



# TranspireBio

Delivering Breaths for Life

**We are a clinical-stage global specialty biopharmaceutical company applying our extensive inhalation expertise to develop innovative medicines with improved therapeutic outcomes for a wide range of diseases with unmet needs.**



# Our Strategies: Driving Innovation through Inhalation

## Advancing a Two-Pronged, Diversified, Risk Mitigated Inhalation Portfolio

### Generic Inhaled Portfolio

Combining our platform technologies with our deep expertise to develop and commercialize complex, high-value generic inhaled products

- Generate near term cash flow and growth
- Validate our platform technologies for innovative product development
- Improved probability of success with demonstrated bioequivalence

### Innovative Inhaled Portfolio

Targeting molecules with known mechanisms of action to treat diseases with high unmet needs

- Clinical benefits are well-defined to improve the chance of clinical and commercial success
- Our proprietary technologies are essential to maximize clinical outcomes

Ongoing Opportunities for Partnership and Co-Development Deals Across Both Portfolios

# Why Inhalation?

## Inhalation Enables Rapid and Efficient Delivery of Medicines

- Effective targeting of lungs for local lung diseases
- Bypasses first-pass effects in the gastrointestinal tract and liver
- Facilitates ultra-rapid drug transport directly from the lungs or nasal cavities, across blood-brain barrier to the brain
- Overall improvement to safety profile compared to other routes of delivery



# Inhalation is Applicable to Large, Growing Markets in Different Therapeutic Areas for Both Orphan and Chronic Conditions

## Chronic lung diseases

Interstitial lung diseases(e.g. IPF)

**~4.7M patients<sup>1</sup>, ~\$2.0B<sup>2</sup> globally**

Pulmonary arterial hypertension (PAH)

**~120K<sup>3</sup> patients, ~\$7.5B<sup>4</sup> globally**

## Asthma and COPD

Asthma

**~300M patients<sup>5</sup>, \$25.7B<sup>6</sup> globally**

COPD

**~480M patients<sup>7</sup>, ~\$19.8B<sup>8</sup> globally**

## Neurological diseases

Glioblastoma

**~250K patients<sup>9</sup>, \$2.6B globally<sup>10</sup>**

Parkinson's related Psychosis & related neurological diseases (seizures, etc.)

**~3M patients<sup>11</sup>, ~\$4.9B<sup>12</sup> globally**

1. [Frontiers in Medicine July 2023](#) 2. [The Business Research Company January 2024](#) 3. [Prevalence, incidence, and survival of pulmonary arterial hypertension: A systematic review for the global burden of disease 2020 study - PMC \(nih.gov\)](#) Orphanet: Idiopathic pulmonary arterial hypertension 4. [Pulmonary Arterial Hypertension Market To Reach USD 12.2 Billion By 2032 | DataHorizon Research \(yahoo.com\)](#) 5. [The Global Asthma Report 2022](#) 6. [Precedence Research 2024](#) 7. [JAMA Network Open December 2023](#) 8. [Transparency Market Research October 2022](#) 9. [Brain and Spine, 2023; 3: 101775](#) 10. [Fact.MR 2021](#) 11. [World Health Organization August 2023](#) 12. [Spherical Insights June 2024](#)

# High Entry Barriers Leading to Limited Competition in the Inhalation Space

- The development of complex drug-device combinations requires highly specialized skills, which are hard to come by in the industry
- The manufacturing of inhaler devices and drug-device combinations requires custom-made equipment, which takes long lead times (ca. 12-24 months) with significant investments to develop, construct and qualify by specialized CDMOs
- Regulatory requirements are more stringent for drug-device combinations than other dosage forms, increasing development cost and time to market
- Limited competition leads to high return on investment for Transpire Bio investors.



We have all the key elements to capitalize on the vast potential of inhalation therapies: people, facility, investment and validated technologies



# Leadership: Highly Seasoned Management Team

200+ Years Combined Experience Spanning Inhalation Discovery to Commercialization



**Xian-Ming Zeng, PhD**

Chief Executive Officer

**30+ years industry and leadership experience**



**Mark S. Lepore, MD, FAAAAI**

Chief Medical Officer

**~30 years working with respiratory diseases**



**Abhishek Gupta, PhD, PMP**

Chief Scientific Officer

**25+ years of product development & business experience**



**Kevin McCabe**

General Counsel

**25+ years of legal & business experience**



**Stuart Loesch**

Chief Commercial Officer

**30+ years of commercial and leadership experience**



**Axel Perlwitz, PhD**

Chief Regulatory Affairs Officer

**25+ years of inhalation experience**



**Michael Goller, PhD**

Chief Project Officer

**20+ years of inhalation experience**



**William Schachtner**

Chief Technical Operation Officer

**40+ years of industry experience**



# Transpire Bio's State-of-the-Art US Based cGMP Laboratory Facilities



# Recent Co-Development Agreement Signed with Major Public Bio-Pharmaceutical Company

Public company sought out Transpire Bio as a development partner after extensive due diligence, validating Transpire Bio's SMI\* platform and its ability to extend its technology to innovative molecules.

