \$15 million in a private placement. Nasus believes that it holds sufficient cash to support operations until 2Q:27.

Partners

Contract research organizations (CROs) have assumed a larger role in the development of drug candidates as the complexity and cost of trials has increased. Finding appropriate populations to participate in clinical trials has become more difficult due to the shift to biomarker defined groups, screening for specific mutations, personalized medicine and orphan indications that address small clusters of patients. This shift has increased the dependence upon specialized CROs for project management and clinical monitoring services that add additional risks related to third parties. Nasus has used the same CRO for all of its studies. Due to the nature of the PK/PD studies and the underlying drug, only one site has been necessary to run the Phase II trials. Nasus expects to use the same CRO and site for the pivotal study.

A CRO partner may face competing demands which can adversely affect the work they are managing on behalf of the client. CROs and subcontractors must abide by strict execution and trial parameters that if violated can jeopardize trial execution or data validity. Patient recruitment may be difficult. Subcontractors supervise and execute research as well as conduct biometric and pharmacovigilance, which are complex tasks. Clinical investigational centers need sufficient capacity and the candidate drug needs to be manufactured in compliance with current Good Manufacturing Practices (cGMP) and be available to administer to patients. Finally, the data itself needs to produce results that achieve sufficient statistical significance and clinical relevance to justify regulatory approval.

Regulatory Environment

All drugs must navigate the regulatory approval process in the US, EU, Japan and other countries before commercialization. Success is uncertain and may take years depending upon the needs and desires of the determining authority. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Identifying companies that have a history of research success in drug development, with opinion leaders and experts in the field are important factors that can help mitigate this risk. Companies and management teams that have achieved previous success with the FDA or other regulatory agencies are more attractive than those that are new to the process. The underlying drug for Nasus' lead candidate is epinephrine, which has already been approved by the FDA. Products that are new formulations of underlying drugs that are already approved may use less burdensome routes to approval via a new drug application (NDA). Nasus will submit its application package to the FDA using the 505(b)(2) route which relies on safety and efficacy data generated by others. Since the underlying molecule has already been approved, we anticipate a higher probability of success compared to a new chemical entity. Below we summarize the average probability of success for a new chemical entity to move to the next stage of approval, which is approximately 58% for a Phase III asset to advance to an NDA. We estimate NS002's probability of success will be higher as discussed in our valuation section as the efficacy of the product has already been demonstrated and it is following the less burdensome 505(b)(2) pathway.

Exhibit XIV – Success of Phased Trials and Regulatory Approval⁴⁶

Phase	I - II	II - III	III - NDA/BLA	NDA/BLA - Approval	I - Approval
Probability	52.0%	28.9%	57.8%	90.6%	7.9%

Competitive Environment

Many firms participate in the epinephrine and nasal delivery space; however, no others have a highly effective powder formulation of epinephrine starting pivotal trials. While ARS Pharmaceuticals offers a nasally administered, needle-free, rapid acting emergency treatment for allergic reactions, Nasus' formulation offers faster absorption rates and higher peak epinephrine concentration. We note that there are other competitors waiting in the wings such as Orexo; however, the product is at a much earlier stage of development and appears to be inactive. Other epinephrine products include the traditional injectable versions of epinephrine, both branded and generic. Many larger competitors offer powder technology and nasal delivery that could compete against NS002 if they were incentivized to do so. However, if Nasus has an FDA approved product, an established pharmaceutical competitor would likely acquire Nasus or its NS002 asset rather than develop its own. We think Nasus' formulation improves upon the shortcomings that exist with other approved epinephrine products.

Marketing and Commercialization Risk

Successful marketing of approved drug candidates relies on adoption by patients and providers. An approved drug must have convincing clinical trial data and maintain a favorable reputation among prescribers. Marketing is expensive and requires an experienced sales force and a presence in the marketing region. Marketed products remain under surveillance and any unexpected adverse effects may lead to regulatory authorities revoking marketing authorization. Inclusion of the drug in insurance plan offerings is also important. Rapidly obtaining a preferred position on health plans and payor formularies is critical to achieving target penetration rates. If health plans and payors cannot agree on appropriate pricing for the drug and the compound fails to offer a significant benefit above standard of care, sales may be limited. Nasus is about two years away from marketing and commercialization activities. We anticipate that the company will hand off its assets after further development to a larger partner who will assume commercialization responsibilities; however, the company maintains the option to commercialize the product internally if this route is expected to maximize shareholder value.

