First Indication: Pulmonary Hypertension (PH) Overview

NO is an established therapeutic option for patients suffering from Pulmonary Hypertension worldwide

Pulmonary Hypertension Overview

- Life-threatening condition from increased pulmonary vascular resistance resulting in decreased pulmonary blood flow
- Generally not diagnosed until multi-organ system function is affected
- NO is the de facto standard of care for PH in the hospital setting

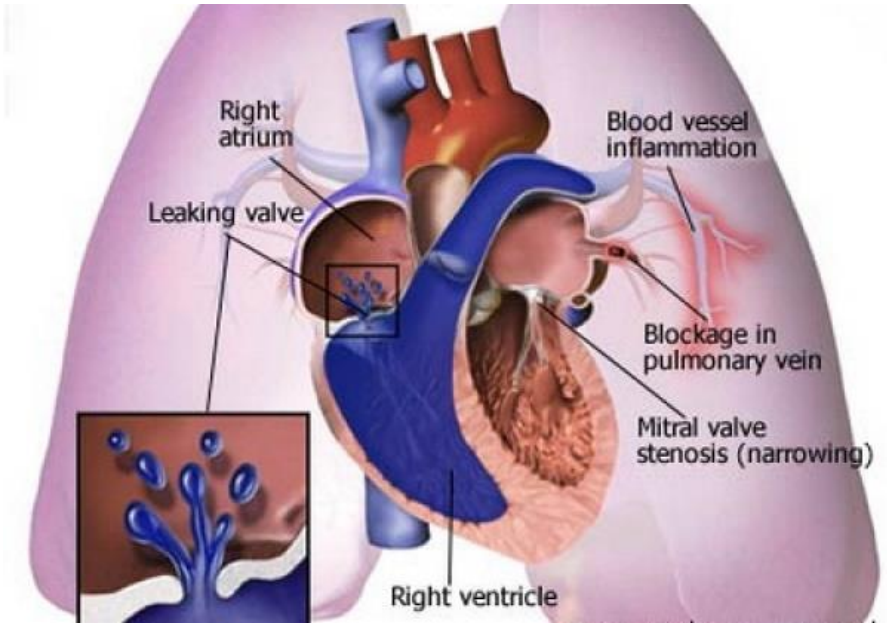
Benefits of NO in Treatment of PH[2]

- NO has been used as a long-term therapeutic option for patients with pulmonary hypertension
  - Approved in the U.S. by the FDA in 1999 for PPHN[3]
  - Approved in the EU in 2001 for PPHN[3] and cardiac surgery
- Inhaled NO causes increase in the concentration level of intracellular Cyclic Guanosine Monophosphate (cGMP) and an activation of the soluble guanylate cyclase
  - Causes smooth muscle relaxation, which increases blood flow to the lungs and decreases the workload on the right ventricle.

Effects of Pulmonary Hypertension[1]

Narrowing of the Pulmonary Arteries

Failure of Right Ventricle



(1) "Pediatric Pulmonary Hypertension" – Guidelines from the American heart Association and American Thoracic Society
(2) Pulmonary Hypertension News – "Pulmonary Hypertension and Nitric Oxide"
(3) Persistent Pulmonary Hypertension of the Newborn

PH Market Dynamics & AIT Plans

Due to lack of innovation, one company has a >$500M(1) monopoly in the United States and a handful compete ex-US with similar, archaic technology:

AIT plans to dominate the space

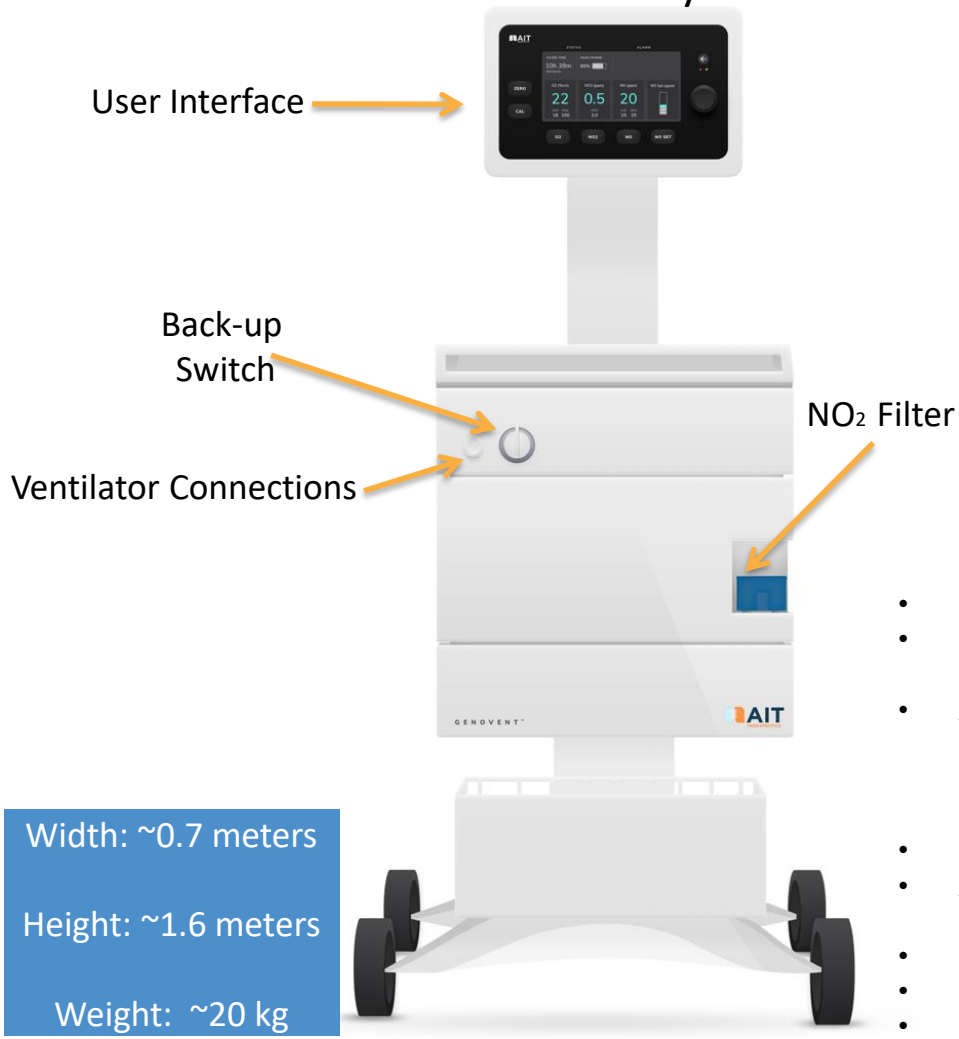
- US in-hospital PH market was **$505m** in 2017 with 2018 sales through 9 months at $404m[1]
  - AIT will expand the market
    - Service hospitals that do not have NO today due to cylinder system
    - Increase use with a lower cost and ease of use vs. cylinder systems
- AIT system has been granted a **"device designation" at FDA** (Not a drug)
  - AIT plans on filing a **PMA with FDA in the second quarter of 2019** for PPHN
  - **Gating factor** for regulatory submission is manufacturing
    - Contract manufacturer is Sparton, a premier vendor in the space
    - System for use with breathing circuit and mask has been manufactured at commercial scale with Sparton – process will be repeated for use with ventilators to facilitate submission to FDA
  - AIT to seek regulatory approval on a global basis after US submission
    - Ex-US regulatory submissions will include PPHN and cardiac surgery where appropriate
- **First Half 2020 launch** in the US with our partner
  - AIT anticipates ex-US launches with a partner beginning about 1 year after US
    - Ex-US < US market sales, but may exceed the US with our system
  - AIT anticipates garnering the majority of global market share with it's partner/s

(1) MNK Company Reports

GeNOvent System Partnered in the United States & 1 other Country

AIT outlicensed the GeNOvent system to a commercial partner with an established presence in the specialist hospital market for the US and another country

GeNOvent System



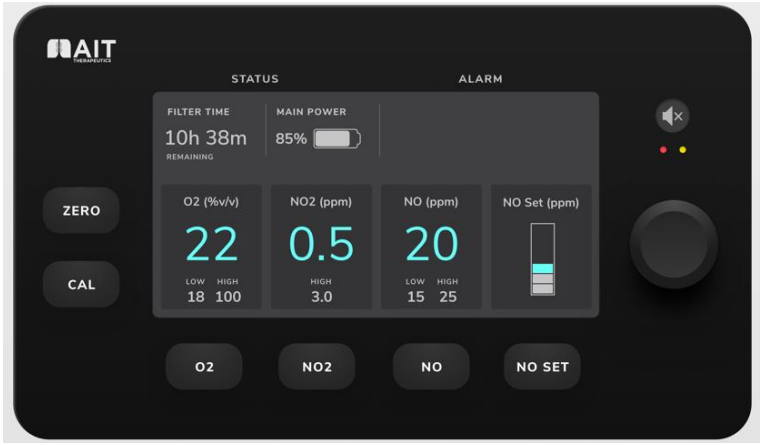
Width: ~0.7 meters

Height: ~1.6 meters

Weight: ~20 kg

For illustration purposes only
For investigational use only

User Interface



Partnership Details

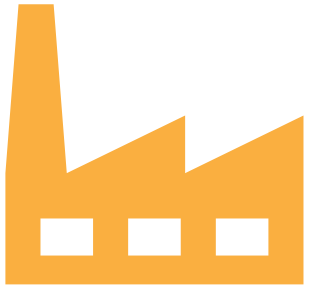
- $32.5 million is potential up-front and regulatory milestones ($31.5 million for the US)
- GeNOvent system is ventilator compatible for use in the hospital setting to treat conditions causing hypoxic respiratory failure (HRF)
- AIT will receive royalties on annual gross profit
  - 15% up to $100m
  - 20% above $100m
  - Gross profit defined as net sales less only the cost of GeNOvent and NO_2 filters
- Partner will pay AIT cost plus for GeNOvent and NO_2 filters
- AIT is responsible for all development, manufacturing, regulatory submissions and in-market system repairs
- Partner is responsible for all commercial sales and marketing functions as well as logistics
- PMA filing with FDA is anticipated in the 2Q 2019
- FDA approval decision expected in 4Q 2019
- First half 2020 US commercial launch planned

Losing the High-Pressure Cylinder is a Significant Gain

Hospitals will have significant cost & logistics Advantages

- Improved operating economics for the hospital
- No significant capital investment required
- No burdensome inventory and storage requirements
- NO supplied as a non-hypoxic gas mixture
- No purging procedures or additional safety measures due to NO_2 buildup
- Functional in hospitals that are unable to use cylinder-based NO
- Reduced training burden
- Pregnant staff members not impacted

AIT will have significant cost Advantages



AIT does not have any expenses associated with a **manufacturing facility** for nitric oxide

AIT does not have any expenses associated with **logistics** related to nitric oxide cylinders

Pulmonary Hypertension in-Hospital Development Timeline