## A multi-billion-dollar market with a large and growing unmet need in lung disease

- Transpire Bio retains commercial rights in large global markets (including China and South America)
- Tiered royalty arrangement and nine-digit milestone payments
- Planning for an NDA submission as early as late 2026

\*SMI = soft-mist inhaler

Transpire to cover CMC costs, partner to cover clinical costs; Transpire to deliver clinical and commercial supply to partner; Proceeds from partnership to be allocated towards expanding in-house high-volume manufacturing capacity.



# Innovative Product Pipeline

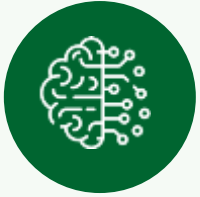


# Our Innovative Pipeline Capitalizes on the Unique Characteristics of Inhalation Therapies

Indication	US Epidemiology	Unmet Need	Competition	Total Addressable Market
<b>TRSB001, Parkinson's Disease – Related Psychosis</b>	~600k	High	Low	\$29.2B
<b>TRSB002, Glioblastoma</b>	Orphan	Very High	Low	\$9.7B
<b>TRSB003, Idiopathic Pulmonary Fibrosis</b>	Orphan	High	Low	\$27.8B
<b>TRSB004, Pulmonary Arterial Hypertension</b>	Orphan	High	Low	\$11.5B

**Parkinson's  
Disease-Related  
Psychosis**  
TRSB001

# Overview of Parkinson's Disease Related Psychosis (PDP)



## Description:

A neurodegenerative disorder that primarily affects the dopaminergic (motor) system

Non-motor symptoms that are debilitating and develop in the later stages of Parkinson's Disease

Affects up to 60% of all Parkinson's patients over their lifetime<sup>1</sup>

## Current Standard of Care:

NUPLAZID® is the first and only approved drug.

Off-label, second-generation antipsychotics are also used.

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## Unmet need:

With only one FDA approved product, off-label use of older drugs is common with varying success rates.

KOL feedback regarding efficacy of NUPLAZID is mixed, underscoring the unmet need.

1. [\*Innovation in Clinical Neuroscience\* January 2022](#)

# Parkinson's Disease Related Psychosis (PDP)

## PDP Market Opportunity

TAM

**\$29.2 Billion**

(U.S. market only)

GROWTH

Market forecasted to grow

**2.6% CAGR<sup>1</sup>**

from 2024 to 2034

INSURANCE COVERAGE

**Yes**

PRICE/MONTH PER PATIENT

**\$4,880**

## LARGE & GROWING UNMET NEED in United States



**1,000,000<sup>2</sup>**

People living with  
Parkinson's Disease



**600,000<sup>3</sup>**

Up to 60% of  
Parkinson's patients  
have Related Psychosis

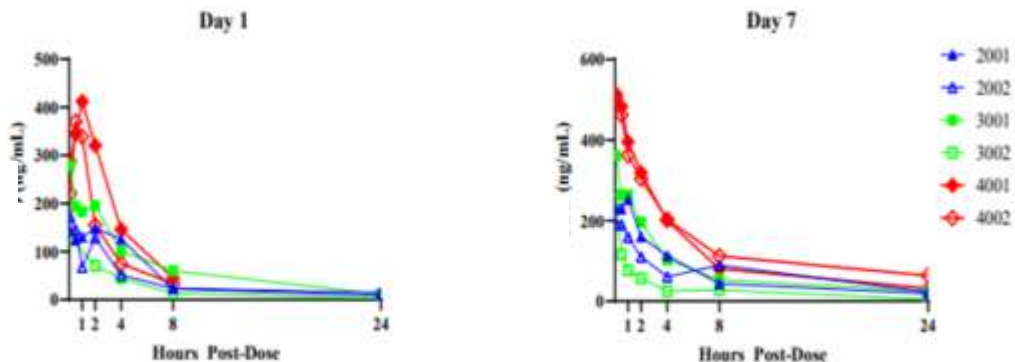
1. <https://www.einpresswire.com/article/702569715/parkinson-s-disease-psychosis-market-size-analysis-industry-statistics-and-latest-insights-till-2034> 2. <https://www.parkinson.org/understanding-parkinsons/statistics>  
3. *Innovation in Clinical Neuroscience* January 2022

