# The Role of Inhaled Therapies in the Fight Against Respiratory Syncytial Virus (RSV)

**In Short:**

- **The market for RSV therapies could grow to $7.2 billion by 2030.**
- **There were 218 drugs in development for the treatment of RSV in November 2025.**
- **Most therapies are at the pre-clinical stage, 17 in Phase I-III and 3 with IND/CTA filed.**
- **Vaccines, proteins and antibodies are the leading molecule types.**
- **Inhaled RSV therapies are emerging as attractive options, with soft mist inhalers such as MRX004 poised for a meaningful share of the market.**

Respiratory Syncytial Virus (RSV) is a common viral infection typically causing cold-like symptoms. By the age of two, almost all children are believed to have contracted RSV, with the virus affecting around 64 million individuals globally every year.[1] Symptoms are mild in most cases but can become severe for babies, infants and certain adults at high risk, including older adults or those with chronic lung or heart disease. In such cases, the virus can worsen asthma or chronic obstructive pulmonary disease (COPD) symptoms and lead to further life-threatening infections such as pneumonia and bronchiolitis.

According to the World Health Organization, RSV causes more than 3.6 million hospitalisations and approximately 100,000 deaths in children aged under five each year.[2] Hospitalisation rates are highest in infants under six months or those who are born pre-term or with a low birth weight. According to a report by the UK Government, RSV infections are responsible for up to 80% of lower respiratory tract infections in young children and are one of the leading causes of hospitalisation in the first year of life.[3] Meanwhile, yearly estimates for the US alone stand at 110,000 to 180,000 hospitalisations for individuals aged 50 or above.[4]

## Marketed Drug Landscape

Unmet therapeutic needs for RSV infections are significant. While the pathogen was first identified in 1956, vaccine developments has faced significant setbacks, with early candidates worsening illness severity and leading to two infants' deaths. Following these outcomes, research was halted for many years.

Between 1998 and 2023, just one monoclonal antibody was used to prevent infections via passive immunisation. SYNAGIS ® (palivizumab) was reserved for at-risk pre-term infants, requiring five intramuscular injections over the course of a single RSV season due to its short half-life. This dosing schedule created a logistical burden for parents, while the uncomfortable delivery format could cause potential distress for babies and parents. SYNAGIS® was discontinued and unavailable from 31 Dec 2025.

In 2023, things began to look up. A single-dose, long-lasting monoclonal antibody (mAb) was approved for babies and infants in their first RSV season, and the first prophylactic vaccines for adult RSV hit the market, starting with GSK's AREXVY ® for over 60-year-olds and at-risk individuals aged 50 to 59. Not long after, Pfizer introduced ABRYSMO® for at-risk adults aged 18–59 and pregnant individuals between 32 and 36 weeks gestation, providing a unique form of protection for newborn babies in their crucial early months. This was followed by Moderna's mRESVIA® launch for at-risk 18–59-year-olds.

After decades of no or slow progress, new products have driven increased public awareness and government-sponsored immunisation campaigns, the first of which commenced in England in September 2024.[5] In light of these changing tides, it is forecasted that the RSV prophylaxis market could grow from $582 million in 2020 to $7.2 billion by 2030, reflecting a compound annual growth rate of 28.6%.

The numbers of clinical trials commencing in this area each year is also soaring, reaching an all-time peak in 2024 and growing 138% between 2016 and 2025. Accordingly, there were 218 RSV drugs in development by November 2025, 50% of these were prophylactic vaccines. The majority of which are delivered by injection. The second largest category is inhaled drugs, accounting for a third of the pipeline. (see Figure 1)

## Exploring the Potential Behind Inhaled Therapies

RSV infects the airway epithelium, releasing new virus particles into the airway mucus as the virus replicates. With infections confined to the airways, pulmonary or nasal inhaled delivery could potentially offer a more effective pathway for treating and preventing the RSV infections. As most inhaled drugs being developed for delivery via nasal spray/drops or hand-held nebuliser, and even a few via dry powder inhaler devices, inhaled therapies pave the way for easy, at-home treatments and vaccinations which could be used during virus outbreaks.

