HydraENT, INC.

Investment Prospectus 2025

Introduction

HydraENT, INC is a medical device company that is focused on developing medical devices for Ear, Nose and Throat (ENT) needs. Founded in August of 2022, the company is a Spin-Off of Hydra Vascular, LLC., and has exclusive rights to a technology we call SPARx (US 10918840 / US 20210154444). We aim to treat symptoms associated with all ENT diseases from chronic sinusitis to polyp and turbinate reduction. Our approach allows us to offer the simplest solutions for complex problems resulting in better patient health and the most effective clinical outcome. Our mission is to offer therapies that improve quality of life for our patients.

Market Research

HydraENT, INC is responding to the need for ENT medicine to offer products that are patient focused and easy to use for our doctors. From our portfolio of products, our company plans to commercialize a dilation device to treat chronic sinusitis with superiority over current ENT procedures. The total addressable global market for sinus dilation is $3.5B with a compound annual growth rate of 10%. This market is dominated by North America and European countries with an emerging market in the Asia Pacific. The upsurge in chronic sinusitis is the market driver and is expected to reach a revenue potential of $8.3B by 2033 (see table below). Some of the most recent activities showing the momentum behind this market are the acquisitions of some of the biggest players in this market such as Acclarent, Inc. (acquired for $275M by Integra), Entellus, Inc. (acquired by Stryker for $662M) and Intersect ENT, Inc. (acquired by Medtronic for $1.2B).

Leading Sinuplasty/Sinus Dilation Companies such as Cook Medical, CR Bard, Smith&Nephew, Medtronic, Johnson&Johnson, Stryker, Braun Melsungen AG, Cregana and Olympus are seeking portfolio development to secure a bigger revenue position in the ENT space.

Industry Report Metrics [SINUS DILATION]	Details
Market Revenue SIZE in 2024	$3.5 billion
Projected Revenue by 2033	$8.3 billion
Market Forecast (2024-2027)	10% CAGR
Market Segment	By Product, Procedure, Patient Type, Patient Care Setting and Region
Market Driver	Upsurging Cases of Chronic Sinusitis

Data collection by Dimension Market Research September 2024

There are two classifications for procedures in the sinus dilation device market, which are stand-alone and hybrid. For obvious reasons the stand-alone procedures are going to be the most desired by clinicians, patients, and their health insurance providers resulting in higher procedural reimbursement rates (revenue). Shorter recovery time, less postoperative nasal bleeding and timely symptom improvements are the driving factors for stand-alone therapies. SPARx has demonstrated the ability to deliver on all these driving factors while focusing on the long-term health of our patients.

Market Driver

Rising prevalence of chronic sinusitis cases across the world is stimulating the development of sinus dilation devices and tools. Due to a continued demand for effective treatment methods, the market for sinuplasty balloons is leading the market in growth potential.

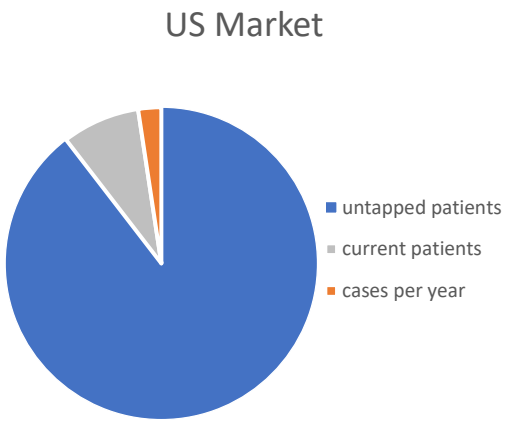
Reimbursement policies in the US have increased to reflect the demand for more advanced sinus treatments. These policies are aimed at fostering the market through better technology to increase patient and physician participation. According to the National Institute of Health (NIH), approximately 15% of the US adult population suffer from Chronic sinusitis resulting in twenty-two (22) million clinical visits which cost our healthcare system about $5B annually.

Recent Market Developments

The Medical device industry has responded to this need through mergers and acquisitions (M&As).

- In 2022, Medtronic acquired Intersect ENT ($1.1B)
- In 2023, Medtronic acquired RhinoSensis (undisclosed)
- In 2018 Stryker acquired Entellus ($662M)
- In 2023 Stryker launched their own SinuFx balloon dilation system
- Boston Scientific partnered with Sylexis implant technology
- Dalent Medical develops Sinusleeve bioabsorbable
- In 2023 Envista Therapeutics developed Envista Nasal Sinus implant

Given the rapid growth in this market, many medical device companies have been developing their ENT portfolios to capitalize on the need for effective products. Recent CDC data suggest that over 30M adults are diagnosed with sinusitis, yet only 2.7M visits to physician offices were for chronic sinusitis as the primary diagnosis. Over 800,000 cases of sinus surgery are performed annually in the US to treat chronic sinusitis, while it is estimated that more than 250,000 cases are reported to include balloon sinuplasty. These numbers suggest that there is a fairly large untapped market for sinus balloon dilation.