# Proof of Concept Pre-Clinical Data

Demonstrated safe delivery of high concentrations of TRSB001

FY23-160AB: Dose Range Finding and 7-Day Repeat Dose Toxicity Study of TRSB001 in Beagle Dogs via Face Mask Inhalation

TRSB001 Concentrations in Plasma (Days 1 and 7)



## Pre-Clinical Studies

- 14-Day Repeat Dose Inhalation Toxicity Study of TRSB001 in Propylene Glycol using Sprague-Dawley Rats (Q2 2024)
- Single-Dose Inhalation Pharmacokinetics Study of TRSB001 Liquid and Dry Powder Formulations using Sprague-Dawley Rats (Q3 2024)
- 14-Day Repeat Dose Inhalation Toxicity Study of TRSB001 in Dry Powder Formulations using Sprague-Dawley Rats\*
- 14-Day Repeat Dose Inhalation Toxicity Study of TRSB001 in Dry Powder Formulations using Beagle Dog\*

## Preliminary Conclusions

- Delivery supports targeting known pathways and processes
- TRSB001 dry powder delivered via inhalation can achieve high concentrations in the brain and plasma in 2 species
- Adverse events level (NOAEL) permits human dosing margins that permit dosing in expected efficacious range

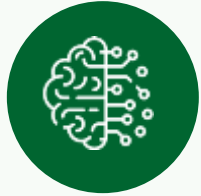


# **Glioblastoma**

## **TRSB002**



# Overview of Glioblastoma



## Description:

A malignant tumor affecting the brain or spine.

Median survival is 15–18 months.<sup>1</sup>

## Current Standard of Care:

Maximal surgical resection

Radiotherapy

Chemotherapy (typically, temozolomide)

Recurrences are treated with additional radiotherapy, chemotherapy or other approved drugs.<sup>2</sup>

## Unmet need:

No therapeutic advancements in the past two decades

Conventional therapy resistance

Neurotoxicity

Standard of care only yields 15–18 months median survival

1. The four approved drugs for GBM are temozolomide, lomustine, bevacizumab and carmustine

2. Rupesh Kotecha et al., Key Clinical Principles in the Management of Glioblastoma. JCO Oncol Pract 19, 180–189(2023).

# Glioblastoma is the Most Common Primary Malignant Brain Tumor in Adults

## Glioblastoma Market Opportunity

TAM

**\$9.7 Billion**

(U.S. market only)

GROWTH

Market forecasted to grow

**8.6% CAGR<sup>1</sup>**

from 2024 to 2032

INSURANCE COVERAGE

**Yes**

PRICE/MONTH PER PATIENT

**\$17,276**

## LARGE & GROWING UNMET NEED in United States



**240,124<sup>1</sup>**

6.94/100,000 Incidence  
of Malignant Brain  
Tumors



**111,390<sup>2</sup>**

3.19/100,000  
incidence of GBM



**3%-15%<sup>3</sup>**

GBM as % primary  
CNS tumors in  
children



**56K**

serviceable  
market  
Transpire Bio

1. <https://www.gminsights.com/industry-analysis/glioblastoma-multiforme-treatment-market>
2. <https://pubmed.ncbi.nlm.nih.gov/37793125/>
3. <https://pubmed.ncbi.nlm.nih.gov/28521700/>
4. <https://pubmed.ncbi.nlm.nih.gov/21220190/>

# Proof of Principal: Murine Animal Model

## Study:

In conjunction with researchers at Augusta University, an animal model of GBM was established

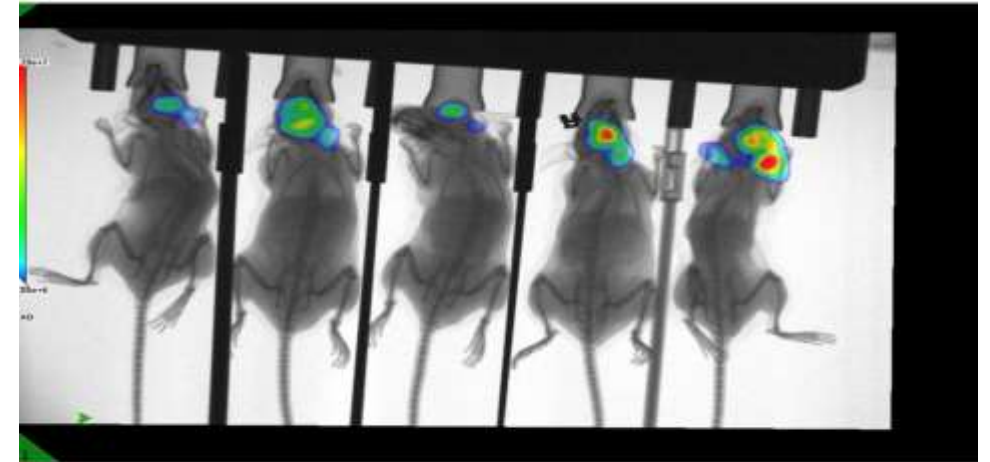
## Design:

Human GBM cells were implanted in mice orthotopically. Tumor growth was confirmed via bioluminescence on Day 8. TRSB002 via inhalation was delivered to the animals from Day 8.

