Aspire Biopharma, Inc.

February 2025

Investor Presentation

Nasdaq: ASBP

Outline

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Overview – The Technology

Aspire Biopharma, Inc. has developed and acquired disruptive technologies for delivering prescription drugs and other products sublingually (i.e. under the tongue and through buccal tissues in the mouth) [(1)].

This technology delivers a variety of drug and other products in a fast-acting granular or powder form which has been developed by using our patented methodology and "trade secret" process, and can even deliver products into the bloodstream that currently must be injected.

These results come from a new route of administration (absorption pathway) which allows for rapid sublingual absorption in the mouth.

(1) Aspire has acquired US Patent No. 62/794141, and has two new patents pending, application number 63/456,290, filed in March 2023, and application number 63/702,381, filed October 2, 2024.

Overview – The Technology

- Fast-Acting: Products delivered by our sublingual technology enter the bloodstream and reach their targets much more rapidly
- Perfects Dosage Management: Drugs do not pass first through the liver to be metabolized, more of the drugs are usable in the body meaning doses can be smaller and cost of manufacturing reduced
- Bypasses the Digestive Tract: Eliminates adverse reactions in the gastrointestinal tract caused by products that are swallowed in tablet, capsule, or liquid form
- Easily used: Many people struggle swallowing pills. Products using our technology absorb quickly and easily under the tongue– even an unconscious person can be given life-saving drugs!

Delivery Method

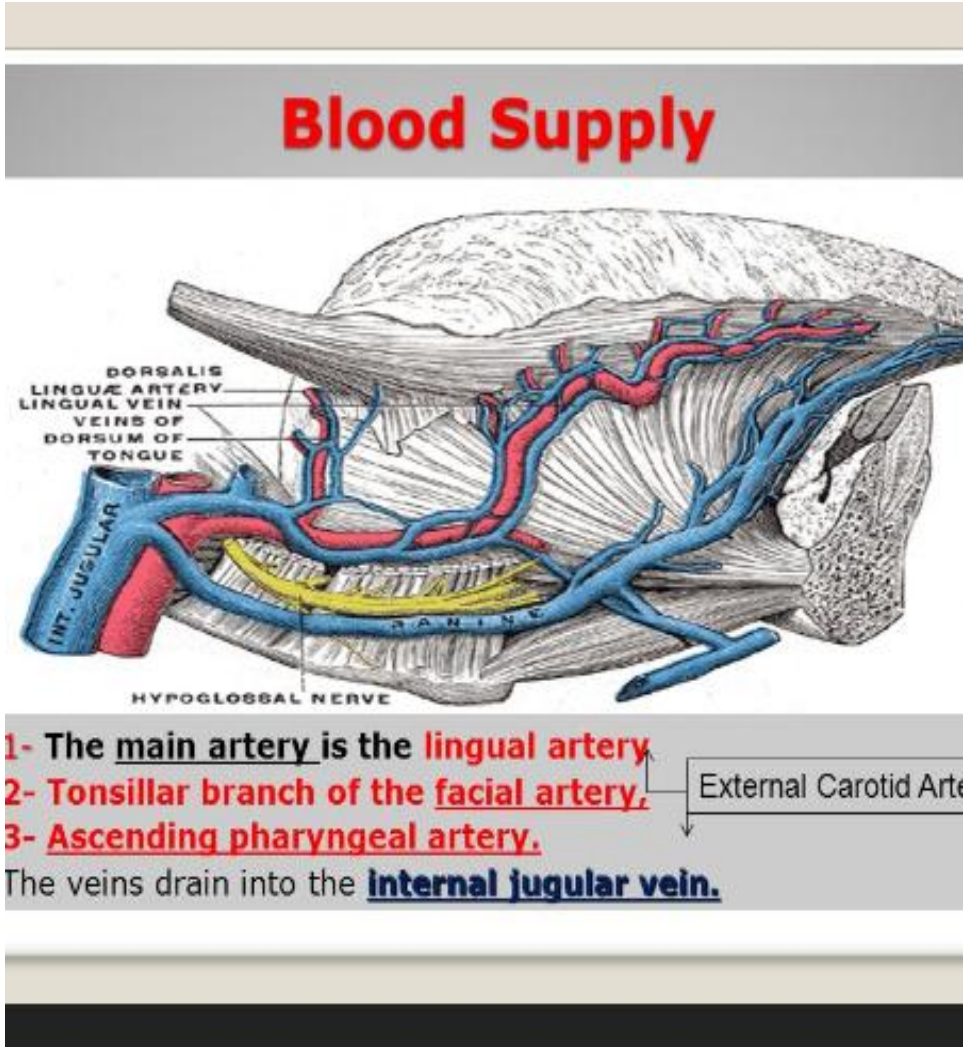
First Pass Metabolism Alternative Routes:

suppository	intravenous
injection	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