There are currently just two inhaled molecules for RSV treatment on the global market, including interferon alfa, a recombinant protein nasal spray marketed in

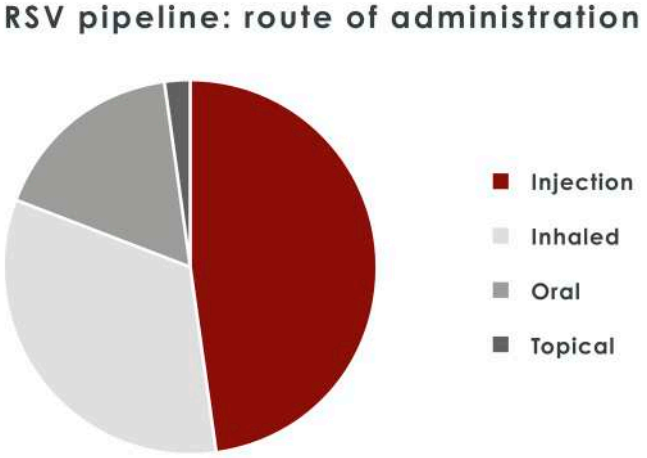


*Figure 1: RSV pipeline by route of administration*

Russia, and aerosolised ribavirin (VIRAZOLE®), a synthetic nucleoside with antiviral activity. Originally in an oral dosage form, Ribavirin was first approved in 1968 for infants and young children hospitalised with severe lower respiratory tract infections caused by RSV. It has since been formulated as a powder for solution, inhaled via nebuliser, and is currently marketed in Canada, Mexico, Australia, and Russia. VIRAZOLE® was recently discontinued in other markets, though generic versions are available in the US and China.

It is clearly early days for inhaled RSV therapies but the inhaled route is gaining some traction. As shown in Figure 2, most of the therapies are in the preclinical stage of development, but there are 17 in Phases I-III as well as three with an IND/CTA filed. Meanwhile, when looking at the pipeline by molecule types (Figure 3), vaccines, proteins, and antibodies are the clear frontrunners.

**Intranasal vaccines for RSV**

Vaccines make up 25 of the inhaled therapies in active development for RSV, which represents more than half of the pipeline. In addition, almost all of these candidates have been formulated for nasal delivery. Most of the vaccines are being developed in the United States (Figure 4).

Until recently, the leader had been Sanofi's intranasal live attenuated vaccine (LAV), SP0125, which was being evaluated in infants in a Phase III study scheduled for completion in 2027. However, in October 2025, Sanofi revealed it was terminating the trial due to efficacy limitations.

In the LAV category, a number of vaccines are being developed at the National Institute of Allergy and Infectious Diseases headquartered in Maryland, USA. These include three Phase II nasal drop vaccines for preventing RSV infections, as well as a further three products in Phase I development.

Within the recombinant vector vaccine group, a BLB-201 is being progressed through Phase I/II trials, with completion expected in December 2026. BLB-201 is a paediatric intranasal recombinant vector vaccine developed on the parainfluenza virus 5 platform. In December 2024, promising interim results from the study were published, with data from the first 63 participants suggesting that those who received the vaccine were more than 80% less likely to contract symptomatic RSV infections than participants who received placebo.

