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Breathe Well, Live Well™



Co-funded by the Horizon 2020 SME and EIC Pilot programmes of the European Union

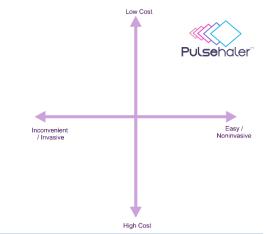


Close to Market





Unique Market Position



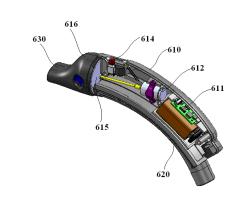
Experienced Team

Pending

FD

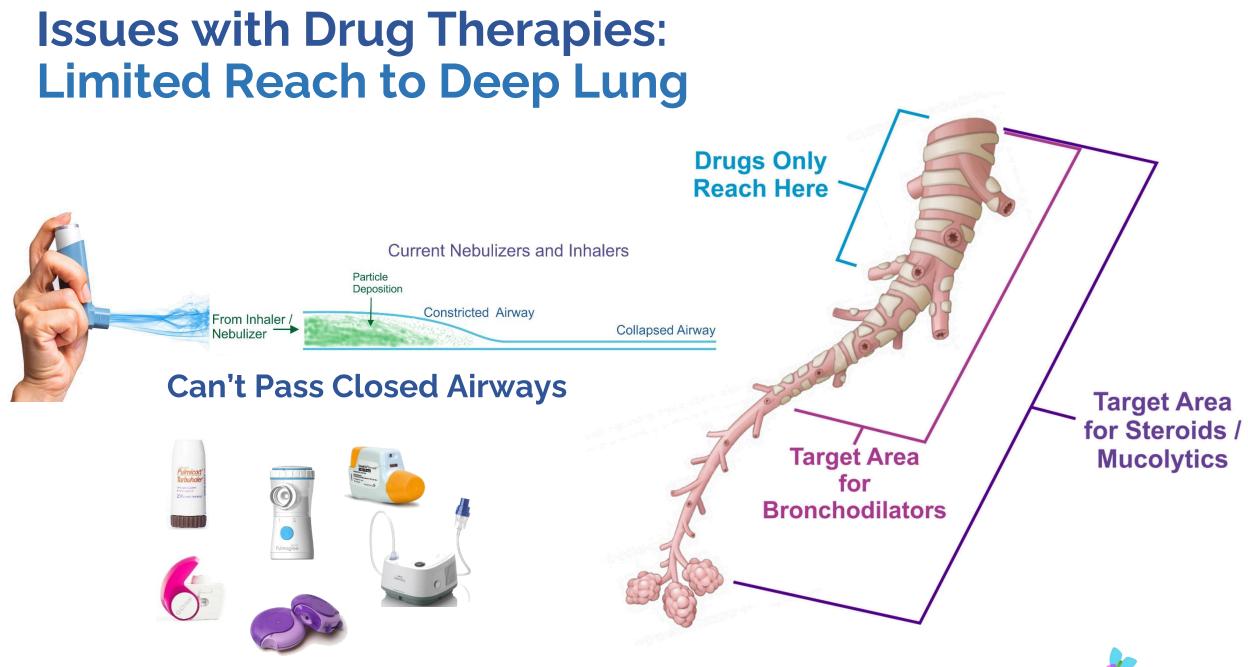
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Strong Broad IP



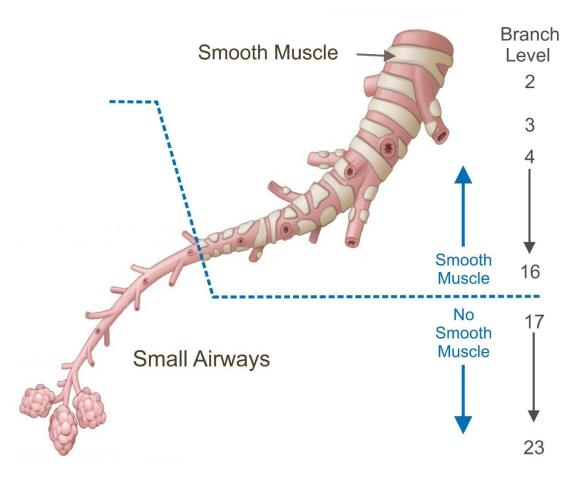
Disruptive Pipeline



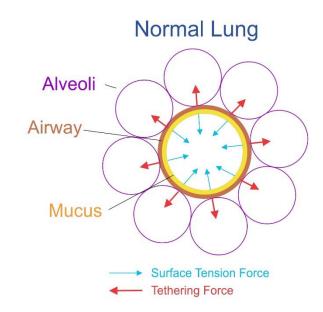


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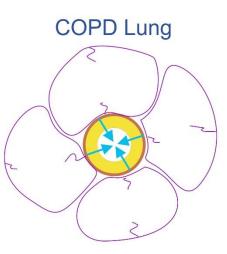
Addition Issues in COPD: Small Airway Collapse not Addressable by Drugs



Upper airways can be constricted by muscle...