Market Opportunity

Aspire's novel, disruptive technology can be applied to any number of proven, FDA-approved prescription and over-the-counter drugs as well as nutraceuticals. For example:

Analgesics: global analgesics market (including opioids) valued approximately $77.0 billion in 2021 and is projected to grow at a 5% CAGR and reach to roughly $103.0 billion by 2028

Erectile Dysfunction (ED): global ED market valued approximately $3.6 billion in 2021 and is projected to grow at a 6.9% CAGR and reach to roughly $5.9 billion by 2028

Traumatic Brain Injury (TBI): global N-acetylcysteine (NAC) market was valued at $1.1 billion in 2021 and is projected to grow at a 21.5% CAGR and attain a market value of $4.2 billion by 2028

Manufacturing Strategy

A contract manufacturing strategy is being pursued with the potential for multiple supplier relationships.

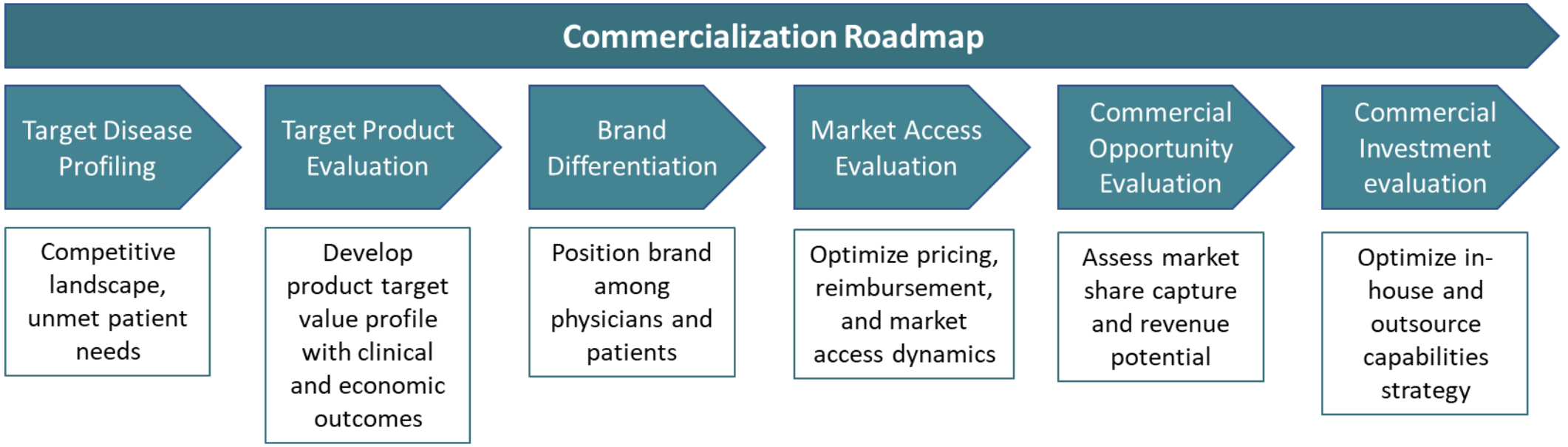
- Glatt Air Techniques
  - Technical Manufacturing Development Partner
  - Pharmaceutical Development Agreement signed June 2022
  - Has created aspirin products for Aspire for clinical trials and feasibility studies

- ThermoFisher Scientific
  - Currently in discussions for an alternate outsourced manufacturer
  - Discussions include developing a rapid dissolving sublingual tablet form

Employing a contract manufacturing strategy with proven supplier(s) reduces the risks and capex associated with building and running a manufacturing facility while increasing ROI by avoiding large capital investments

Commercialization, Marketing, Distribution, Sales Strategy

Aspire plans to engage a proven commercialization partner that specializes in design and execution of the company's Marketing, Distribution and Sales strategy.



