

April 2025

Investor Presentation

Nasdaq: ASBP





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Outline

- Company Overview
- Product Pipeline and Planned 2025 Milestones
- Market Opportunity
- Manufacturing
- Marketing, Distribution & Sales
- Sublingual Aspirin Lead Product Candidate
- Investment Considerations



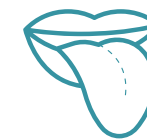
Overview – The Technology



Aspire Biopharma has developed and acquired disruptive technologies for delivering drugs and other products sublingually⁽¹⁾.



Technology delivers a soluble, fast acting granular or powder form drug formulation which has been developed by using our patent-pending methodology, and "trade secret" process.



New mechanism of action (absorption pathway) allows for rapid sublingual absorption and entry into the bloodstream.

(1) Aspire filed a patent application (No. PCT/US2024/022318) on March 29, 2024 for its low-dose aspirin. Aspirin filed a second patent on October 2, 2024 (No. 63/702,381) for its high-dose aspirin.



Technology Overview

01

Fast Acting

Powder-form medication developed using our patent-pending technology enters the bloodstream in a fraction of the time as compared to oral tablets and capsules

02

Water Soluble

Dissolves easily under the tongue

03

Dosage Management

Drugs do not first pass through the liver and are not metabolized like oral products

04

Bypasses the Digestive Tract

Eliminates adverse reactions in the gastrointestinal tract

05

Ease of Use

Easy for patient or caregiver to administer



Delivery Method

First Pass Metabolism Alternative Routes

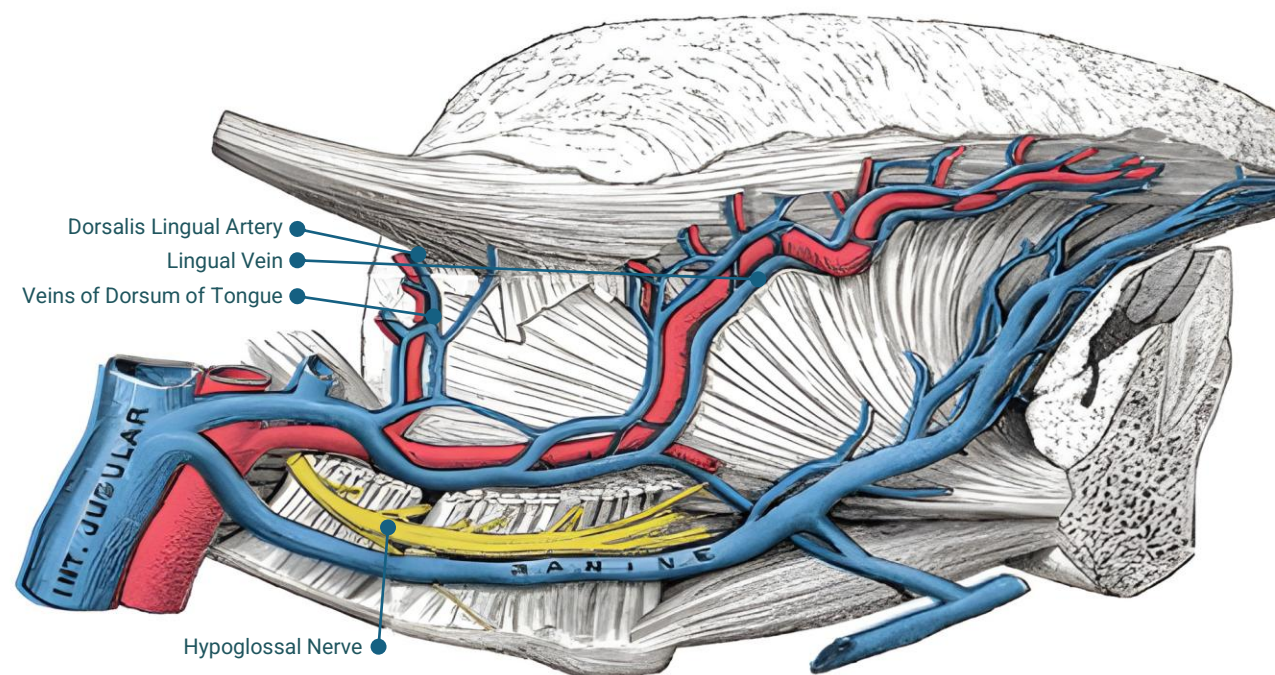
- Suppository
- Intravenous
- Intramuscular
- Inhalational aerosol
- Transdermal
- Sublingual or buccal routes