⁴⁶ Summarized from [Clinical Development Success Rates 2011-2020](#). Compiled by Zacks Analysts.

Manufacturing

Pharmaceutical companies can either produce medicines in-house or rely on third parties to manufacture them. While there are many benefits to owning manufacturing facilities and exercising direct control, in most cases small and medium size biopharmaceutical companies work with partners through supply agreements to make their products. Working with a partner confers several benefits including economies of scale, a management team dedicated to compliance with regulatory requirements and the flexibility of engaging other manufacturers based on changing circumstances. The use of a partner also limits the capital burden of a single product company and more closely aligns volume, costs and their respective timing. While there are numerous benefits to outsourcing manufacturing, a drug sponsor may also be exposed to several risks. Manufacturing partners may not prioritize client projects and may run afoul of regulatory requirements. The manufacturer may experience quality control or volume constraints that could disrupt demand. Minimum volume contracts could force the client to accept more product than can be sold in a reasonable time, impacting cash flow and producing excessive inventory which could expire before sale. Using outside contractors could also allow internally developed trade secrets to be compromised.

Nasus does not own the manufacturing facilities that produce its products. It uses a third-party contract manufacturing organization located in Canada which is able to meet the required regulatory standards and complex techniques that are used in the production of NS002. Nasus asserts that the spray drying process is unique to this manufacturing facility. Active Pharmaceutical Ingredients (API) are placed in the device in Canada where the CDMO partner takes possession and performs the labeling, quality control tests and packaging. Finished product will be shipped to the clinical trial site. The identity of the contract development and manufacturing organization (CDMO) has not been disclosed. However, Nasus works with consultants and conducts its own due diligence to ensure that its CDMO partners are in compliance with current good manufacturing practices (cGMP) and that they pass quality audits. The CDMO is manufacturing other FDA approved products.

Intellectual Property

Despite the existence of patents, exclusivity and trade secrets, infringement of intellectual property is a risk. Nasus' intellectual property portfolio consists of two patent families that relate to the basic powder formulation and intranasal administration of pharmaceutical products. Patents have been granted in the United States, India, Japan, Mexico and Israel. There are pending patents in Europe, Australia, Canada and China. Nasus holds patents relevant to NS002 that expire in 2038 and 2040. We believe that Nasus will be eligible for patent term extension, which could potentially extend this protection until 2041.

Geopolitical

Trade tensions between the U.S. and China were exacerbated by the COVID pandemic. There had been a cross-pollination of capital and drug development between the two countries which has slowed as a result of trade and political disputes. This conflict may reduce the availability of capital, partnerships and future development and commercialization deals between companies in the two nations. The UK withdrew from the European Union in 2020, creating new trade, transportation and other barriers between the UK and mainland Europe. The European Commission Decision Reliance Procedure, which allows the UK regulatory apparatus to rely on EU centralized marketing authorization decisions, has expired. Following this date, sponsors must obtain UK marketing authorization for product sales in the UK from the Medicines and Healthcare products Regulatory Agency (MHRA). The war between Ukraine and Russia has disrupted clinical trials in these countries. Sanctions have also been placed on Russia and many of its businesses which may lead to product shortages. Refugees fleeing the war in Ukraine may also impact nearby countries and their productivity which could affect nearby clinical trials and commercialization.

Nasus is headquartered in Israel, which is exposed to conflicts on multiple fronts including Gaza, Lebanon and Iran. War conditions have weighed on the region since 2023 and there is a threat of rocket attacks displacing civilians and affecting operations throughout the country. Companies in the high-tech, defense or cybersecurity industries have demonstrated resilience compared with tourism and construction industries. Nasus is headquartered in Tel Aviv, which has experienced few disruptions over the last three years compared to other regions of the country. Despite the lower level of disruption, companies with a presence in the city remain at risk.