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

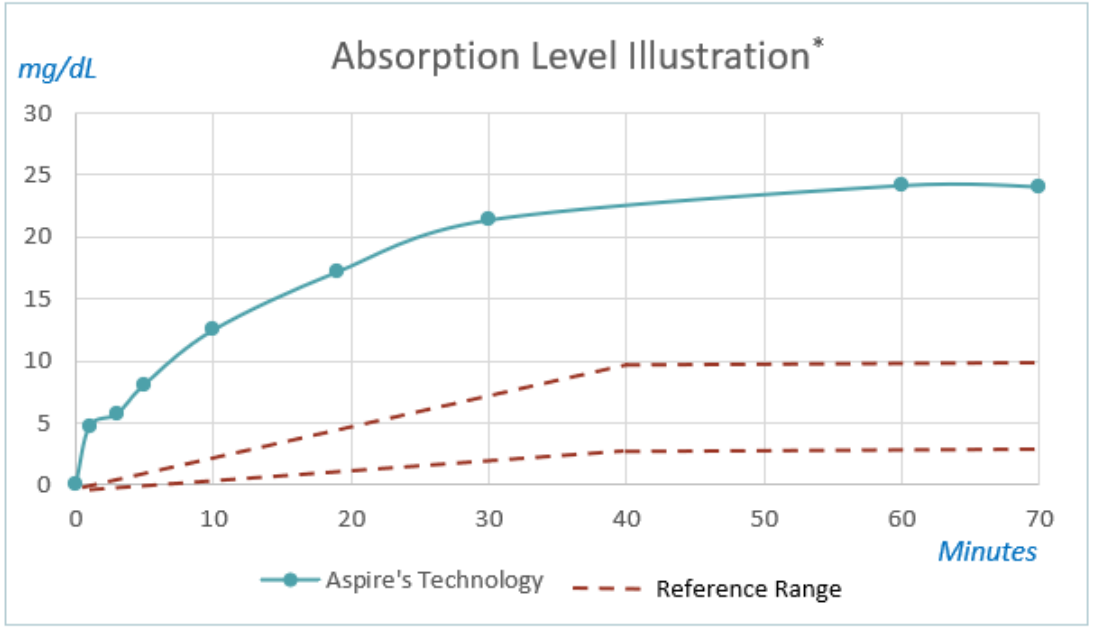
Sublingual Aspirin

Aspire's Launch Product

Sublingual Aspirin Product: Overview

Addresses cardiology emergencies and pain management, is a granular or powder formulation of a soluble, Ph neutral, fast-acting aspirin which has been developed by using our patent-pending sublingual absorption formulation.

Benefits of “rapid absorption” aspirin include: to stop 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

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

Aspirin is believed to be the most-studied drug, with an approval pathway that benefits from its proven properties and benefits.

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

We have developed a novel formulation of sublingual aspirin that increases rapid absorption, eliminates the GI tract side effects, and by-passes first pass liver metabolism resulting in faster peak serum concentration and rapid inhibition of cyclooxygenase (Cox-1).

Sublingual Aspirin Product: Background

What we know about ASA (benefits and risks)

- Benefits (Good):
  - ASA acetylates protein targets e.g., COX-1 and COX-2 which inhibit and prostaglandin synthesis and platelet aggregation. These 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 (Bad and Ugly):
  - 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 avoids the risks above

