



PremieBreathe

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



Local Problem

> **90,000** neonatal deaths per year in Ethiopia

50% are related to respiratory insufficiency

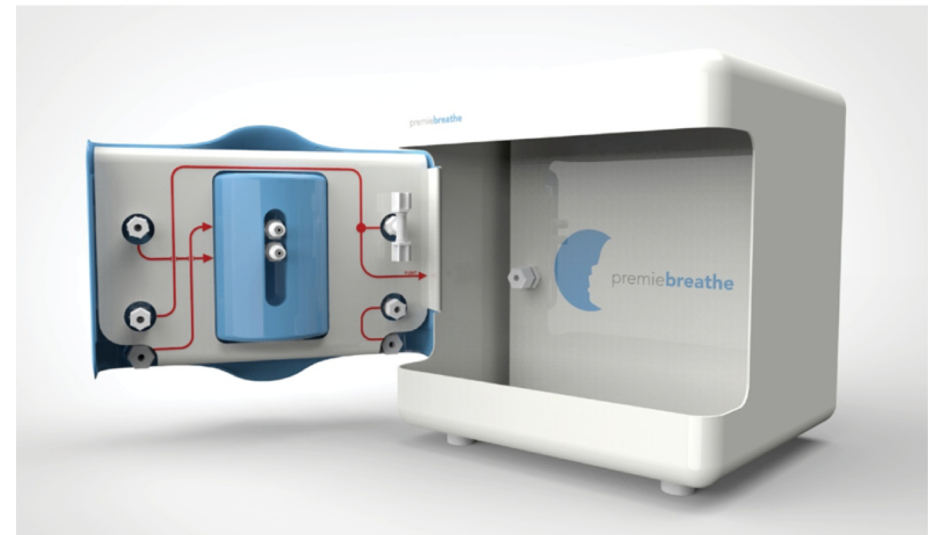


The Local Technology

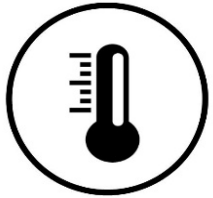


PremieBreathe

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*



Heated

32 ° C



Humidified

90-95% Relative Humidity



High-Flow

0-10 Liters Per Minute

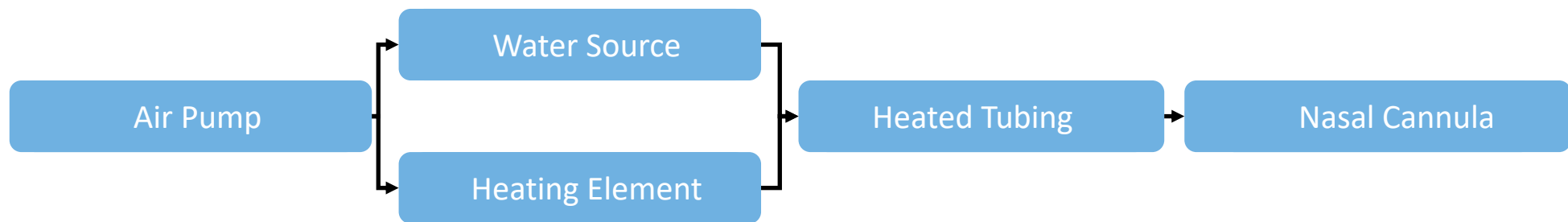


Oxygenated

21-100%

The Technology

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

	HHFNC 	CPAP (Gold Standard) 	Improved Care (Bottles) 	PremieBreathe 
Humidified		X	X	
Warmed		X	X	
Auto H2O Sterilization	X	X	X	
Safe		X	X	
Locally-Available Parts	X	X	X	
Price (USD)	\$5,000	\$1000-\$3000	Low	\$500

Market Size:

Pediatric Respiratory Health (USD)

