The Upcoming Inhaled Biologics Therapies: *A Data-Driven Analysis of the Inhaled Biologics Clinical Pipeline*

In Short

The pipeline is filling up fast. 346 trials registered in 2025 and more than 100 already in 2026, with 127 InhBioX candidates now in Phase II and III.

Infectious disease leads, and vaccines dominate. Infectious disease and COPD are the main indications, and 60% of Covid-19 trials are vaccines.

Synthetic peptides top the molecule list, followed by recombinant proteins and recombinant vector vaccines.

The device gap is the opportunity. Nasal accounts for 57% of the delivery choice because of late phase COVID vaccines, and there is not a single portable inhaler candidate in Phase III: this is a huge opportunity.

Terminations of clinical trial are rarely about the science. Of 68 discontinued trials, 33% stopped for recruitment challenges and 19% for business or strategic reasons. Adverse events, lack of efficacy and regulatory issues accounted for just 10% each.

Biotechs are the creation engines, while Big Pharma has specialised in filing and commercialisation.

The inhaled biologics field is no longer emerging; it has emerged. A structured interrogation of commercial and clinical trial databases identified 346 inhaled biologic trials commencing in 2025 and over 100 already registered in 2026, with 117 candidates in Phase II and III. Biologics now represent 58% of the inhaled clinical pipeline: biologics lead inhaled pipelines. Three molecule classes lead, commanding 40% of the pipeline between them: i. synthetic peptides (16%), ii. recombinant proteins (14%), and iii. recombinant vector vaccines (10%). The pipeline concentrates on two mechanistic strategies: a. receptor agonism and, b. ion-channel activation.

Infectious diseases dominate the indications, with cystic fibrosis, RSV and idiopathic pulmonary fibrosis, the principal unmet needs. Innovation is, above all, a small-biotech story: 57% of Phase I trials are led by private companies. Analysis of discontinued programmes (N=68) shows that inhaled biologics do not fail on science: recruitment (38%) and regulatory issues (14%) dominate terminations, while adverse events and lack of efficacy together account for only 19%.

Biologic drugs have transformed the treatment of chronic and infectious disease, but their delivery has remained dominated by injection because large molecules do not survive the gastrointestinal tract.[1] Two upstream forces are now reshaping this position. First, the science of inhaled biologics, mechanisms, targets and the behaviour of macromolecules in the airway, has been studied intensively. Second, the pace and expertise of biologics manufacturing have accelerated, allowing candidates to be produced at scale. Inhalation and nasal delivery offer a credible alternative route for local delivery to the respiratory epithelium, and for systemic exposure where it is required.

The objective of this work was to quantify the public and searchable inhaled biologics clinical landscape from clinical and commercial databases to establish, on the evidence, what therapies might be coming and when. We looked at volume, molecule classes, targets, indications, sponsors, delivery routes and the specific therapies being advanced.

Methods

For brevity, inhaled biologics are referred to throughout as "InhBioX". Commercial and clinical trial datasets were extracted from GlobalData's market and clinical intelligence platforms.[2] Records were verified against public sources (regulatory registers, company disclosures and the peer-reviewed literature) and checked against drug names and sponsoring organisations.

Candidates were classified by molecule type, biological target, therapy area, development phase, sponsor type and geography, and delivery route. Phase II candidates were mapped against published Phase Transition Success Rates to weigh their probability of advancing, as defined by the GlobalData database. All figures are drawn from published or publicly verifiable sources, and no proprietary or non-public data are relied upon.

Scale and Shape of the Pipeline

Inhalation at large is highly active: 346 new inhaled trials commenced in 2025, 162 completed, and 88 approvals were recorded. Of these approvals, 80 were Chinese generics and 99% were low-molecular-weight molecular entities. Against this backdrop the key finding is unambiguous: the present is low-molecular-weight entities, and the future is biologics (58% of the inhaled clinical pipeline). The field spans more than 680 therapies across over 350 active organisations.

Development is young and front-loaded. Approximately 100 InhBioX trials were registered in 2026. Across all InhBioX trials registered in 2025 and 2026, 34% are in Phase I and 32% in Phase II.

Above all, innovation is a small-biotech story. Sponsorship reveals a consistent hand-off: 57% of Phase I trials are led by private



#	Molecule type	Programmes	Share
1	Synthetic peptides	19	16%
2	Recombinant proteins	17	14%
3	Recombinant vector vaccines	12	10%
4 =	Live-attenuated vaccines	9	7%
4 =	Monoclonal antibodies	9	7%
6	Gene therapies (mRNA + viral vector)	8	7%
7	Exosomes / extracellular vesicles	6	5%
–	Unclassified / undisclosed	18	15%

Table 1. InhBioX candidates by molecular class (Phase II/III). A further 24 programmes (20%) could not be assigned to a class and are not listed.

companies, whereas 74% of Phase II and III trials are led by institutions. Many of these trials are part of a COVID tail-off, hence the dominance of institutions. Small biotechnology companies and academic groups originate and create these programmes; large pharmaceutical companies buy assets late and act principally as the regulatory and commercial or marketing vehicle that carries them to market.

The United States leads by trial count, but growth is concentrated in Asia-Pacific, and innovation is now genuinely global, exemplified by the outlier NeuroEPO, Cuba's intranasal therapy for Parkinson's disease.

The Therapies Now Advancing

A cohort of named InhBioX candidates is progressing towards the clinic and market (Table 2). They are a heterogeneous group: Rein Therapeutics' LTI-03, a first-in-class Caveolin-1 peptide for idiopathic pulmonary fibrosis; Nano24's EXO-CD24 exosome for ARDS; and two nasal candidates, Blue Lake's PIV5-vectored BLB-101 for COVID-19 and Ethris's IFN-λ mRNA ETH47 for asthma and COPD.