Opioid Crisis Opportunity

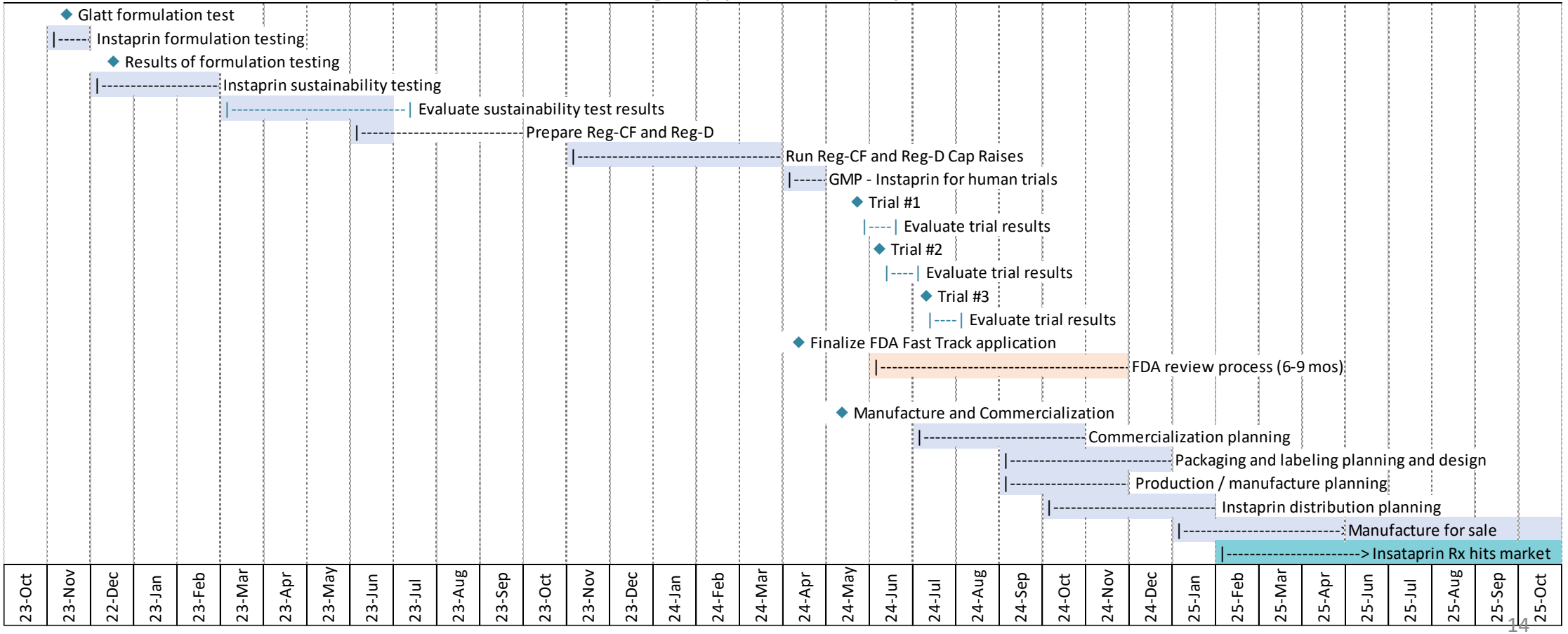
- Opioids, while still broadly prescribed, have become the driver of one of the most significant consequential health crisis of our time, resulting in destructive social, cultural, economic, and ethical impacts.

- Our sublingual aspirin product has the potential to gain support and tailwinds from regulatory bodies, the medical industry, medical insurance markets, political constituents, as well as the patient population, as a post-surgical analgesic and anti-inflamatory.

- We are in the process of seeking “Fast Track” FDA approval for Sublingual Aspirin Product, leveraging the issues of the current anti-opioid initiatives: the FDA has literally requested innovation in alternative pain treatments that could reduce reliance on opiodes.

Sublingual Aspirin Projected Timeline

Sublingual Aspirin Product “do-no-harm” formulation, readily available ingredients, FDA opioid imperative, and FDA’s Fast Track approval process are collectively expected to facilitate an accelerated timeline for testing, approval and product launch.



Sublingual Aspirin Product: Formulation
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 in an effort to evaluate the composition and process feasibility

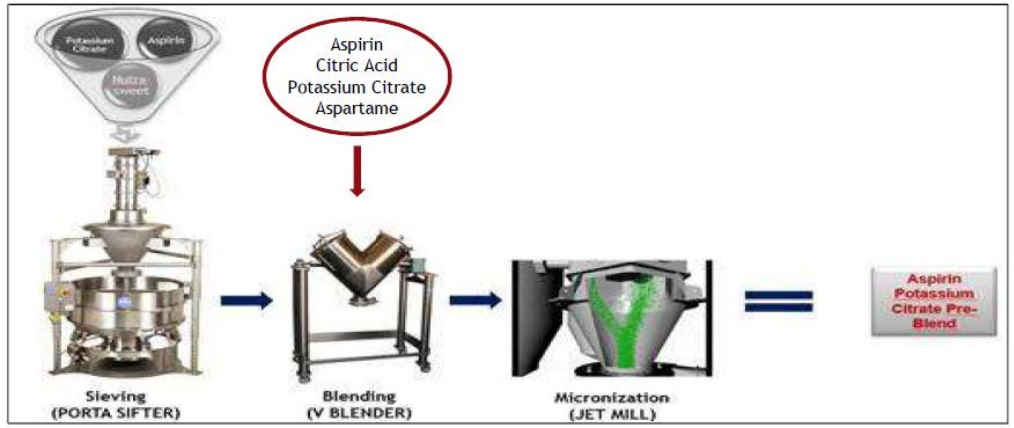
- Results:
  - All analytical procedures resulted in consistent readings in targeted ranges, including weight, impurities, dissolution, pH, Solubility, and CU/BU