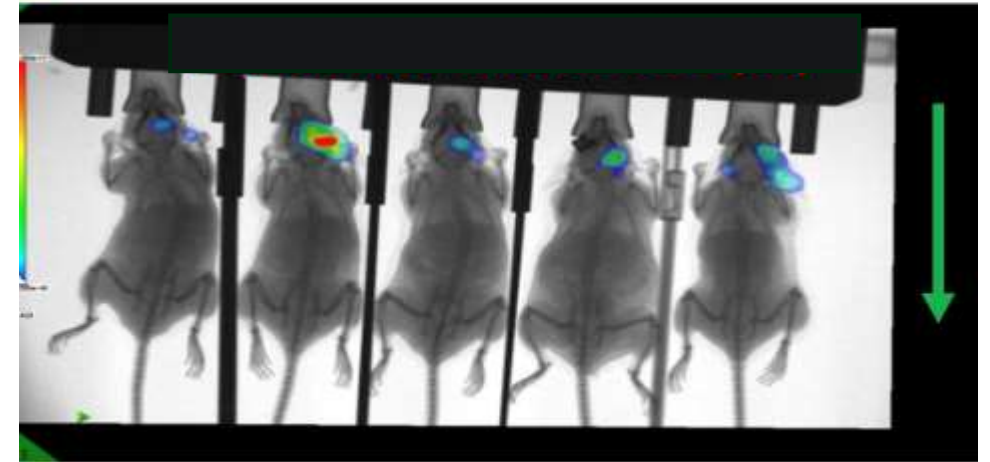
## Results:

Animals treated with inhaled TRSB002 demonstrated a significant reduction of the size of the tumors on Day 17