Small Airways are collapsed by internal forces which cause them to close... and keep them closed.





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1. COPD Problem: Drug Therapy can't reopen collapsed small airways

Solution: Pulsehaler™ directly reopens collapsed small airways 2. Drug Delivery Problem: Drugs can't reach their targets deep in the lung

Solution: Pulsehaler™ DD delivers drugs while opening airways = deeper delivery

Pulsehaler[™] Technology Solves BOTH!





Pulsehaler™ Technology Platform

Dynamic Air Pressure Pulse Therapy

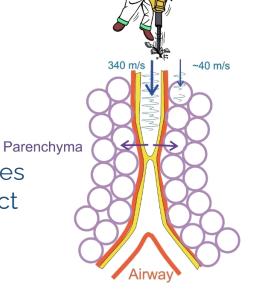
- Proprietary Waves, Frequencies, Pressures
- Independent of Drugs





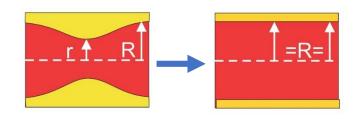


- P_{Airway} > P_{Parenchyma}
- Transmural Pressure Changes
 - = "Gentle Jackhammer" Effect



(2) Changes Mucus Viscosity

- Liquify thick mucus & spread it
- Thixotropy = "Ketchup bottle" Effect





Initial Launch Product: Pulsehaler™ (non-drug) For COPD

Direct Healthcare Cost \$200B+



COPD (Chronic Obstructive Lung Disease) >350 Million Patients and Growing #3 Killer of all Diseases

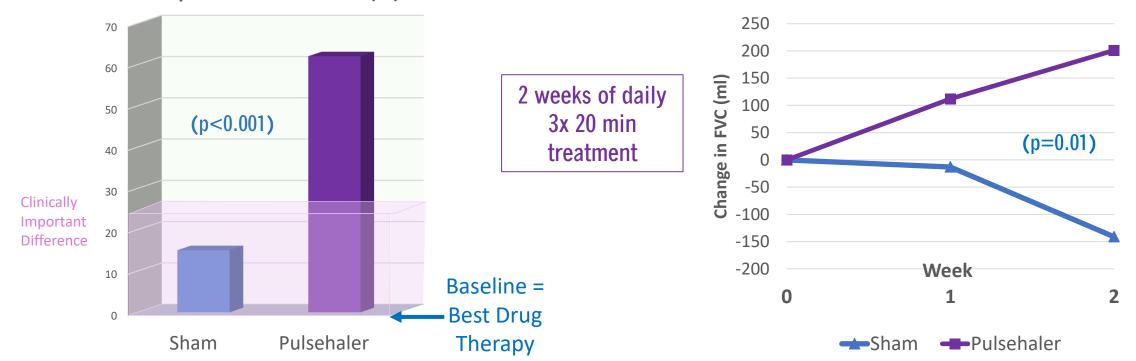


Clinically Proven in COPD

ORIGINAL RESEARCH

Randomized Controlled Crossover Trial of a New Oscillatory Device as Add-On Therapy for COPD

Zvi G. Fridlender,¹ Nissim Arish,¹ Uri Laxer,¹ Neville Berkman,¹ Allon Leibovitz,² Gershon Fink,³ and Raphael Breuer¹



Improvement in 6MWD (m)

Exercise Capacity: 2.5x the "Clinically Important Difference"