Aspire's sublingual dose form avoids the harms of various drug therapies while maintaining or enhancing benefits

- Avoid direct damage to mucus secreting goblet cells lining the GI track
- Avoid bioavailability reduction by first pass hepatic metabolism

The most common set of side effects for drugs that work inside your body involves the gastrointestinal system

Blood Supply



1. The main artery is the lingual artery
2. Tonsillar branch of the facial artery
3. Ascending pharyngeal artery

The veins drain into the internal jugular vein



Aspire Product Pipeline and Planned 2025 Milestones

Aspirin Products

High Dose

- ✓ **Commence clinical trial to evaluate the pharmacodynamic effect of a single dose of our aspirin product on platelet inhibition compared to that of standard oral aspirin in April 2025.**
- File 505(b)(2) application with the FDA end of Q2 2025
- Request “fast track” approval on its NDA for the high dose aspirin product to the FDA.
- High dose sublingually administered aspirin for pain relief (rheumatological and other pain). Building on previous clinical trial as set forth above, we anticipate seeking FDA approval in the latter part of 2025.

Low Dose

- Clinical trials in Fall 2025 of low dose sublingually administered aspirin for preventative care.

Non-aspirin Prescription Drug Products

- Testosterone formulation for sublingually administration.
- Phase 1 clinical test planned for 3Q 2025.
- Sublingual semaglutide formulation.
- Early studies of migraine relief product second half 2025.
- Erectile dysfunction (sildenafil/tadalafil) formulation development in Q4 2025.

Non-prescription Products

- ✓ **Commenced initial production of single dose pre workout supplement utilizing sublingual delivery technology.**
- **Planning consumer and safety testing during Q2 2025**
- **Pre-workout supplement features 100mg of caffeine and beta alanine (which helps reduce lactic acid buildup) and is designed to support sustained energy and mental focus, helping athletes and fitness enthusiasts maximize performance.**
- **Pre-workout product expected to launch in 2025.**
- Sublingually administered melatonin sleep-aid product expected to launch in 2025.
- Sublingually administered vitamins D, E and K 2H 2025.



Market Opportunity

Aspire believes its disruptive technology can be applied to a number of approved drugs and supplements.

Global Analgesics Market

Valued at \$47.32B in 2023 and projected to reach \$75.73B by 2032, growing at a compound annual growth rate (CAGR) of 5.39% over the forecast period 2024-2032. (Source: SNS Insider)

Global Opioid Analgesics Market

Opioid analgesics market is experiencing significant growth, with estimated projections of \$26.78B by 2034. The market is expected to grow at a CAGR of 1.5% from 2024 to 2034. (Source: Biospace)

Global Erectile Dysfunction (ED) Market

Expected to reach \$3.9B by 2034, growing at a CAGR of 6.53% during the forecast period from 2024 to 2034 (Source: Biospace)

Global Pre-Workout Market

Supplements market valued at \$19.90B in 2023. Estimated to reach \$29.77B by 2032, growing at a CAGR of 4.58% during the forecast period (2024–2032). (Source: Straits Research)



Manufacturing Strategy

A contract manufacturing strategy is being pursued with the potential for multiple supplier relationships to reduce risk and capex investments



