Premie Breathe
Low-Cost Breathing Aid for Newborns

Blavatnik Innovation Fund
May 2018
Global Problem

3 million newborns die within the first 28 days of life every year
> 90,000 neonatal deaths per year in Ethiopia

50% are related to respiratory insufficiency
The **Local Technology**
PremieBreathe

Our solution is a sustainable, rugged and affordable, respiratory device to reduce newborn deaths as a result of respiratory distress in resource-limited facilities.

*most recent prototype*
PremieBreathe’s respiratory device oxygenates, warms, and humidifies air before it is delivered. It incorporates a UV water sterilization mechanism housed in a single, compact and mobile enclosure.
Overview of Successes

Product Validation

• 2016 – 2018 USAID/BMG Saving Lives at Birth Validation Award $250,000
• IP
• Fully-functional prototype

In-Market Validation

• MOU with Armauer Hansen Research Institute, Mekelle University, and Ayder Hospital
• 1000 Unit initial commitment from EFMOH with 3500 Unit expansion plan
• Alignment with Global Good Fund, Intellectual Ventures, UNICEF, MSF

Recognition

• 2017 Saving Lives at Birth DevelopmentXChange Competition award winner
• 2017 WHO Global Forum on Medical Devices presentation held in Geneva, Switzerland
• 2016-2017 VentureWell award for Market analysis and Market development workshop
• 2013-2018 Yale-affiliated support and awards
PremieBreathe Advantages

First to Market
for affordable HHFNC device in LMIC

Innovation
First auto-sterilizing humidified respiratory support

Replaceable Parts
Locally sourced replacements

Promotes Maternal Care
Encourages breastfeeding and kangaroo care

Promotes Natal Health
No belly bloat or respiratory dryness*
Reduces risk of blindness*  
* issues caused by CPAP or locally-made solutions
## Competitive Advantage in LMIC

<table>
<thead>
<tr>
<th>Feature</th>
<th>HHFNC</th>
<th>CPAP (Gold Standard)</th>
<th>Improvised Care (Bottles)</th>
<th>PremieBreathe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humidified</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Warmed</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Auto H2O Sterilization</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Safe</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Locally-Available Parts</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Price (USD)</td>
<td>$5,000</td>
<td>$1000-$3000</td>
<td>Low</td>
<td>$500</td>
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Market Size:

Pediatric Respiratory Health (USD)

Global Respiratory
$981 Million
Total Market

Low & Middle Income Respiratory
$576m
Addressable Market

First Expansion
$158m

Ethiopia
$29m

1.5 M lives/year

50,000 lives/year

+$24B

+$87m

World Bank 2016
Product Development Roadmap

Phase 1
Ideation & Concept Development
- Interdisciplinary venture in resource-limited settings

2012-2015

Phase 2
Technical Development
- StudioRed partnership
- Fully-functional prototype

2016 - 2017

Phase 3
Pre-Clinical Trial
- Practitioner feedback
- Yale, Ethiopia IRB
- 5 devices commercially manufactured

2018

Phase 4
Clinical Trial
- FDA 510k
- 20 devices tested for efficacy with 150 patients in Ethiopian hospital

2019

Phase 5
Initial Market Entry
- Procurement Lists Approval (WHO List of Priority Medical Devices, Ethiopia, USAID)
- Strategic contracts

2019 - 2021

Blavatnik support

Financing
In-kind contributions and financial support from Yale-affiliated partners, VentureWell and USAID/Gates Foundation Saving Lives at Birth award.
Business Development Strategy

- Manufacturing Partners
- Distribution channels
- Strategic investors
- Licensing
- Expand market reach

PremieBreathe Technology

Sales & Licensing

Global Health Networks

Reduction in LMIC neonatal mortality
Use of Blavatnik Funds

$300,000 for 18 months of financing

- **$150,000**
  - Consultants
  - FDA and 510k approval
  - Secure strategic investors and partners

- **$100,000**
  - 20 prototypes for clinical trial

- **$50,000**
  - Commercialization Strategy
  - Market implementation
  - Explore horizontal markets

Blavatnik funds will be leveraged toward investments from USAID/BMG
Team

Dr. Anjelica Gonzalez
Lead Engineer, Inventor
Associate Professor of Biomedical Engineering

Erica Linnander, MPH, MBA
Implementation Support
Senior Technical Officer
Global Health Leadership Institute

Kidest Nadew, PNP
On-site Project Manager, Ethiopia
Ethiopia Country Director
Global Health Leadership Institute

Dr. Linda Arnold, MD
Clinical Director
Associate Professor of Pediatrics and Emergency Medicine
Strategic Partnerships

- Product Development and Market Analysis
- Clinical Implementation
- Ethiopia and Africa
- Global Health Strategy

Institutions involved:
- Yale
- CBIT
- StudioRed
- Ahri
- VentureWell
- Federal Ministry of Health
- USAID
Thank you!

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Premie Breathe
Breathing Aid for Pediatrics and Neonates

Blavatnik Fund Pitch Deck
US Market Strategy
Key Trends and Insights: LMIC

**Powerful Data**
- Clinical demand in LMIC.
- Case Study: Pumani, low-cost bCPAP device in Malawi. Currently sold and distributed in 30 countries.
- Strong training and implementation partners.
- Increasing expansion of MNCs into emerging markets. Currently seeking low-cost innovations for their portfolios.