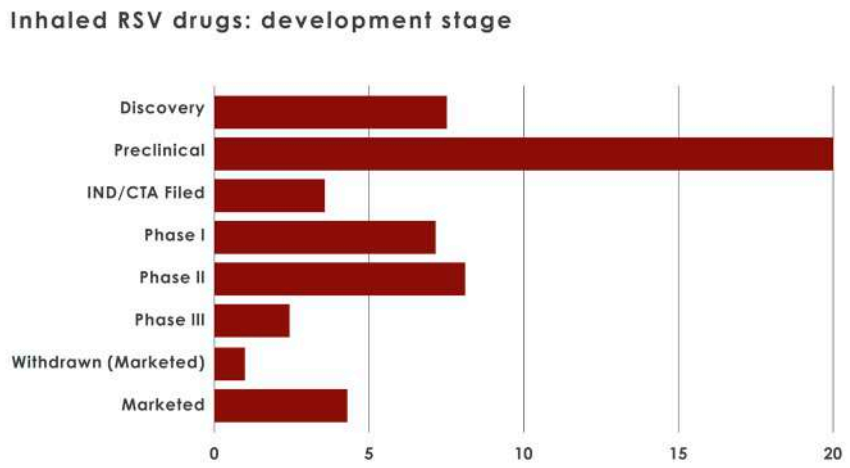


*Figure 2: Number of inhaled RSV programmes per development stage*

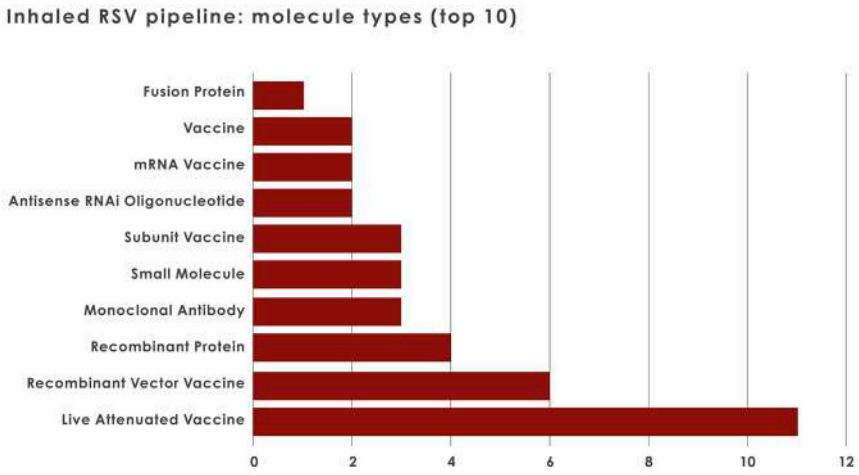


*Figure 3: Number of inhaled RSV programmes per molecule type*

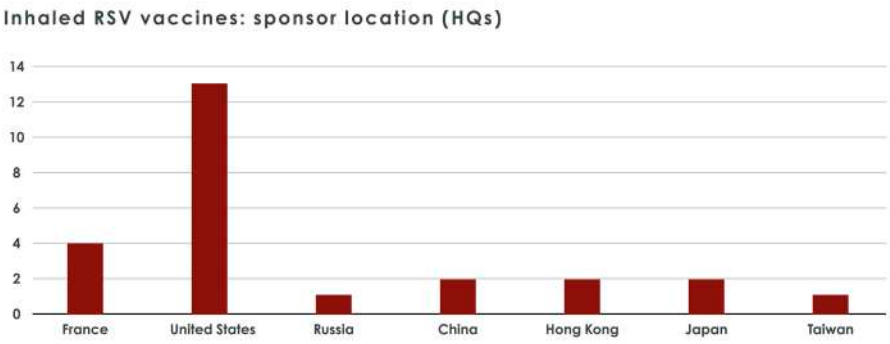


*Figure 4: Number of inhaled RSV vaccine pipeline by location of sponsor company's headquarters*

Other vaccine categories showing potential for inhaled delivery include subunit vaccines and mRNA vaccines. The mRNA space is dominated by an innovative nanoparticles platform to develop intranasal vaccines for RSV.