Glatt Air Techniques

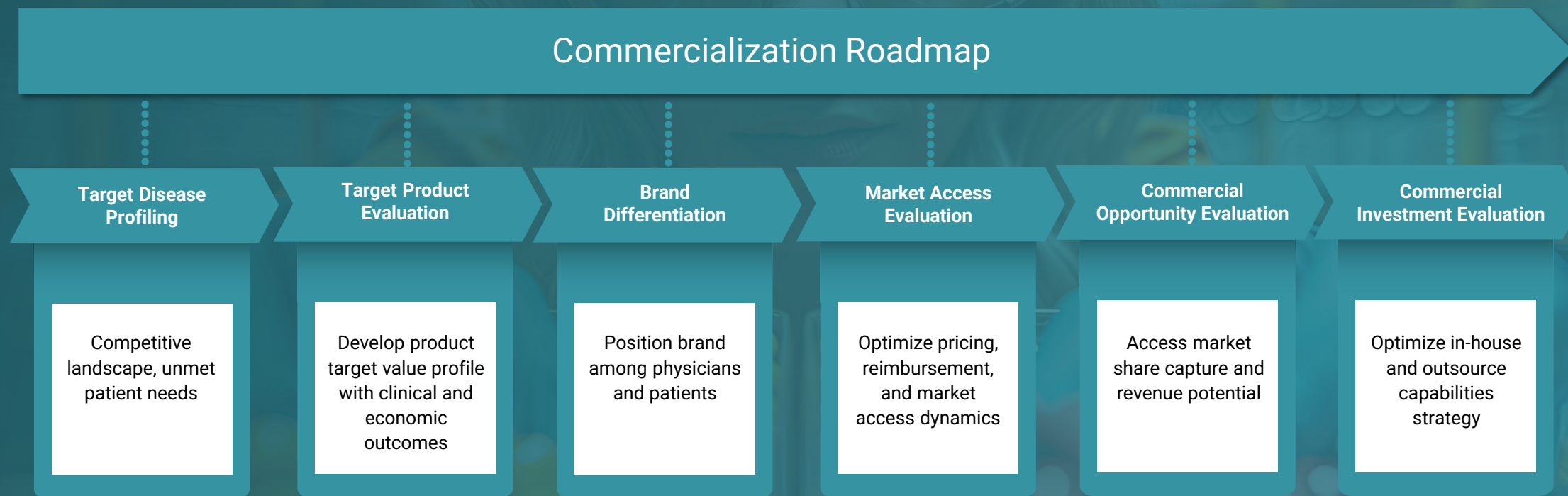
- Technical Manufacturing Development Partner
- Pharmaceutical Development Agreement signed June 2022
- Produced low-dose aspirin product and performed studies in 2023
- Produced feasibility/testing batch of high-dose aspirin in December 2024
- Performed testing on high-dose aspirin product to meet FDA requirements for human trials in Q2 2025
- Completed production of GMP batches of high-dose aspirin product for clinical trials in April 2025



Commercialization, Marketing, Distribution, Sales Strategy

Aspire plans to engage a proven commercialization partner

Commercialization Roadmap



Generally, Aspire prefers to pursue an “RX first” strategy (may depend on the drug) before launching new products into the OTC market