**Following  
Implantation  
(Day 8)**



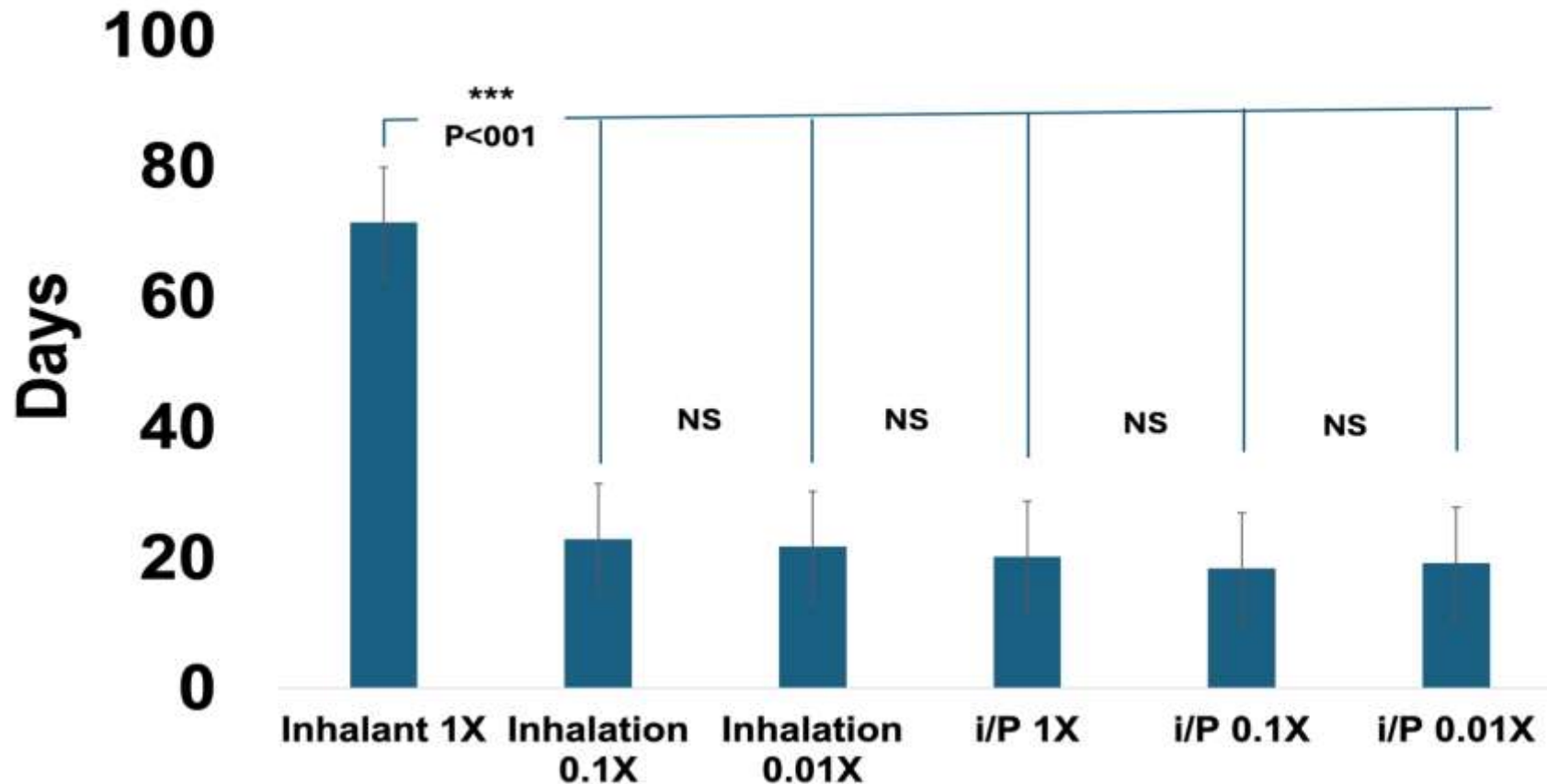
**Post  
Treatment  
(Days 8-17)**



**Significant reduction in tumor size**

# Proof of Principal: Murine Animal Model

## Survival Chart



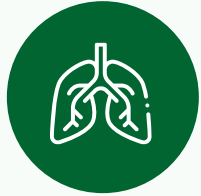
### Results:

- In addition to a significant treatment effect in tumor size, animals treated at the starting dose demonstrated an improvement in survival
- In contrast to inhalation administration, intraperitoneal administration had no effect

**Idiopathic  
Pulmonary Fibrosis  
TRSB003**



# Overview of Idiopathic Pulmonary Fibrosis (IPF)



## Description:

An orphan lung disease that causes shortness of breath and occurs when lung tissue becomes damaged and scarred; median survival: 2-3 years<sup>1</sup>

## Approved Treatments:

OFEV<sup>®</sup> (nintedanib).

ESBRIET<sup>®</sup> (pirfenidone).

Both tyrosine kinase inhibitors

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## Unmet need:

Current Treatments have challenges due to GI adverse events and liver toxicity

1. Ley B, Collard HR, King TE Jr. Clinical course and prediction of survival in idiopathic pulmonary fibrosis. Am J Respir Crit Care Med. 2011 Feb 15;183(4):431-40.

# Idiopathic Pulmonary Fibrosis (IPF)

## IPF Market Opportunity

TAM

**\$27.8 Billion**

(U.S. market only)

GROWTH

Market forecasted to grow

**6.1% CAGR<sup>1</sup>**

from 2024 to 2034

INSURANCE COVERAGE

**Yes**

PRICE/MONTH PER PATIENT

**\$12,995**

## LARGE & GROWING UNMET NEED in United States



**650,000<sup>2</sup>**

People affected by  
Interstitial Lung Disease



**214,000<sup>2</sup>**

Idiopathic Pulmonary  
Fibrosis accounts for 1/3  
of ILD cases

1. <https://www.biospace.com/idiopathic-pulmonary-fibrosis-market-size-to-reach-usd-6-906-1-million-by-2034-impelled-by-strong-drug-pipeline>

