

## EXECUTIVE SUMMARY

Dynaris is seeking up to \$2.5 million to launch its first product — the **Apogee**, a unique portable oxygen delivery system for ambulatory patients. While Apogee is the company's first medical device, other products will soon follow.

The Apogee uses “Selective Oxygen Delivery” — a patented process that tracks the changes in nasal resistance and delivers oxygen only to the patient’s most receptive nasal passage. Because waste is minimized, that same tank can deliver oxygen up to two times longer. Our unique technology provides significant cost and therapeutic advantages over all other portable oxygen systems on the market today.

The milestones we’ve achieved to date have reduced the investment risk to prospective Dynaris partners, i.e. They include receiving EUA (Emergency Use Authorization) during COVID-19 as well as the FDA 510(K) and protection by 6 foundation patents issued and 4 pending. Our manufacturing facility, which achieved ISO-13485 compliance, is located in St. Louis County, MO. Having our own manufacturing facility affords enhanced quality control, streamlined R&D, reduces overall costs and improves time to market.

Production of the Apogee is currently underway. We expect to launch our second oxygen delivery device — the **Select O2** for stationary use — in Q4, 2021. Together, the Apogee and the Select O2, will provide cutting-edge therapy for both portable and stationary oxygen use markets. Like so many other businesses, Covid has left its mark... longer lead times, higher material costs and larger minimum orders. This is factored into our production costs. The requested \$2.5 million in new funding is earmarked for sales, marketing, inventory and staffing. We expect this infusion to bring us to profitability as early as Q-4 2022. Revenue for the U.S. market alone for the Apogee, by year five, is projected to be \$280,000 million with gross margins up to 62 percent.

## BACKGROUND

### The Problem

Since 1948, most oxygen patients have received their oxygen through a nasal cannula that splits the prescribed oxygen flow equally to each nostril. Yet, numerous studies now agree that individuals do not breathe equally between the left and right nostrils. They find, instead, that everyone “nasal cycles.” That is, we breathe in a cyclic pattern where our nasal passages alternate from a congested to decongested state — leaving a single dominant nostril for breathing most of the time. These studies further show that when oxygen is delivered equally to both nostrils and one nostril is blocked, as much as 50 percent of the oxygen is wasted into the atmosphere. This loss can jeopardize therapy and require as much as two times the oxygen flow to reach the same prescription goals.

### The Solution

The Apogee is a complete lightweight, portable oxygen system for ambulatory patients using a compressed gas cylinder. It uses Dynaris' patented Select Oxygen Delivery technology — delivering oxygen only to the most open nasal passage. The Apogee’s microprocessor senses each nostril independently with its patented dual sensors and determines the best pathway. The Apogee consists of an attractive carry bag, a custom regulator, the patented disposable Dynamic Nasal cannula and the Dynamic Oxygen Controller (DOC).

### Advantages of the Apogee

Because oxygen is not wasted, the patient receives the intended prescribed oxygen. The blocked nasal passage now has time to rest and repair — avoiding the irritation and drying that often occurs when oxygen is delivered to the blocked nasal passage. This efficient technology enables the patient to use a smaller and lighter oxygen tank as the oxygen lasts longer.

The Apogee will make it possible for the home care dealer to deliver fewer oxygen tanks to the patient – thus substantially reducing operating costs, while at the same time providing the patient with greater benefit. For the typical provider, the Apogee may pay for itself in a few months. Early adopters will clearly have a competitive advantage.

### Comparison to POCs on the market today

The Apogee’s portable oxygen system compares quite favorably to portable oxygen concentrators (POC) of similar size and weight. The average selling price of the Apogee is \$800 compared to the POC’s \$2000-\$3700 range. At around 5 pounds, the Apogee is quieter and should last about 13 hours on a single tank — several hours longer than a similarly sized POC. Equally impressive, the Apogee delivers >99 percent oxygen purity rather than the mid-80 percentile for most POC’s. The Apogee also delivers a uniform pulse volume that remains the same even as breath rate increases. POCs with a built-in conserver deliver a “minute volume” (a fixed volume of oxygen delivered each minute) and with increased breath rates, this volume diminishes.

When compared to compressed oxygen portable systems with a conserver, the Apogee device is competitively priced for the consumer. The Apogee, however, extends the oxygen tank much longer — giving the patient more ambulatory time and more consistent oxygen therapy. There are also significant cost savings when factoring in fewer home deliveries and tank replacements.



### **Company Profile**

Founded: July 8, 2014 as Incoba, LLC, dba Dynaris

Industry: Medical Devices

Contact: Lon Aylsworth

EMAIL: [Lon@Dynaris.com](mailto:Lon@Dynaris.com)

Company Stage: Ship ready, FDA Cleared, EUA, FDA Registered Facility

Valuation: \$19,929,600  
Capital Seeking: \$2,500,000

## **Market Size and Contributing Factors**

The U.S installed patient base for home oxygen is projected to grow from 5.5 million in 2019 to 9.1 million patients by 2026. The worldwide market should reach 46.9 million by 2026. Portable oxygen makes up nearly 30 percent of this base. By 2030, 20 percent of the U.S. population will be over 65. People are living longer, are more active and more proactive in selecting medical treatment options. Life expectancy for persons reaching 65 has increased to 82 years for men and 84 for females.

## **Sales Strategy**

The Apogee will be marketed Direct-To-Consumers, a proven model for oxygen-dependent patients in addition to manufacturing rep groups and direct reps — both domestically and abroad. We have begun communications with prospective users via our social platform with positive interest shown. Home care dealers should find significant advantages for their patients from both the Apogee's therapeutic and cost savings benefits. Medicare pays a flat fee (around \$50/month) for portable oxygen, regardless of how many cylinders one requires. The Apogee will cut down on deliveries and require fewer tank refills that cost the dealer about \$4 each.

## **University Validation**

Recent research by Stanford, Texas State University, and Trakia University has redefined nasal breathing. Their studies confirm the need for improved technologies that address the dynamics of nasal airflow. These observations are cited in multiple medical school textbooks, such as "Rhinology, Diseases of the Nose, Sinuses, and Skull Base" by David W. Kennedy and Peter H. Hwang ISBN 978-1-60406-060-7, Texas State University Respiratory Care 2016, *Journal of Respiratory Care* Issue 2, Volume 61, March 2016.

## **Company Management**

Dynaris was founded by Lon Aylsworth and Lawrence Spector, co-inventors of its technologies. With 28 issued patents, they have more than six decades of combined experience in the medical device industry and the homecare market. The partners' expertise spans product development, patent process, medical device manufacturing, FDA submissions, and marketing of medical devices in the homecare space.