**Political Will and Strategic Relevance**
- UN Sustainable Development Goal 3.2: measurable indicator for newborn survival.
- Increase in 'Oxygen Access' country coalitions i.e. Ethiopia United4Oxygen Coalition; Nigeria, India, China, among others.
- Globally coordinated and local institutional markets: multi-stakeholder partnerships and funding to end preventable deaths of newborns.

**Improved Medical Infrastructure**
- 80% of LMIC births now take place in hospitals.
- LMIC hospitals are not technically equipped to deliver proper care due to prohibitively expensive high-income-country devices.
- Only 10-30% of current, mostly donated, equipment is operational giving rise to 'tech graveyards' in LMIC hospitals.
3 key problems with CPAP:

1. Mechanical difficulties of maintaining CPAP apparatus in nose.

2. CPAP commonly causes nasal septum trauma.

3. CPAP is tightly affixed to nose and face- causes intolerance with patient movement, trauma, need for sedation.
PremieBreathe is a non-invasive, auto-sterilizing, respiratory support device for neonatal and pediatric treatment.
U.S. Market Potential: Oxygen Therapy

Key U.S. Healthcare Trends

• Increasing use of respiratory devices supplemented by rapid consumption of disposables is driving growth.

• Increasing usage rate for home settings, hospitals, clinics, patient support transport vehicles and extended care facilities.

Possible Pediatric Applications

• Respiratory Distress Syndrome
• Bronchiolitis
• Apnea of prematurity
• Chronic Lung Disease
• Infants weaning from invasive ventilation and CPAP
• Cystic Fibrosis
• Pneumonia
• Asthma
PremieBreathe is an auto-sterilizing, less invasive mode of respiratory support for neonatal and pediatric treatment.
**Premie Breathe Benefits for US Market**

**One-size fits all**
- One machine fits infants from different age groups and sizes
- Minor modifications in increase flow rates for adult populations

**Innovation**
First UV auto-sterilizing and humidified respiratory support system

**Payers**
- Reduced cleaning and maintenance requirements
- No need for secondary cleaning devices

**Providers**
- Small and easy to move device
- Marketing opportunity

**Patient Comfort**
- Reduces need for intubation
- Minimally invasive
- Leaves mouth free for talking, eating, coughing
- Promotes breastfeeding and mother contact
- Ideal for at home use

*issues caused by CPAP*
Global Oxygen Therapy

$7.09 Billion*
Total Market

US Market by application

$2.8bn
- Chronic Obstructive Pulmonary Disease
- Asthma
- Obstructive Sleep Apnea
- Respiratory Distress Syndrome
- Cystic Fibrosis
- Pneumonia
- Others

*(CAGR of 11.1%: 2015 - 2024)

Source: https://www.transparencymarketresearch.com/pressrelease/high-flow-nasal-cannula-market.htm

Global High-Flow Nasal Cannula Market

$3.42bn
- Air/oxygen blender
- Nasal cannulas
- Active humidifier* (leading share)
- Single heated tube
- Other consumables

(CAGR of 11.8%: 2017 - 2025)

Source: https://www.grandviewresearch.com/industry-analysis/oxygen-therapy-market
## US Pediatric Market (0-17 y/o)

<table>
<thead>
<tr>
<th>US Pediatric Market (USD)</th>
<th>Annual Sales (with CPAP)</th>
<th>Annual Sales (Consumables only)</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td><strong>Cystic Fibrosis</strong></td>
<td>$15,000,000</td>
<td>$1,200,000</td>
<td>• Assuming 100% patient penetration</td>
</tr>
<tr>
<td>(15,000 existing patients)</td>
<td></td>
<td></td>
<td>• $1,000 price point</td>
</tr>
<tr>
<td><strong>Sleep Apnea</strong></td>
<td>$1,476,000,000</td>
<td>$118,080,000</td>
<td>• 100% consumables adherence</td>
</tr>
<tr>
<td>(1,476,000 existing patients)</td>
<td></td>
<td></td>
<td>• Consumables include air filter, nasal mask, tubing and humidifier chamber</td>
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<tr>
<td><strong>Asthma</strong></td>
<td>$3,019,400,000</td>
<td>$241,552,000</td>
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<tr>
<td>(3,019,400 moderate patients)</td>
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Go-to US Market Strategy

Phase 1
- PremieBreathe in-use at early adopters/influencer sites: academic teaching hospital
- License technology to hospitals and charge for disposables

Phase 2
- Leverage treatment experiences and journal publications to influence insurance reimbursement policy
- Cite cost advantages for insurance companies with ‘blanket coverage' goal
- Marketing partnership toward patients

Phase 3
- Insurance companies launch ‘blanket' policies
- Launch to mass market
- Increase license fees
- New segments
“My goal is to support research that is interdisciplinary and non-traditional, because that is where the truly revolutionary breakthroughs will come from. I am drawn to and intrigued by the work of smart, young scientists and engineers, as a way to leverage their enormous brain-power to improve health and life.” –Leonard Blavatnik
Thank you!

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