Global Respiratory
\$981 Million
Total Market

1.5 M lives/year



+\$24B

Low & Middle Income
Respiratory
\$576m

Addressable Market

First Expansion
\$158m

Ethiopia
\$29m

50,000 lives/year



+\$87m

Product Development Roadmap

Blavatnik support



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

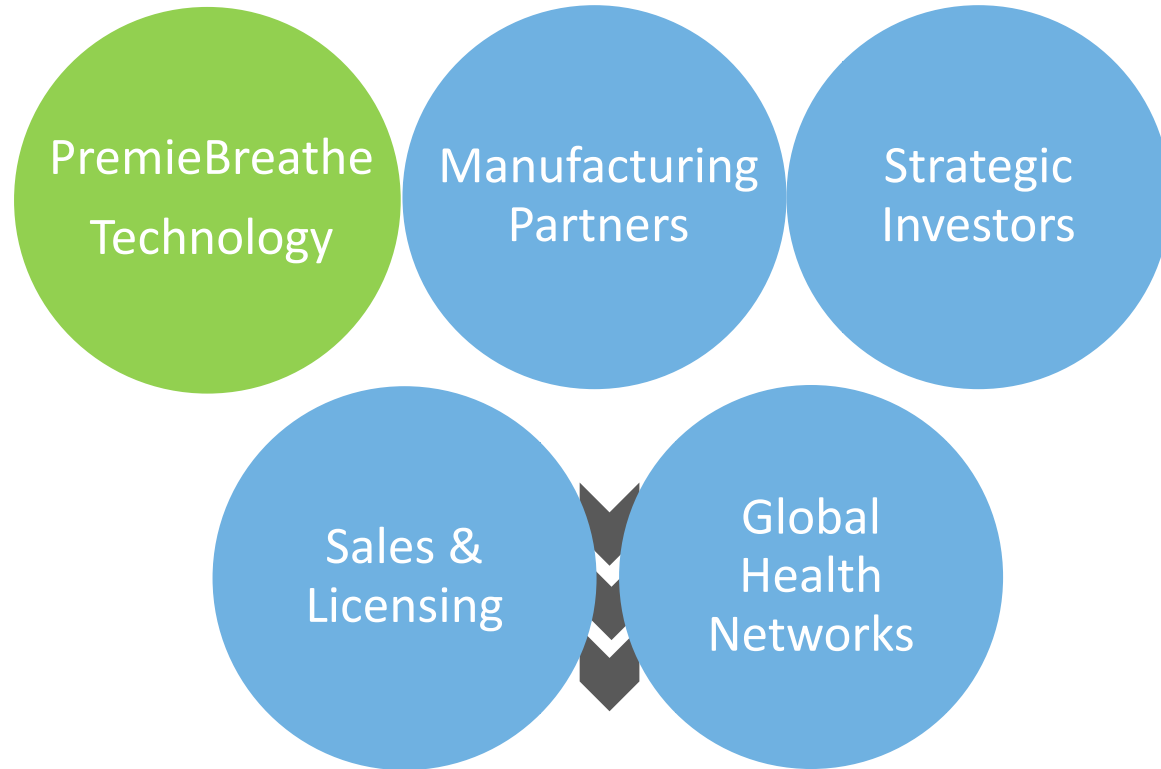
- Procurement Lists Approval (WHO List of Priority Medical Devices, Ethiopia, USAID)
- Strategic contracts

2019 - 2021

Financing

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

Business Development Strategy



Reduction in LMIC neonatal mortality

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

Use of Blavatnik Funds

\$300,000

for 18 months of financing



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
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Ethiopia Country Director
Global Health Leadership Institute



Dr. Linda Arnold, MD
Clinical Director

Associate Professor of Pediatrics
and Emergency Medicine

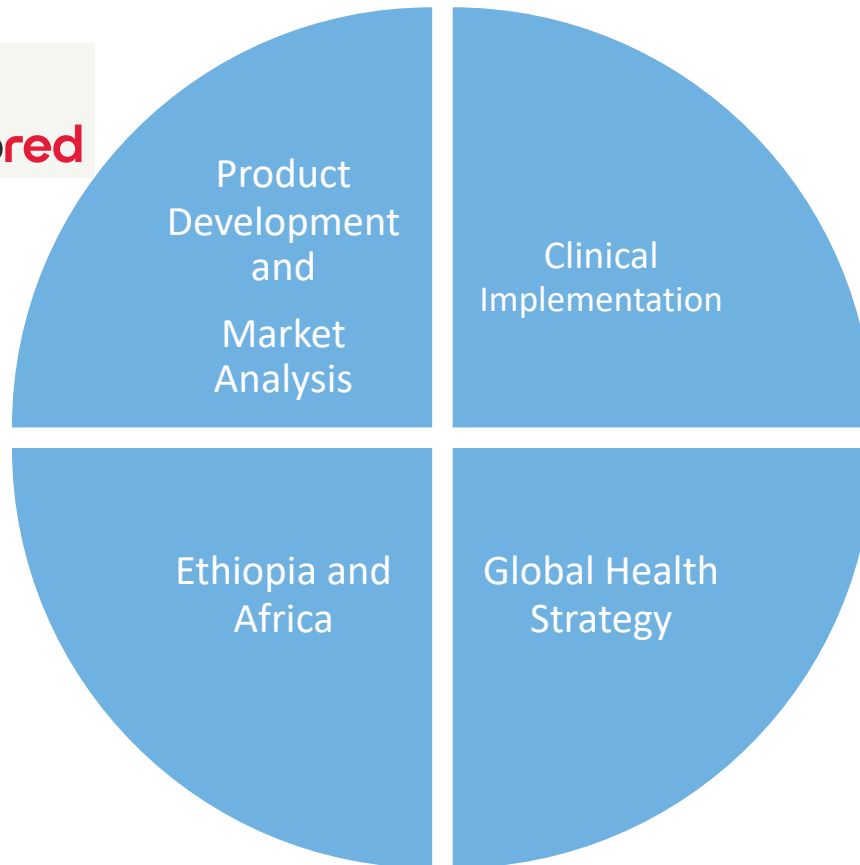
Strategic Partnerships



CBIT
Yale Center for Biomedical &
Interventional Technology



Center for Engineering
Innovation and Design



VENTUREWELL™
idea to impact



Food, Medicine and Healthcare
Administration and Control
Authority of Ethiopia



Federal Ministry of Health



USAID
FROM THE AMERICAN PEOPLE



PremieBreathe

Thank you!