Cost Burden and Inflation

Drug price inflation has gained attention as it and other health care costs have risen at a materially faster pace than the consumer price index. As new therapies have been approved, drug prices have increased to reflect higher development costs and improved pricing power of pharmaceutical and biotech companies. On the demand side, deductibles have been steadily increasing over the last decades, and in some cases, individuals and families must cover several thousand dollars in costs before the benefits of insurance begin. Cost sharing or co-insurance is another component of insurance plans that directly increases a patient's burden. This has resulted in greater elasticity in demand for drugs than was previously the case. Individuals with high deductibles or no insurance may be sensitive to price and avoid treatments with high cost.

Epinephrine for anaphylaxis is a well-known example of a drug product associated with rapidly increasing prices. EpiPen rose from \$100 for a two-pack in 2009 to over \$600 by 2016 which caused a consumer uproar and led to congressional hearings. Public pressure precipitated the release of generic alternatives by Mylan and competitive products from other providers. We expect that the competitive market will limit prices compared to historical levels. This should also permit movement along the demand curve, allowing for greater unit sales.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these potential outcomes and our target price reflects an assumption of these risks faced by biotechnology companies.

VALUATION

Nasus is advancing its NS002 powder-based formulation of epinephrine to treat anaphylaxis in multiple clinical trials. Based on our review of the literature we have settled on an addressable market of just over 10 million individuals in the United States or about 3% of the total population. Outside the United States, we see a similar prevalence of susceptibility to severe allergic reaction in the approximately 1 billion individuals in the developed world and other selected markets. This equates to approximately 30 million individuals. It includes countries such as Japan and Brazil as well as the European Union. We define the addressable market as persons that are susceptible to serious allergic reactions and who would benefit from epinephrine treatment.

Nasus has completed its Phase II epinephrine study, demonstrating faster absorption and a higher proportion of subjects achieving target therapeutic threshold compared to EpiPen. NS002 is preparing for a pivotal study that is expected to start in 4Q:26. We anticipate that the trial will be quick, with a readout in 1Q:27 and an NDA submission in 2H:27. FDA regulatory review lasts about a year, which suggests a 2H:28 approval of NS002. Nasus is expected to be negotiating with partners during this period and our model anticipates that management will be able to secure an arrangement that will generate economic value equal to 25% of net sales of NS002. While the licensing package will most likely consist of upfronts, milestones and royalties, we simplify the approach and assume that each of those components are captured in a royalty of 25%. We believe that this royalty is reasonable given that NS002 offers a new method of delivery rather than a new chemical entity. Furthermore, it addresses weaknesses in existing administration methods and the supply and manufacturing chain has been constructed so that it may easily be transferred to a partner.

We expect that NS002 will be available for commercialization in the United States in 2H:28, following FDA approval. Initial sales penetration is estimated to be 32 basis points of the ~10-million-person addressable market rising to 9.0 percentage points by year seven. This is expected to be followed by mid-single digit growth then low single digit growth until 2041, after which, we anticipate competition will lead to market share loss in the mid-single digit range. Initial penetration is equivalent to 33,000 two-packs sold in 2028 rising to 976,000 two-packs sold by year seven (2034). Based on our discussions with management and review of pricing by EpiPen and neffy, we estimate a net price in the United States of \$400 per two-pack growing at 2.5% per annum. In terms of product revenues, our assumptions generate product sales of \$13.8 million in year one, rising to \$476 million by year seven. Nasus is expected to receive 25% of net revenues, an amount which also captures the value of milestones and other accrued value.