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

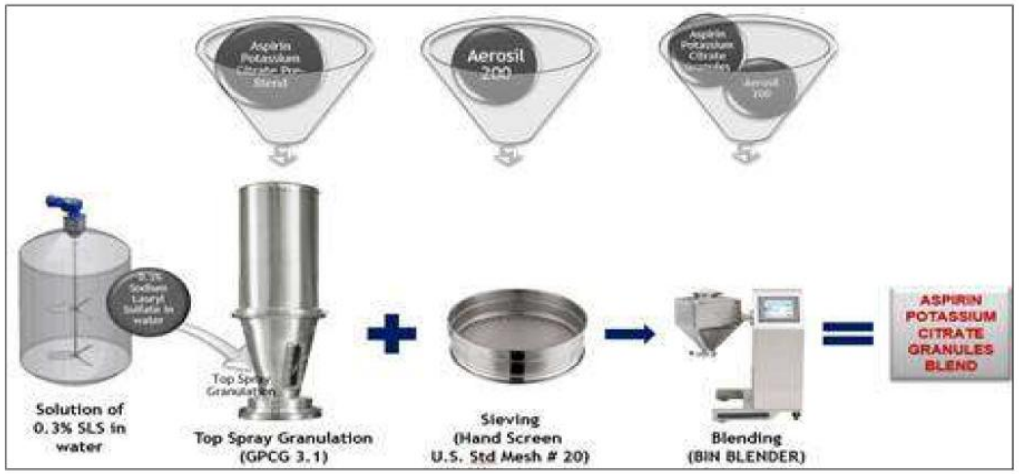
Sublingual Aspirin Product: Manufacturing

Glatt Pharmaceutical Services – process flowchart

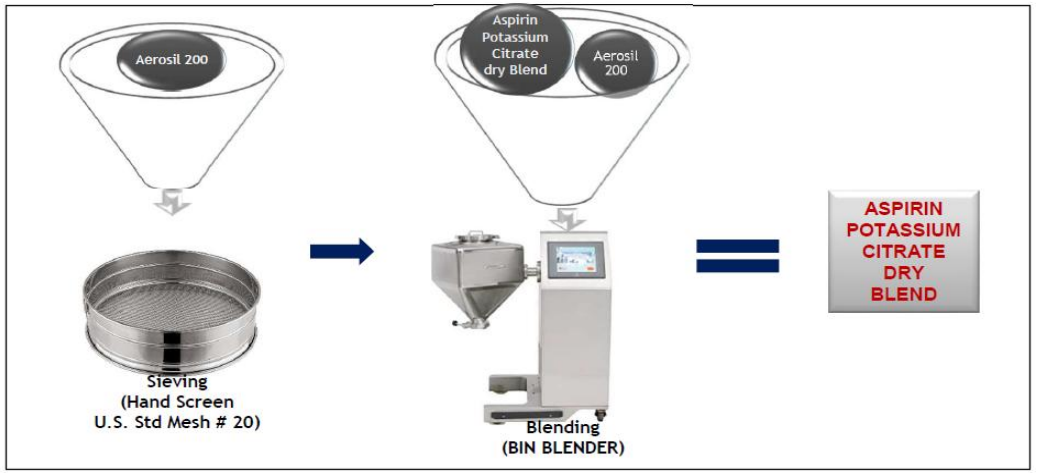
Micronization



Wet Granulation



Dry Blend



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

Sublingual Aspirin Product:
Caliira – CRO coordination and research partner

Caliira is well positioned to partner with Aspire in considering the needs of our key stakeholders, investors, regulators, payers, physicians and patients 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:

Caliira employs “follow-the-molecule model”

- Provider of end-to-end services within the framework of an integrated strategic model to support the complete clinical development cycle
- The follow-the-molecule approach facilitates moving along the development continuum from pre-clinical support to early and late phase study management, to commercialization and post marketing study execution, structured in a turnkey solution under one roof
- The benefits of the model are:
  - Cost predictability and reduced costs of managing relationships
  - Engaged and education internal and external stakeholders
  - Faster cycle times
  - Optimally aligned assets
  - Unwavering quality
  - A comprehensive eye on the end goal