2. <https://jamanetwork.com/journals/jama/article-abstract/2817849>



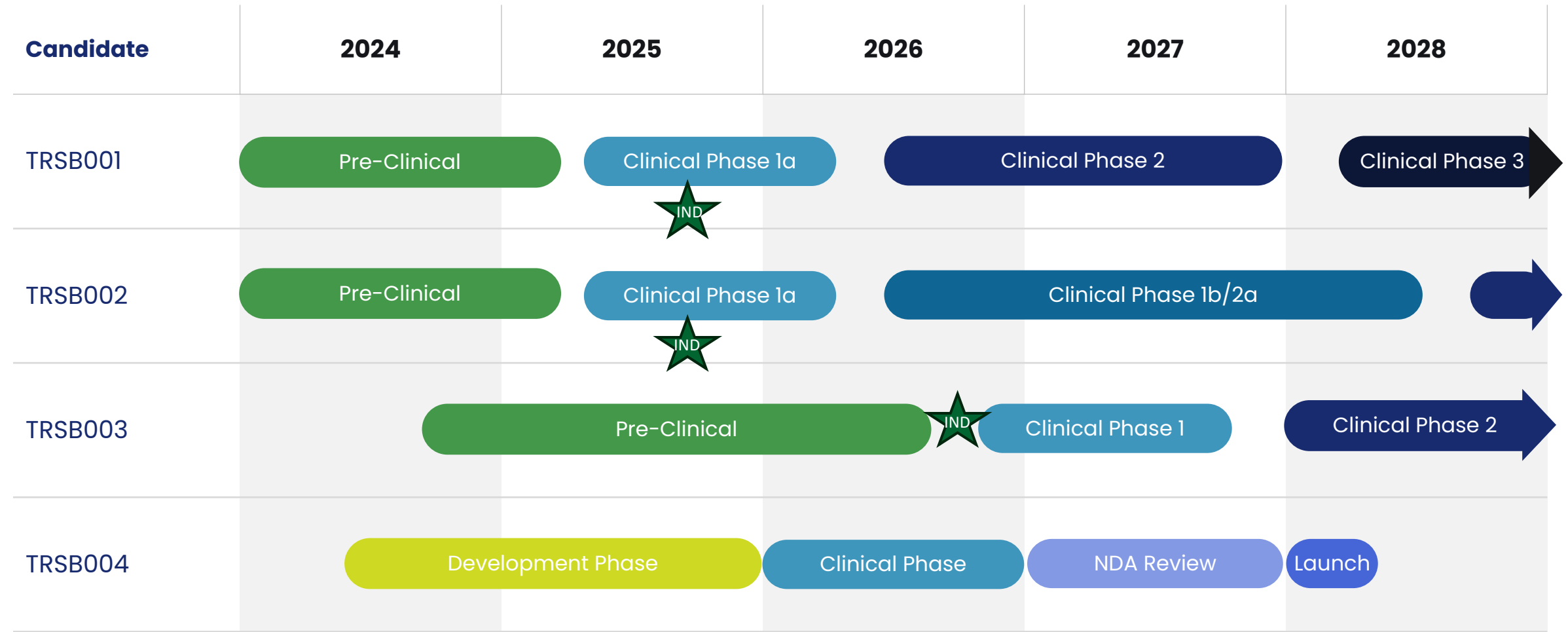
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# Upcoming Catalysts



# Innovative Portfolio Development Timeline

## Projected Milestones through 2028





# Supporting Revenue



# Asthma and COPD Markets Represent an Opportunity to Leverage Expertise of Transpire Bio and bring Cost-Effective Medicines to a Market Where Technology is a Barrier

## Asthma and COPD Markets

TAM (Combined)

**\$131.4 Billion**

(U.S. market only)

GROWTH

Asthma market forecasted to grow

**5.4% CAGR<sup>1</sup> (2024-2033)**

COPD market forecasted to grow

**5.1% CAGR<sup>2</sup> (2022-2030)**

INSURANCE COVERAGE

**Yes. Tier 1**

Gx PRICE/MONTH PER PATIENT

Asthma (Average price per month)

**\$238.10**

COPD (Average price per month)

**\$404.40**

## LARGE & GROWING UNMET NEED in United States



**16,000,000<sup>3</sup>**

Patients diagnosed with  
COPD



**28,000,000<sup>4</sup>**

Patients diagnosed with  
Asthma

1. <https://www.biospace.com/asthma-therapeutics-market-size-to-hit-usd-45-96-billion-by-2033>

2. [https://www.insights10.com/report/us-chronic-obstructive-pulmonary-disease-copd-therapeutics-market-analysis/?srsltid=AfmBOor7w7xhSFVDXHHrMDT9AFJD2R0rNn\\_Vw40LaW74SfdQRT79pCBn](https://www.insights10.com/report/us-chronic-obstructive-pulmonary-disease-copd-therapeutics-market-analysis/?srsltid=AfmBOor7w7xhSFVDXHHrMDT9AFJD2R0rNn_Vw40LaW74SfdQRT79pCBn)

3. <https://www.cdc.gov/cdi/indicator-definitions/chronic-obstructive-pulmonary-disease.html>

4. <https://aafa.org/asthma/asthma-facts/>

# We are Applying our Platform Technologies To Existing Inhalation Medicines for Asthma and COPD and Beyond...

Transpire Bio is developing multiple products in these franchises and beyond

Transpire Bio's Rollingstar™ DPI platform can be utilized for the franchise below as well as other molecules\*



Transpire Bio's Springboard™ SMI Platform can be utilized for the franchise below as well as other molecules\*



\*Molecules can include small molecules, polypeptides, protein, oligoneucleotides, biologics and vaccines