Sales outside the U.S. in developed markets are expected to begin one year later than in the United States. Markets that hold particular interest are Japan, Brazil, Europe and Australia. Desirable markets outside of the United States are estimated to have a population of about 1 billion and an addressable market of about 30 million individuals that are at risk of severe allergic reaction. We anticipate that it will take an additional year following U.S. approval to address the regulatory and pricing negotiations required overseas prior to approval in those regions. This assumption models first sales in 2029 where we see initial penetration of 5 basis points rising to 3.75 percentage points of penetration by year seven. This equates to 15,000 two-pack units sold in 2029 and 1.23 million two-pack units sold by 2035. This will be followed by mid-single digit growth thereafter and then a mid-single digit decline as competition emerges in 2042. Outside of the U.S. we anticipate a price of \$150 for a two-pack growing at 1% per year. These assumptions generate revenues of \$2.3 million in year one rising to revenues of \$196 million by year seven. Nasus is also expected to receive a royalty of 25% of net revenues for international sales.

Estimates for operational costs call for \$11 million in cash expense for 2026, \$11.2 million for 2027 and \$8.8 million in 2028 reflecting a decline in research and development costs which will contract as regulatory activities take the baton from development. Following commercialization, research and development amounts are predicted to fall to zero and an estimated \$3 million in general and administrative expenses will rise at inflationary rates. If Nasus is not sold to an established biopharmaceutical company and out-licenses NS002, we anticipate that it will begin to develop the other assets in its pipeline. At that time, we will reflect the costs and benefits of the new lead product.

Following the generation of profits, net operating losses (NOLs) will be consumed. After NOLs are exhausted, we forecast a 25% cash tax rate on earnings. After tax cash flows to the company are discounted at a 15% rate with a terminal growth rate of -10% beginning in 2048. We apply a 60% likelihood of success for NS002 as the asset has generated successful Phase II data, is on the cusp of starting pivotal work, has sufficient capital to proceed and will follow the less burdensome 505(b)(2) route.

For our per share valuation, we use year-end 2025 shares outstanding, add the 2.7 million shares from the February capital raise and acknowledge the associated warrants. Warrants are assumed to be exercised with cash proceeds added to the enterprise value. Shares used to calculate our target price are approximately 14.4 million.

Despite the conservative stance of our assumptions, penetration into addressable markets can potentially be higher for NS002 if its benefits are quickly recognized and if markets overseas are receptive to the product. Japan in particular may be an area with a high likelihood of upside surprise given the documented fear of needles and low penetration of injectable epinephrine along with Brazil where the EpiPen is neither approved nor available. We note that the determinant for many of the variables in our model will be the ultimate success of the pivotal trial and successful review by the FDA. We will update our model accordingly as new information becomes available.

Based on the assumptions identified in our discounted cash flow model, we generate a valuation of \$19.00 per share.