There are a growing number of companies that have responded to the need for product improvements in the ENT sinus infection and Functional Endoscopic Sinus Surgery (FESS) market. These are a few companies that are seeking market share opportunities.

- Smith&Nephew
- Braun Melsungen AG
- Olympus Corporation
- TE Connectivity
- Cregana
- Sinusys Corporation

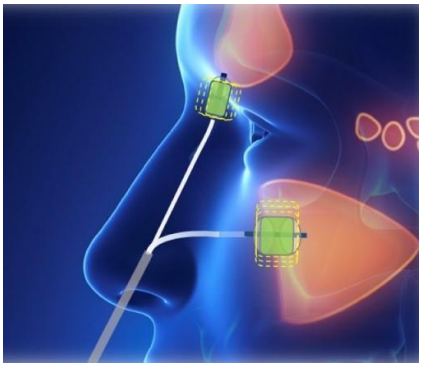
HydraEnt Strategy

Currently valued at $20M (pre-money), HydraENT, INC. seeks to raise $3,000,000 to reach a First in Human (FIH) feasibility milestone. We see a clear path to raising our company valuation while establishing strategic partnerships with larger medical device companies leading to M&A discussions. Our capital raise will fund R&D efforts to demonstrate our technology compatibility with existing FDA approved balloons that are on the market. This approach is an attractive opportunity for companies that are seeking new opportunities for portfolio growth as it derisks R&D/product development. Our modular approach allows our technology to become a sub-assembly to any existing sinuplasty manufacturing process which is attractive to potential strategic partners as we move toward our clinical goals and exit milestones.

HydraENT, INC.

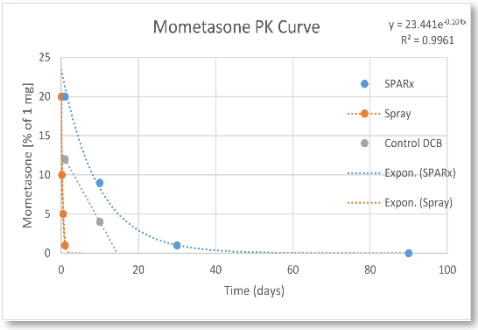
Pursuing a PMA-505(B)(2) FDA approval path will start with human feasibility data (clinical safety) comprising of 4-8 patients with no existing conditions. The result of this feasibility study will be presented to the FDA through a contracted Clinical Research Organization (CRO) as a non-biased 3rd party entity. The company's product is currently manufactured by Zeus Medical the Contract manufacturing Organization (CRO) and potential strategic partner.

Technological Advantage



Our technology is uniquely designed as a combination drug/device product that will demonstrate clinical superior over current devices. The balloon sinuplasty "SPARx" (patented electroporation/iontophoretic drug delivery) system dilates the sinus ostium (opening) while localizing a dose of glucocorticoid within the tissue. This small, but significant process keeps the drug at the lesion site for an extended period of time through crystallization and slow release.

Our preclinical and proof of concept shows a significant time release of the drug over a 45+ day period as compared to the existing clinical practices. In the standard of care, physicians are performing in-office multi-step procedures which start with a lavage, navigation & placement followed by sinuplasty inflation, irrigation and then a corticoid prescription to maintain inflammation suppression. This cumbersome method requires patient compliance as the corticoid application has a half-life of 5 hours and is lost in the mucus and swallowed. Other non-standard of care methods include dilation, followed by a polylactic acid (PLA) scaffold or applicator implant that is impregnated with mometasone furoate (MF/Nasonex).



HydraENT's SPARx product was tested against the Nasonex spray applicator in an animal model to generate a dose response curve (PK). What we found in the Nasonex cohort is the loss of effectiveness after 5-10 hours when the application is not continued within the half-life window. This data is aligned with published data regarding mometasone and its half-life as an amorphous steroid. Our dose curve suggests that the SPARx system reached the threshold for mometasone crystallization within the ostium tissue forming a depot. This data is aligned with cortisone crystallization in synovial fluid (joints) of athletes who receive steroid injections. Prolonged inflammatory suppression from a single in-office procedure is well adopted by the ENT community, however further characterization is needed.

Capital Raise Strategy

The current Series A round of $5M has a pre-money valuation set at $20M.

- $500,000 earmarked for 8 person non-adverse event feasibility study
- $400,000 earmarked for device manufacturing and ISO 13485/21 CFR PART 820
- $2,500,000 regulatory personnel and operations
- $1,600,000 R&D New Product development

Given the economic and political environment, our capital raise traction has been with small family offices, individual Angels and Angel Groups. The most current investment vehicle is safety notes with terms of $3M qualified financing.

Following the close of the $5M Series B round, HydraENT, INC., will be raising $20M at a valuation of $150M to pursue regulatory manufacturing compliance and a pivotal clinical trial for FDA Pre-Market Approval. Our course of action is simple and executable, and we hope that our investors will be encouraged to join us on our journey.

HYDRAENT, INC.

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