# Proprietary Delivery Platforms Agnostic to Therapy and Inhaler

Platform flexibility supports both innovative and substitutable pipelines

## Prototypes In Development



Rollingstar™ Springboard™

## Clinical Stage Assets

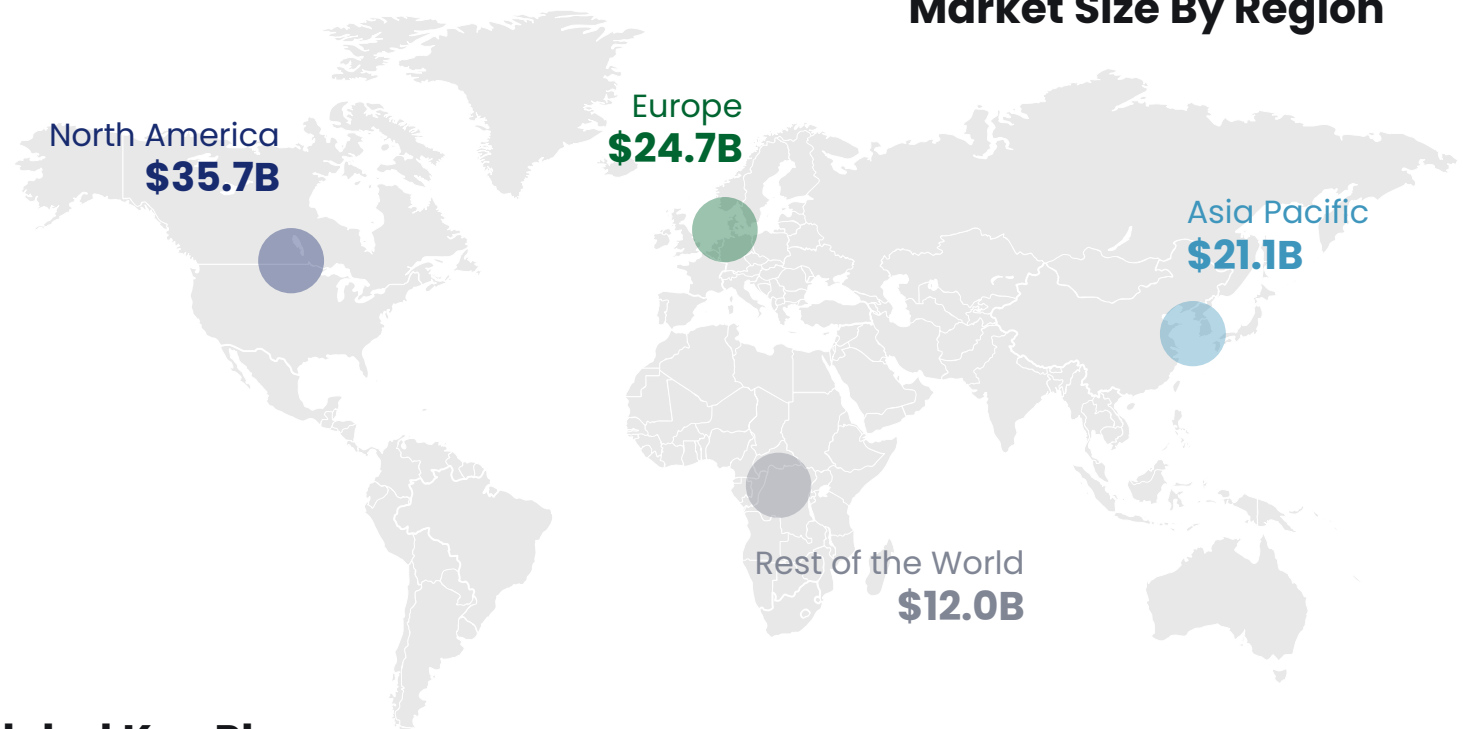
# Addressing Large and Growing Asthma and COPD Markets With Cost-Effective Options Will Fund Transpire Bio's Core Development Programs

Increasing prevalence and incidence rate of Asthma and COPD.

Rising activities by global key players.

Expansion of inhalation drug delivery to non-lung indications.