In the subunit vaccine category, meanwhile, another interesting product stands out. It is an inhalable powder of virus-like particles, which mimic the native viruses, without containing any viral genetic material. With simple self-administration and no need for cold chain infrastructure, it is believed that inhaled powder vaccines for RSV not only offer the "best route of immunisation" via the mucosal surface but could also increase patient acceptance, extend product shelf life, and offer easier distribution, making them valuable tools in the event of an emerging epidemic.

**Inhalable Proteins for RSV**

Beyond vaccines, other key therapies include recombinant proteins and monoclonal antibodies. One protein in particular, interferon, has come to the fore across a wide range of infectious diseases for its broad-

*MRX002+ (HFA pMDi see-through vial)*

*MRX004 (Soft Mist Inhaler)*

spectrum antiviral and immune-modulatory effects. In RSV, an inhaled interferon-alpha1b protein was in active Phase III trials in 2024, was awarded a Breakthrough Therapy designation, and had an IND approved, enabling clinical trials to commence.

UK-based Synairgen is investigating its lead asset SNG001, inhaled interferon-beta, in a large Phase II trial. Initiated in September 2025, the INVENT study investigates SNG001 in mechanically ventilated patients with severe viral lung infections including RSV. Earlier this year, Synairgen raised £18 million to fund the Phase II trial.

Competition could also come from a Phase I trial for an interferon-beta in RSV, COVID-19, and influenza in development by another company. Groundbreaking bioprocessing advancements have overcome traditional stability challenges during the API development, opening the doors to more user-friendly formulations. The molecule is designed for administration via a dry powder inhaler, offering easy storage, simple administration, portability, and accessibility.

Meanwhile, another company is currently exploring its lead asset based on a sialic acid-binding protein, in a wide range of respiratory viruses. Delivered intranasally, it binds to sialic acids on host cells in the nose, blocking the entry of viral cells to the respiratory system. It is currently in preclinical development for RSV and is also showing promise in Influenza A.

**A Future of Innovation Lies Ahead**

After a disastrous start, followed by decades of inactivity, RSV drug development is finally gaining momentum, with new vaccines, longer-lasting monoclonal antibodies, and even a wider range of antivirals now starting to close the treatment gap and prevent the infection in at-risk individuals. There is still a way to go, however, with no paediatric vaccines yet available.

As innovation takes off, inhaled drug delivery is emerging as an attractive option for its ability to deliver potent agents directly to the lungs. As the pipeline of nebulised therapies advances, these aerosolised formulations have the potential to be converted into more convenient, user-friendly devices such as the MRX004 soft mist inhaler. Meanwhile, if companies can overcome the stability challenges that lie ahead, dry powder inhaler-based delivery could come to the fore, with devices such as the MRX003 and MRX006 further accelerating innovation in this growing space.

*MRX003 (Capsule Dry Powder Inhaler)*

*MRX006 (Multidose Dry Powder Inhaler)*

**REFERENCES**


1. https://www.heart.org/en/health-topics/rsv
2. https://www.who.int/news-room/fact-sheets/detail/respiratory-syncytial-virus-(rsv)
3. https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2021/07/phe-ref-ra-21.035-palivizumab-passive-immunisationagainst-respiratory-syncytial-virus-rsv-in-at-risk-pre-term.pdf
4. https://www.cdc.gov/rsv/adults/index.html
5. https://www.infectionpreventioncontrol.net/uk-launches-worlds-first-national-rsv-vaccination-program/



**Philippe Rogueda**

Philippe co-founded Merxin Ltd in 2015. His expertise spans across multiple facets of the inhalation field, particularly with dry powder and soft mist inhalers. Philippe's passion lies in the development of soft mist inhaler technology, particularly for biologics, which he believes holds immense potential to revolutionise the delivery of inhaled therapies. With over a decade of experience in the inhalation sector, Philippe's deep knowledge and innovative approach to inhalation technologies make him a key figure in advancing medical device development for improved drug delivery systems.

**Merxin Ltd**
**WE MAKE INHALERS**