A distinct cystic fibrosis gene-therapy race is under way – ReCode's CFTR mRNA RCT2100, and the AAV programmes SP-101 (Spirovant) and 4D-710 (4DMT). Not all survive: Boehringer Ingelheim's lentiviral BI 3720931 for cystic fibrosis was discontinued in 2026, a reminder that this is a real pipeline with real casualties.

Delivery Routes

57% of Phase II/III candidates use the nasal delivery route, with strong regional variation (Europe 71% nasal; Asia-Pacific leaning pulmonary).

This is highly skewed by COVID vaccines: when all clinical trials are considered, and only trials specifying a route are counted, the nasal route drops to 22.8% and the inhaled route to 24% (unspecified inhaled 17.2%, nebulisers 5%, DPIs 1.8%).

Among Phase III candidates, the identified routes are nebuliser, nasal spray and a single sublingual product; no portable inhaler candidate was identified among the novel biologics.

This is a legacy pattern from COVID trials rather than an optimal or future one. Nebulisers are chosen by default not by design: they are the entry point for Phase I, not the destination, and are routinely dismissed from Phase II onwards, forcing programmes to repeat and bridge earlier studies at avoidable cost and delay. This is a costly and poor strategy that does great disservice.

As a delivery technology for chronic therapy they belong to the last century, providing neither the formulation stability across manufacturing and storage nor the portability and adherence that these medicines will require at scale. The history of inhaled delivery is one of maturation, with pressurised metered-dose inhalers and nebulisers giving way to dry powder and portable devices as each molecule class stabilised, and there is little reason to expect inhaled biologics to be an exception.

The absence of a portable inhaler in Phase III is therefore best read as a lag that will close, not a permanent feature: once a biologic can be stabilised in a portable format, as synthetic peptides and spray-dried proteins increasingly show, the route follows the molecule – a spray-dried, room-stable oxytocin powder for postpartum haemorrhage being one such example among several.

Inhaled biologics do not, for the most part, fail on the science. Of 68 discontinued programmes only 21 record a specific reason. Among those, recruitment challenges are the single largest cause at 38%, followed by regulatory issues at 14%. Adverse events and lack of efficacy together account for 19%, half the recruitment figure.

This pattern is consistent with the sponsorship hand-off above: programmes originated by small companies and carried by larger pharmas are exposed to recruitment difficulty and shifting strategic priorities far more than to any failure of the molecule.

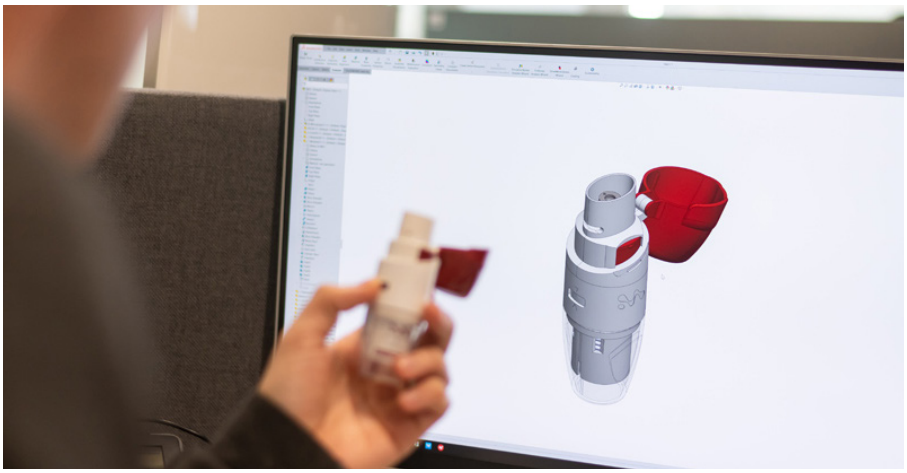
Summary & Conclusions

Analysis of clinical and commercial databases shows that the inhaled biologics pipeline

Company / Programme	Molecule	Indication	Route	Phase
Nano24 / EXO-CD24	CD24 exosome	ARDS	Nebuliser	IIb
Blue Lake / BLB-101	PIV5 vector	COVID-19	Intranasal	IIb
Ethris / ETH47	IFN-λ mRNA	Asthma/COPD	Intranasal	IIa
Rein Ther. / LTI-03	Caveolin- 1 peptide	IPF	DPI	II
4DMT / 4D-710	AAV (A101 capsid)	Cystic fibrosis	Nebuliser	II
Spirovant / SP-101	AAV, CFTR transgene	Cystic fibrosis	Nebuliser	I/II
ReCode / RCT2100	CFTR mRNA	Cystic fibrosis	Nebuliser	Ib

Table 2. Selected advanced and upcoming InhBioX candidates





is real, substantial and moving on defined timelines: 346 trials in 2025, over 100 in 2026, and 117 in Phase II/III.

Biologics now represent 58% of the inhaled clinical pipeline: biologics lead inhaled pipelines. The field is led by three molecule classes (synthetic peptides, recombinant proteins and vector vaccines, 40% between them) and concentrates on two target strategies, receptor agonism and ion-channel activation.

Innovation is a small-biotech story: private companies and institutions originate these programmes, while large pharmaceutical companies buy late-stage assets and act as the regulatory and commercial vehicle.

Critically, inhaled biologics do not fail on the science; recruitment and regulatory issues, not efficacy or safety, are the dominant reasons programmes are stopped. A cohort of named therapies is advancing towards patients.

Those late-stage candidates are today tethered to nebulisers, a last-century technology chosen by default rather than by design and, on the evidence of how every previous inhaled class has matured, an interim step rather than the endpoint.

The inhaled biologics therapies are coming: named, dated, and largely on schedule.



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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.

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