Sublingual Aspirin Product

Aspire's Launch

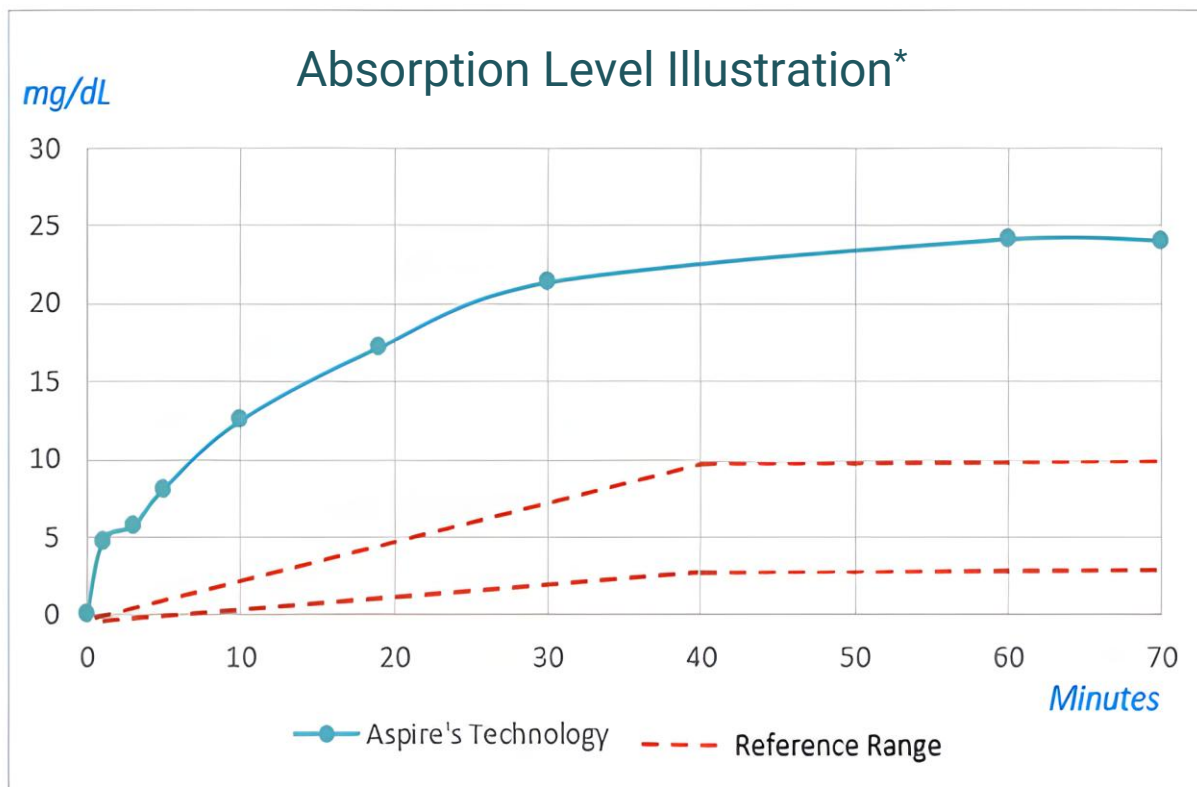


Sublingual Aspirin Product: Overview

- Addresses cardiology emergencies and pain management
- Granular or powder formulation of a soluble, fast-acting aspirin
- Developed using patent-pending formulation, and "trade secret" process

Benefits of "rapid absorption" aspirin

- Address and limit heart attack and stroke
- Allow high dose absorption for pain management including quick headache relief, post surgery, cancer pain management, and general pain relief



*Illustration based on actual test data generated in proof-of-concept study



Sublingual Aspirin Product: Background

01

Oral acetylsalicylic acid (ASA) has been used for its antithrombotic, antipyretic and anti-inflammatory properties for over 100 years

02

Aspirin is believed to be the most-studied drug, with an approval pathway that benefits from its status as known and fully understood drug

03

Aspirin-induced GI bleeding limits the long-term oral use of aspirin and hepatic first pass metabolism limits bioavailability

Aspire's novel formulation of sublingual aspirin is expected to provide rapid absorption, eliminate the GI tract side effects, and avoid first pass liver metabolism resulting in faster peak serum concentration and rapid inhibition of cyclooxygenase (Cox-1)



Sublingual Aspirin Product

Benefits:

- ASA acetylates protein targets e.g., COX-1 and COX-2 which inhibit prostaglandin synthesis and platelet aggregation which have anti-thrombotic and anti-inflammatory effects
- ASA acetylates a variety of other protein targets and biological processes: protein synthesis, cell death, infectious diseases such as COVID-19 (anti-inflammatory and anti thrombotic effects of ASA) and colon cancer

Risks:

- Oral ASA reduces mucus secretion protecting the GI lining
- ASA impairs goblet cells.
- Oral ASA undergoes first pass hepatic metabolism which reduces ASA bioavailability by about 30% (intermediate severity)

The sublingual ASA dose form is designed to avoid the risks above



Sublingual Low-Dose Aspirin Product

Glatt Formulation Testing – October 2022

Objectives:

- Develop a sublingual formulation for a novel API 'Aspirin', for the treatment of analgesic, anti-pyretic, anti-inflammatory and anti-platelet
- Conduct small scale manufacturing trials to evaluate the composition and process feasibility

Results:

- All analytical procedures resulted in consistent readings in targeted ranges, including weight, impurities, dissolution, pH, solubility, stability, and CU/BU

Sample	Batch #	Weight of Sample (mg)	Dilution in USP Water (mL)	pH
Aspirin API	22297	1861.9	5.0	2.62
Aspirin Pre-Blend (Fluid Bed Granulation)	F22006-001	1864.1	10.0	2.36
Aspirin Pre-Blend (Dry Blend)	F22006-004	1866.3	10.0	2.36
Aspirin Granules Blend (Fluid Bed Granulation)	F22006-002	1866.1	10.0	2.31
Aspirin Granules Blend (Fluid Bed Granulation)	F22006-003	1864.8	10.0	2.32
Aspirin Powder Blend (Dry Blend)	F22006-005	1866.7	10.0	2.30



Sublingual High-Dose Aspirin Product

Glatt Formulation Testing: October 2024 – March 2025

- Glatt produced a feasibility batch of Aspire's high-dose aspirin product in the fall of 2024. Testing through March 2024 showed that all essential product performance attributes were confirmed: size, weight, solubility, impurities, dissolution, and stability.
- Based on the feasibility batch, Glatt produced a GMP (Good Manufacturing Practices) batch for use in human clinical trials planned for mid-April 2025
- Glatt has worked closely with T.H.E.M., a technical, R&D, packaging design, and production resource company, to devise appropriate packaging for delivery of Aspire's high dose aspirin product



Sublingual Aspirin Product: Proof of Concept

The Proof-of-Concept study verifies and validates that our formula enters the bloodstream with a therapeutic cardiac dose of aspirin in less than one minute

There is no oral form of aspirin on the market today that

- can be absorbed into the bloodstream in less than 8-12 minutes, and
- will get to a maximum absorption above 12 mg/dl blood to relieve pain by using a 1000mg dose.

