Company and Product Background

Nuvaira, Inc. is a privately held medical device company that develops therapies to improve outcomes for patients suffering from obstructive lung diseases by addressing underlying disease pathophysiology. Specifically, the company has developed a novel, catheter-based system to treat overactive airway nerves, a common disease underpinning of both COPD and asthma, in a procedure called Targeted Lung Denervation (TLD).

Nuvaira was co-founded by Martin Mayse, M.D., and Steve Dimmer to develop an effective and lasting treatment for COPD sufferers. Dennis Wahr, M.D. assumed leadership of the company in 2012 as president and chief executive officer. Nuvaira received CE Mark approval for its Nuvaira® Lung Denervation System in January 2016 but has pursued a strategy of extended clinical development in order to develop robust evidence of TLD safety and efficacy. Nuvaira's extensive pre-clinical development program includes 11 completed bench and animal studies with up to 2 years of follow-up, and completion of three clinical studies in humans: IPS-I/II, AIRFLOW-1, and most recently, the AIRFLOW-2 randomized, sham-controlled double-blinded clinical trial. To date, 184 patients have been enrolled in clinical trials with TLD and followed since 2012.

Nuvaira is the first interventional COPD company to invest in a randomized, sham-controlled, double-blinded Phase 2B trial as the basis for an FDA pivotal design.

In April 2019, Nuvaira received *Forfait Innovation* funding from the French Health Authorities in support of its AIRFLOW-3 pivotal trial, a global, multicenter, randomized, sham-controlled, double-blinded study to evaluate TLD's impact on moderate-to-severe exacerbations in symptomatic, at-risk COPD patients (GOLD Group "D").

AIRFLOW-3 is the first interventional COPD trial targeting a reduction in exacerbations as its primary endpoint.

The Nuvaira lung denervation system is comprised of a console and single use treatment package that contains the specialized dNerva® dual-cooled RF catheter. Targeted Lung Denervation is a bronchoscopic procedure that disrupts pulmonary nerve input to the lung to reduce the clinical consequences of neural hyperactivity. Mechanistically similar to anticholinergics (the principal class of drugs for treatment of COPD) which must be taken daily to block the binding of acetylcholine in the lungs, the one-time TLD procedure can durably reduce acetylcholine release, and thus has the potential to reduce exacerbation risk, improve symptoms, and stabilize lung function.

Nuvaira is headquartered in Minneapolis, Minnesota USA (www.nuvaira.com). The company has raised $151 million through private equity financing rounds and has more than 75 patents issued and pending worldwide.

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