PROJECTED FINANCIALS

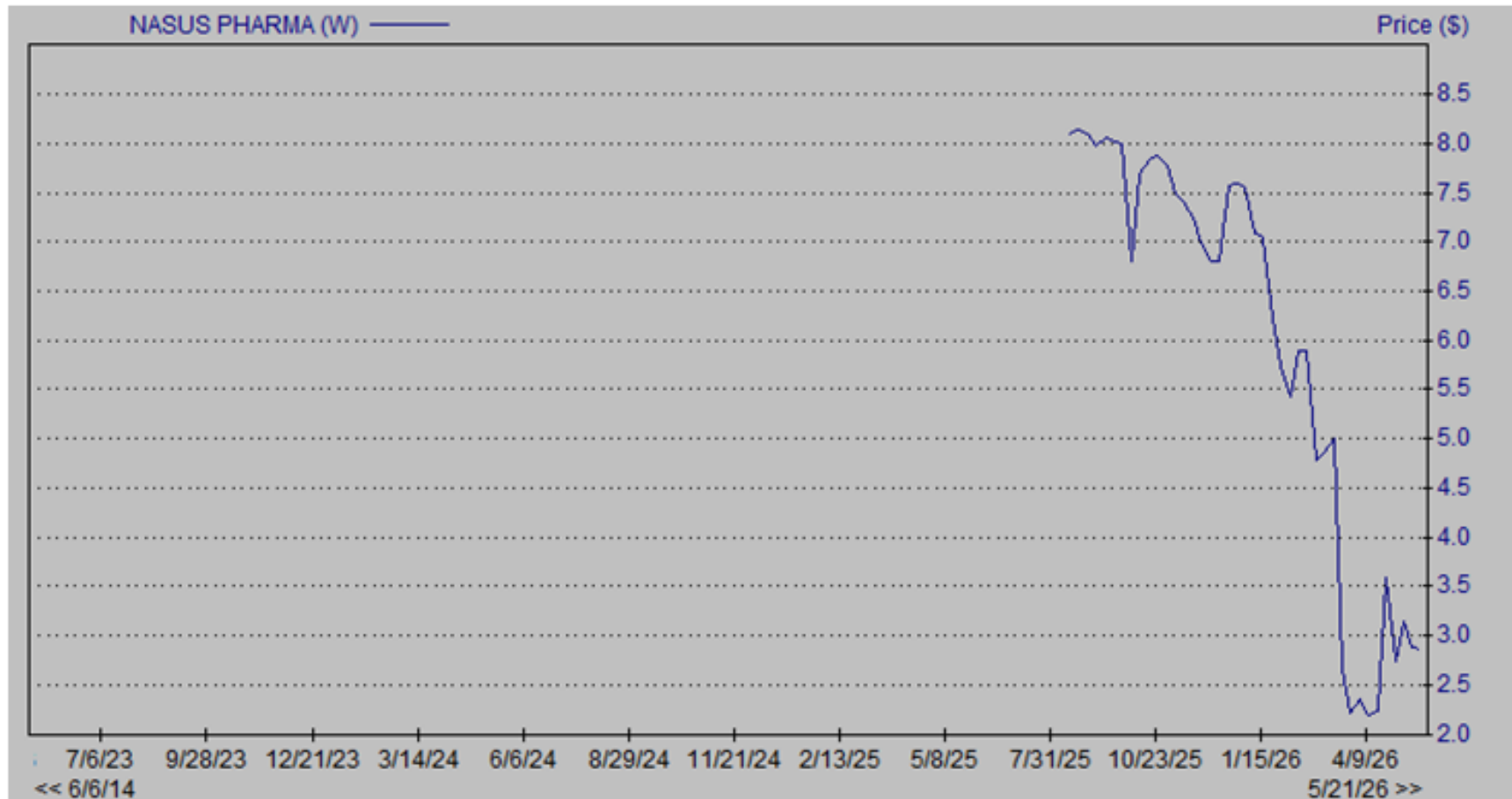
Nasus Pharma Ltd. - Income Statement

Nasus Pharma, Ltd.	2025 A	Q1 E	Q2 E	Q3 E	Q4 E	2026 E	2027 E	2028 E
Total Revenues (\$USD)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$3,443
Research & Development	\$2,237	\$2,550	\$1,530	\$2,210	\$2,210	\$8,500	\$8,600	\$6,000
General & Administrative	\$2,667	\$630	\$615	\$621	\$634	\$2,500	\$2,560	\$2,800
Income from Operations	(\$4,904)	(\$3,180)	(\$2,145)	(\$2,831)	(\$2,844)	(\$11,000)	(\$11,160)	(\$5,357)
Other Items	(\$1,030)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Interest Expense	\$78	\$29	\$24	\$20	\$12	\$85	\$80	\$80
Pre-Tax Income	(\$5,856)	(\$3,151)	(\$2,121)	(\$2,811)	(\$2,832)	(\$10,915)	(\$11,080)	(\$5,277)
Provision for Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Income	(\$5,856)	(\$3,151)	(\$2,121)	(\$2,811)	(\$2,832)	(\$10,915)	(\$11,080)	(\$5,277)
<i>Net Margin</i>								
Reported EPS	(\$0.73)	(\$0.27)	(\$0.18)	(\$0.24)	(\$0.24)	(\$0.93)	(\$0.85)	(\$0.37)
<i>YOY Growth</i>								
Basic Shares Outstanding	8,010	11,500	11,720	11,735	11,741	11,674	13,000	14,250

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Nasus Pharma Ltd. – Share Price Chart⁴⁷



⁴⁷ Source: Zacks Research System

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