Anecdotal study demonstrates the significant absorption level of 27mg/dl blood for pain relief, with

- A formula which meets the FDA's stability requirement, and
- PH neutral product (non-acidic) and has no known negative effect on the stomach or entire gastrointestinal tract

Current Study Comparison

Salicylate Level	0-2 Minutes	2-10 Minutes	10-30 Minutes	60 Minutes
Bayer AG	0	0	4	6
Instaprin	2	7.7	20	27

The speed and level of absorption due to our new mechanism of action into the blood stream is significant and a represents a new disruptive technology



Sublingual Aspirin Product

Caliira – *Aspire's CRO Partner*

As a global Clinical Research Organization, Caliira is well positioned to optimize our development program to save time and resources.



Assign a dedicated point of contact to meet project timelines



Develop an integrated, customized strategy to minimize complexity, accelerate timeliness and reduce fixed costs



Act as your Strategic Advisory Board and think tank to maintain accelerated development



Leverage adaptive, synthetic and/or flexible trial designs for maximum efficiency



Deliver executive sponsorship to support ongoing success



Apply industry-leading translational medicine expertise to generate valuable data



Provide access to specialized resources from world-class experts, including former regulators



Implement innovative patient-centric solutions and the latest thinking around real-world data and evidence



Sublingual Aspirin Product: Clinical Trials

Strategy

Aspire uses existing, approved generic-drug dosages. Generic drugs do not need to repeat the clinical trials related to active ingredients but must demonstrate our sublingual route of administration

- (i) effectiveness
- (ii) amount of drug that gets to the bloodstream and
- (iii) time it takes to get there

Glatt has created a GMP batch of the aspirin product for human trials

Caliira (CRO) is:

- Identifying expedited pathway options and clinical strategies to accelerate development
- Planning for clinical trial protocol and product commercialization

Clinical Trial Timeline

Site selected and preparing for first patient dosing in April 2025

Budget

Clinical trials fully funded



Sublingual Aspirin Product: Clinical Trial Summary

Title

Sublingual aspirin powder vs oral aspirin tablet: Pharmacokinetic and pharmacodynamic characterization

Study Description

Objective: To compare the pharmacokinetic and pharmacodynamic characteristics of normal healthy adult volunteers administered sublingual dose of 162.5 mg aspirin powder with control healthy subjects given 162.5 mg oral aspirin (i.e. two typical aspirin tablets)

- **Condition:** Cardiovascular diseases/Heart Attack intervention
- **Intervention:** drug: sublingual aspirin powder/oral aspirin tablet
- **Study type:** Clinical trial, Phase 1
- **Estimated Enrollment:** as determined by FDA (likely 8-24 participants)



Sublingual Aspirin Product: Clinical Trial Summary

- **Intervention model:** Single group assignment
- **Intervention model description:** single dose, cross-over design

Arms and Interventions

- Healthy adult volunteers given sublingual aspirin (powder containing 162 mg aspirin) or oral aspirin tablet (2X81 mg aspirin).
- Single dose, crossover design with 1-2 weeks washout.
- Sublingual aspirin powder (Aspire's product) and conventional aspirin (162 mg) available commercially.



Clinical Trial Summary

Primary Outcome Measure

- Plasma acetyl salicylic acid concentration versus time data. Time frame: pre-dose and up to 24 hours post dose.