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 aspirin powder with control healthy subjects given tablet-form oral aspirin, to compare speed to the bloodstream and concentration of aspirin in bloodstream.
- Condition: Cardiovascular diseases
- Intervention: drug: sublingual aspirin powder/granules / oral aspirin tablet/capsule
- Study type: Clinical trial, Phase 1
- Estimated Enrollment: 8 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/granules containing 162 mg aspirin) to compare to oral aspirin tablet/capsule (2 standard 81 mg aspirin pills).
  - Single dose, crossover design with 1-2 weeks washout.
  - Sublingual aspirin powder/granules and conventional aspirin tablet/capsule manufactured by Bayer.

A second clinical trial will follow Aspire's pre-IND meeting with the FDA (based on the data from the first trial). This will focus on the platelet inhibition characteristics of aspirin and compare the speed to platelet inhibition in Aspire's sublingually administered aspirin powder/granules compares to tablets/capsules. Platelet inhibition is the fully accepted and known quality of aspirin which makes it a heart attack and stroke inhibitor. Many studies have shown that aspirin in the bloodstream in the critical moments after a cardiac event can greatly diminish bad outcomes and even avoid fatalities. This trial will use 32 volunteers and again compare Aspire's sublingual aspirin with traditional tablet-form aspiring. This trial will also utilize Aspire's sublingual aspirin powder/granules in the final foil packaging that will be used when the product is retailed. Valuable informal feedback will be received from the volunteers on taste, ease of use, flavor, etc.

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 (at various intervals).
- Secondary outcome measures
  - C-max
  - T-max
  - Terminal phase elimination constant
  - $T_{1/2}$
  - 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 seeking approval from FDA's Center for Drug Evaluation and Research (CDER) for Fast Track 505(b)(2) designation (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.

Fast Track 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

- Launch product initially in the Rx market, followed eventually an OTC version, with the strategy of creating and preserving greater long-term value.

- Partner with an experienced end-to-end marketing and distribution firm

- Significant Licensing Opportunity

Sublingual Aspirin Product: Analgesics Market Opportunity

The non-opioid analgesic and opioid markets combined currently make up an $80+ billion market, projected to grow to nearly $100 billion 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

Nutraceutical Market

Aspire has already embarked in creating products for the nutraceutical market, which encompasses products like supplements, fitness and lifestyle products, and natural remedies. Aspire's sublingual absorption technology, with a rapid entry into the blood stream, creates a wealth of product opportunities.

Aspire has already created formulas which are being tested for a pre-workout product and a melatonin sleep aid, among others. Aspire hopes to roll out its pre-workout product before Summer 2025. Pre-workout is a $20 billion market worldwide (see https://www.grandviewresearch.com/industry-analysis/pre-workout-supplements-market) and expected to rise by 6% next year. Aspire's pre-workout will be able to deliver the same effects with far less caffeine and less hassle- no mixing of powders into liquids to be drank, just a small packet under the tongue for the same effect.

Melatonin, a $3 billion sleep aid market in 2024 (see https://www.gminsights.com/industry-analysis/melatonin-supplements-market) is also growing rapidly. Again, Aspire's melatonin product will use less melatonin to achieve the same impacts, but its sublingual absorption technology will allow the impact to happen in far less time. Aspire intends to have a melatonin product tested and ready for market in Q4 2025.

Aspire & Aspirin: Investment Considerations

- **Patented 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
- **Proprietary** formula and manufacturing process
- **Absorbed** instantly 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.
- **Targets** cardiac treatment and intervention; pain relief to help current global opioid crisis

Opportunity:

- **Large Addressable Market:** $80 billion combined analgesics and opioid market
- **Prescription:** FDA Filing in Q3 2024 to meet 505 (b)(2) Fast Track drug approval process.
- **OTC**: Instaprin OTC version after market established with Rx product.
- **First to market:** Prescription strength version to be followed by OTC
- **Proprietary Technology**: Enables ability to pursue broadened applications, using our sublingual absorption technology, which can be used with other drugs (such as testosterone, ED, and hormone products currently under development at Aspire) and nutraceuticals, with pre-workout and melatonin products currently being developed and close to going to market.

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
- **Marc Ayers FDA Advisor, Caliira**, works with companies to devise a strategic planning, new opportunity creation, and strategies to help the company remain competitive in the marketplace