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PremieBreathe

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.

CPAP vs HHFNC

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.

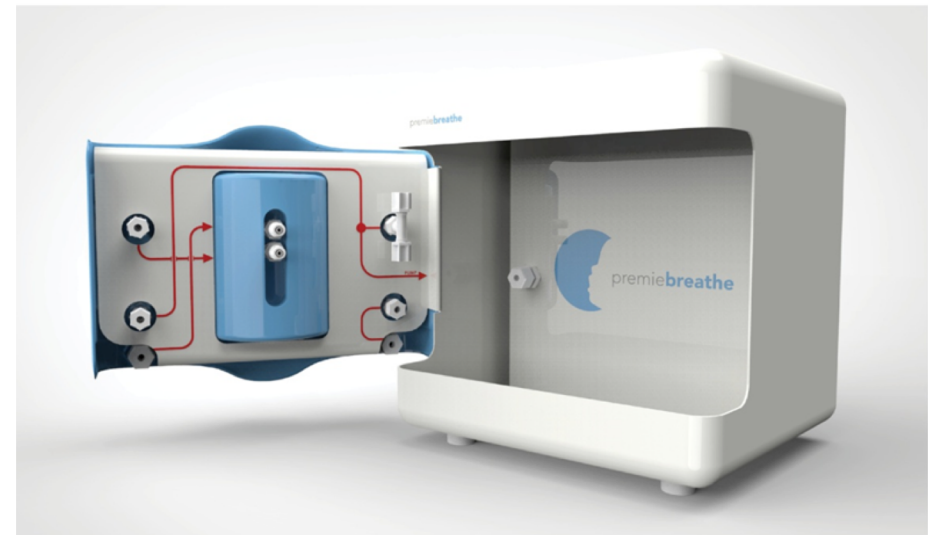


Possible Pediatric Applications

- Respiratory Distress Syndrome
- Bronchiolitis
- Apnea of prematurity
- Chronic Lung Disease
- Infants weaning from invasive ventilation and CPAP
- Cystic Fibrosis
- Pneumonia
- Asthma

PremieBreathe

PremieBreathe is an auto-sterilizing, less invasive mode of respiratory support for neonatal and pediatric treatment.



**most recent prototype*

PremieBreathe 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



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**



Payers

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



Providers

- Small and easy to move device
- Marketing opportunity

Market Size: Oxygen Therapy (USD)

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)

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.transparencymarketresearch.com/pressrelease/high-flow-nasal-cannula-market.htm>

<https://www.grandviewresearch.com/industry-analysis/oxygen-therapy-market>

US Pediatric Market (0-17 y/o)

US Pediatric Market (USD)	Annual Sales (with CPAP)	Annual Sales (Consumables only)	
Cystic Fibrosis (15,000 existing patients)	\$15,000,000	\$1,200,000	<ul style="list-style-type: none"> Assuming 100% patient penetration \$1,000 price point 100% consumables adherence Consumables include air filter, nasal mask, tubing and humidifier chamber
Sleep Apnea (1,476,000 existing patients)	\$1,476,000,000	\$118,080,000	
Asthma (3,019,400 moderate patients)	\$3,019,400,000	\$241,552,000	

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**



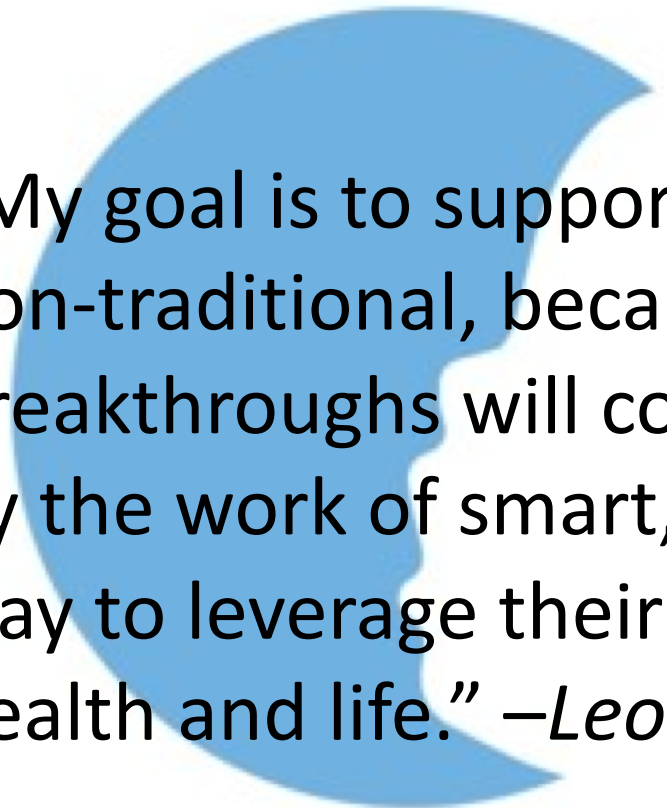
Phase 2

- **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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