Secondary outcome measures

- C-max
- T-max
- Terminal phase elimination constant
- T1/2
- Plasma thromboxane B2 concentration, pre-dose and up to 24 hours post dose
- **Platelet aggregation:** Analyze for group difference between sublingual and oral aspirin treated groups



Sublingual Aspirin Product: FDA Approval Pathway

Aspire is requesting to pursue fast track 505(b)(2) approval from the FDA (for serious conditions that demonstrate substantial improvement for treating the disease or fill an unmet medical need). The fast-track pathway includes eligibility for accelerated approval and priority review. To get fast-track approval, the drug must show some advantage over available therapy, such as:

- Showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes
- Avoiding serious side effects of an available therapy
- Improving the diagnosis of a serious condition where early diagnosis results in an improved outcome
- Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment
- Ability to address emerging or anticipated public health need



Sublingual Aspirin Product Commercialization and Go-to-Market Strategy

- 01 Launch product initially in the Rx market, followed by an OTC version, with the strategy of creating and preserving greater long-term value
- 02 Partner with an experienced end-to-end marketing and distribution firm
- 03 Significant potential licensing opportunity



Sublingual Aspirin Product: Analgesics Market Opportunity

Non-opioid analgesic and opioid markets combined currently estimated at \$80+B and projected to grow to nearly \$100B in five years

	2022	2023	2024	2025	2026	2027
Market Data (\$-Bil)						
Opioids	\$32.5	\$33.6	\$34.6	\$35.7	\$36.8	\$37.9
Analgesics	\$48.0	\$50.3	\$52.7	\$55.2	\$58.0	\$61.0
Analgesics Market Total (incl. Opioids)	\$80.4	\$83.8	\$87.3	\$90.9	\$94.8	\$98.9
OTC \$	\$12.1	\$12.6	\$12.2	\$11.8	\$11.4	\$10.9
RX \$	\$68.4	\$71.3	\$75.1	\$79.0	\$83.4	\$88.0



Aspire's Investment Considerations

- **Patent-pending Delivery System** specifically formulated to allow **rapid sublingual absorption** of aspirin into the blood stream and by-passing the gastrointestinal tract
- **Fast absorption** to help resolve heart attack and stroke and provide quicker analgesic effects
- **Proprietary** formula and manufacturing process
- **Absorbed rapidly** in the mouth, which reduces adverse reactions in the stomach (GI tract)
- **Large dosage escalation** for back pain, arthritis pain, headache, post surgery and cancer pain

Opportunity:

- **Large Addressable Market:** \$80B combined analgesics and opioid market
- **Prescription:** Filing in late 2025 to meet FDA 505 (b)(2) Fast Track drug approval process
- **OTC:** OTC version for FDA compliance in accordance with the existing monograph
- **First to market:** Prescription strength version to be followed by OTC
- **Proprietary Technology:** Enables ability to pursue broadened applications, using our solubility process, which can be used with other compounds

Thank You.



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Appendix

- Medical Advisory Board
- Strategic Advisors





Medical Advisory Board

- **James Kofi Dzandu, Ph.D**, Pharmaceutical Chemistry, Assistant Professor of Pathology and Associate Director of the DNA/Identity laboratory at University of Texas Health Science center, Fort Worth Texas
- **Morhaf Ibrahim, MD, FHRS, FACC**, Electrophysiologist and Cardiologist, Founder and President of Ibrahim Heart Clinic; Founder and President of PremierCardia; Medical Director of the Electrophysiology Lab - Memorial Hospital Jacksonville; Medical Executive Committee Member at Large – Kindred, Encompass Jacksonville, and Encompass St. Augustine
- **Gary Bernard, MD**, Internal Medicine Specialist has over 30 years of experience in the medical field. He graduated from Meharry Med Coll in 1992. He is affiliated with HCA Florida Orange Park Hospital
- **Paul Montanarella, MD**, Chief Anesthesiology, Honor Health Hospital system, board-certified in anesthesiology by the American Board of Anesthesiology (ABA)
- **Edward Kimball, MD**, Medical Advisor, Professor of Surgery at the University of Utah Health Sciences Center and Medical Director of Surgical Critical Care at the Salt Lake VA Medical Center
- **John Mansour, Jr., DO**, Chief of Orthopaedic Surgery as well as Medical Director of Orthopaedic Trauma for The Hughston Clinic at HCA Florida Orange Park Hospital.



Strategic Advisors



Nancy Taylor, FDA Advisor, Chair of the Health Care & FDA Practice at Greenberg Traurig, and focuses her practice on health and FDA related matters



Michael Shuster, Partner, Goodwin's Life Sciences group, providing strategic intellectual property advice to biotechnology, chemical, pharmaceutical, and other life sciences companies



Arthur Marcus, Legal/Securities, Sichenzia Ross FERENCE LLP, with a practice focus on corporate, commercial, and securities law



Miriam Walls FDA Advisor, X-FDA, works with companies to devise a strategic planning, new opportunity creation, and strategies to help the company remain competitive in the marketplace