## Market Size By Region



## Global Key Players



# Robust Patent Portfolio – Pending Protections to 2044

## 61 pending utility patent applications

- *Anticipated expiration dates between 2042-2044*
- *Cover both innovative and generic products*

## 2 pending design applications

- *Anticipated expiration in 2039*
- *Cover dry powder inhaler and soft-mist inhaler designs*

## 2 pending trade dress applications

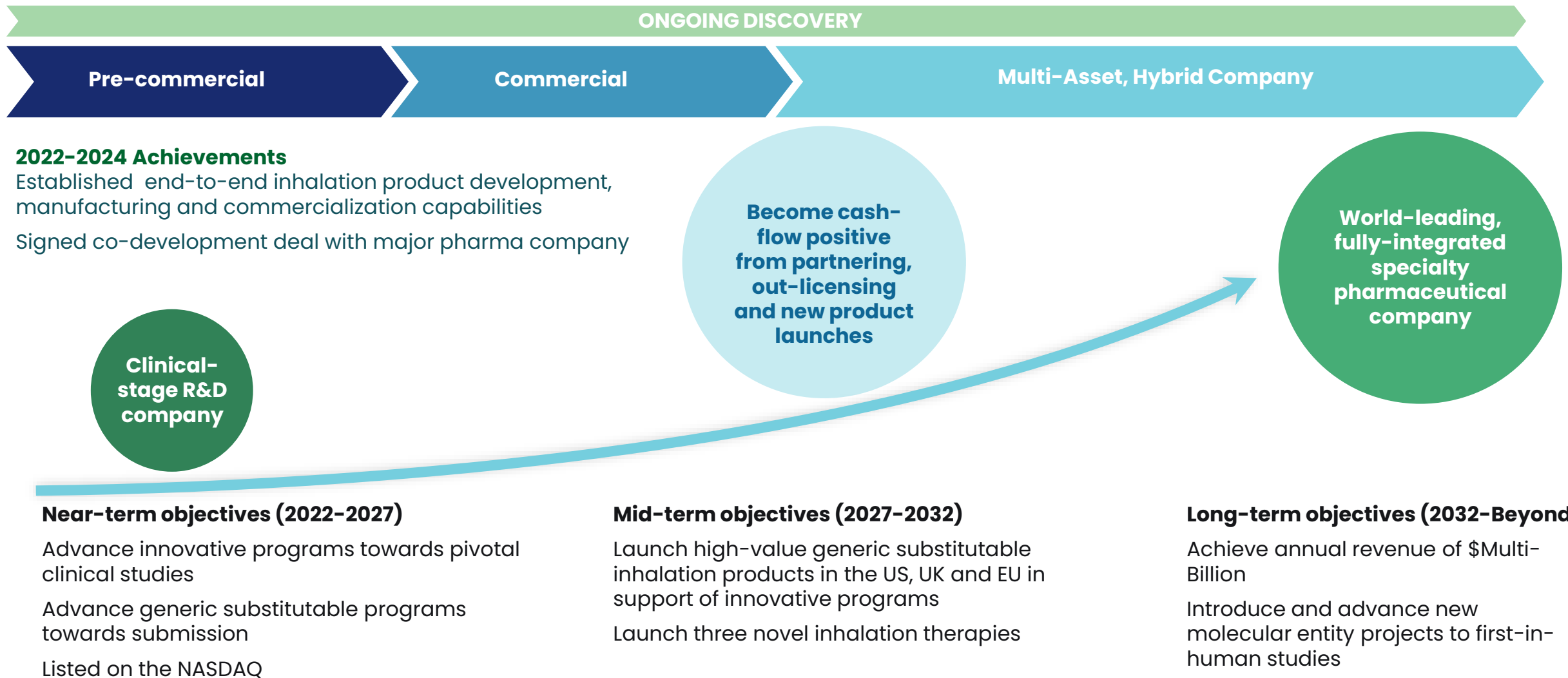
## 18+ pending trademark applications



# Outlook



# Rapid Execution of Our Business Model Towards Becoming a Leading Global Specialty Bio-pharmaceutical Company in Inhalation



# Transpire Bio is Poised to Capitalize on the Vast Potential of Inhalation Therapies by Developing Transformative Products with its Risk-Mitigated Approach

## Highly experienced leadership with expertise in all inhalation technologies

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200+ years collective team experience spanning all phases of development and commercialization of complex inhalation drug-device combination products.

## Well-Capitalized with Validating Partnerships

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Recent development agreement with major biopharma partner validates Transpire Bio's technologies and capabilities and provides endorsement for inhalation as a preferred mode of delivery.

Additional partnerships leveraging technologies and platforms with partner molecules can provide non-dilutive capital to support in-house development of innovative product candidates.

## Diverse Assets in a Risk-Balanced, Innovative Pipeline

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Inhaled delivery offers inherent advantages of rapid absorption and improved safety profile with the ability to target a wide range of high-value and underserved therapeutic areas.

Candidates for delivery optimization are molecules with known mechanisms of action.

Proprietary approach is agnostic to therapeutic area and molecule.

## Lean organization supported by world-class CDMOs with specialized resources

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Capital is optimized for product development and to control operational expenses.

A close-up photograph of two hands, one from a man and one from a woman, gently holding each other to form a heart shape. The background is a soft-focus outdoor scene with greenery and pink flowers.

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for Life