FVC change vs placebo (sham) of 342 ml

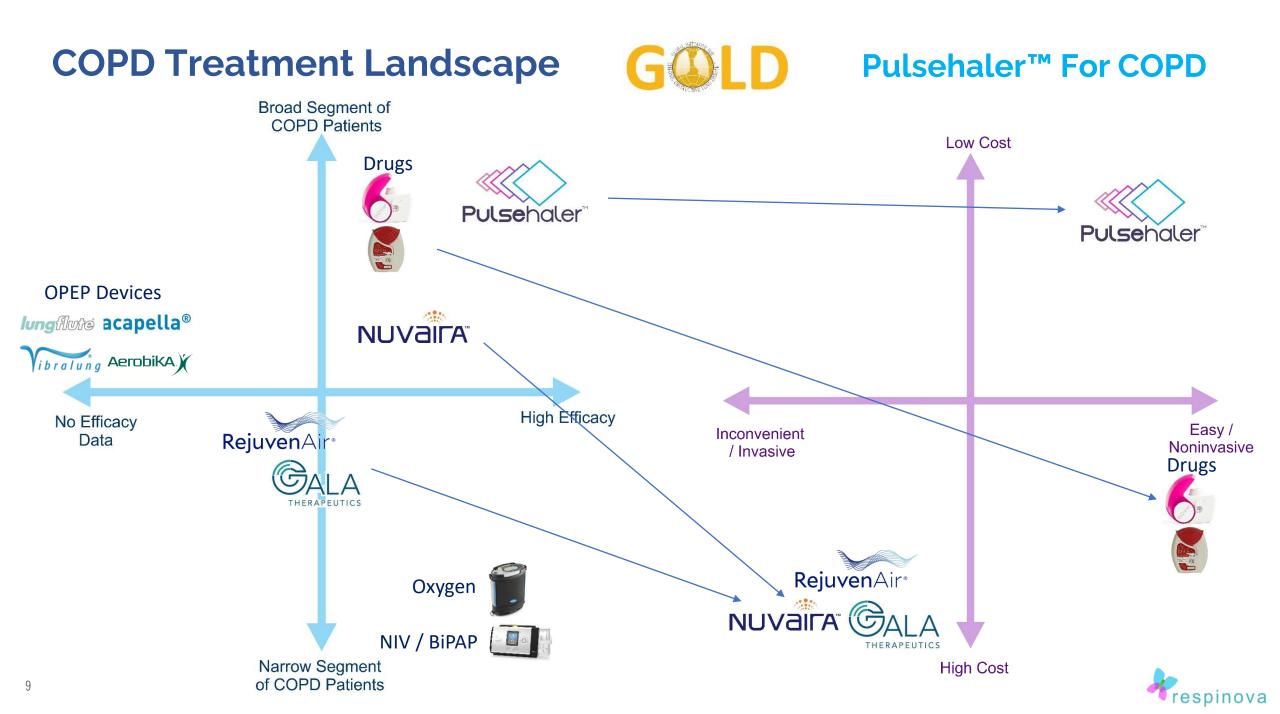
Improved Quality of Life Scores! (p=0.02)





Change in FVC





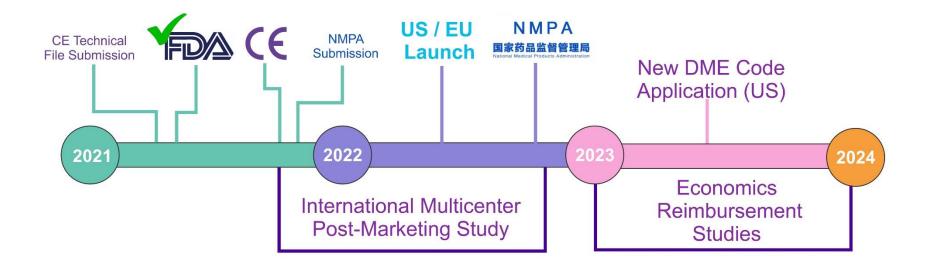
Business Model and Commercial Timeline

- FDA 510k Cleared / CE in Process
- Business Model: Sell systems and Consumables
- Hospital / Clinic Use and Home Use (Daily Therapy)
- Seeking Distribution Partners Globally
- JV Agreements with Vincent Medical for China / Japan



espinova

Pulsehaler[™] For COPD



Breakthrough in the \$36B Drug Delivery Market

Respinova is developing a next generation Drug Delivery platform based on its patented Pressure Wave technology

Pipeline: Drug Delivery Devices







Pulsehaler™ Neb Pulsehaler™ DPI



Proprietary pressure pulses + low-pressure airstream – Opens Airways

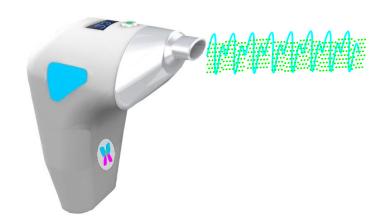


Pulsehaler deposits drug particles deep in the lung

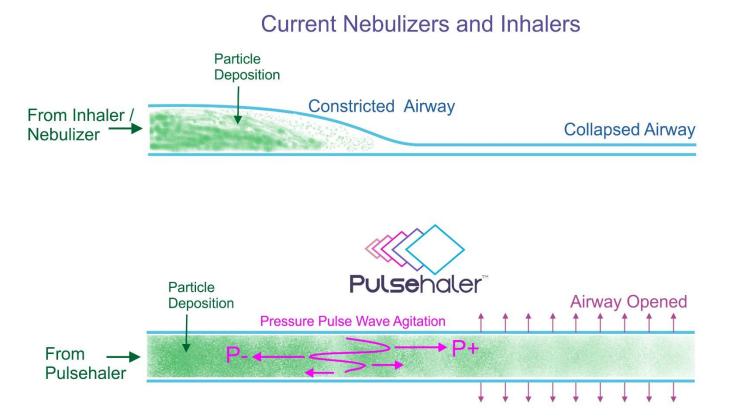


Improved Particle Delivery Mechanisms

- Airway reopening allows drug penetration deeper into the small airways
- Mucus smoothing smoothing of the airways mucus lining which decrease flow disturbance and tendency to re-close
- Effect on aerosol aerodynamics the sharp pressure pulsations retard gravitational sedimentation of the larger aerosol particles, keeping them longer in the flow of air into the lung periphery.



Pipeline Products: Pulsehaler™ for Drug Delivery

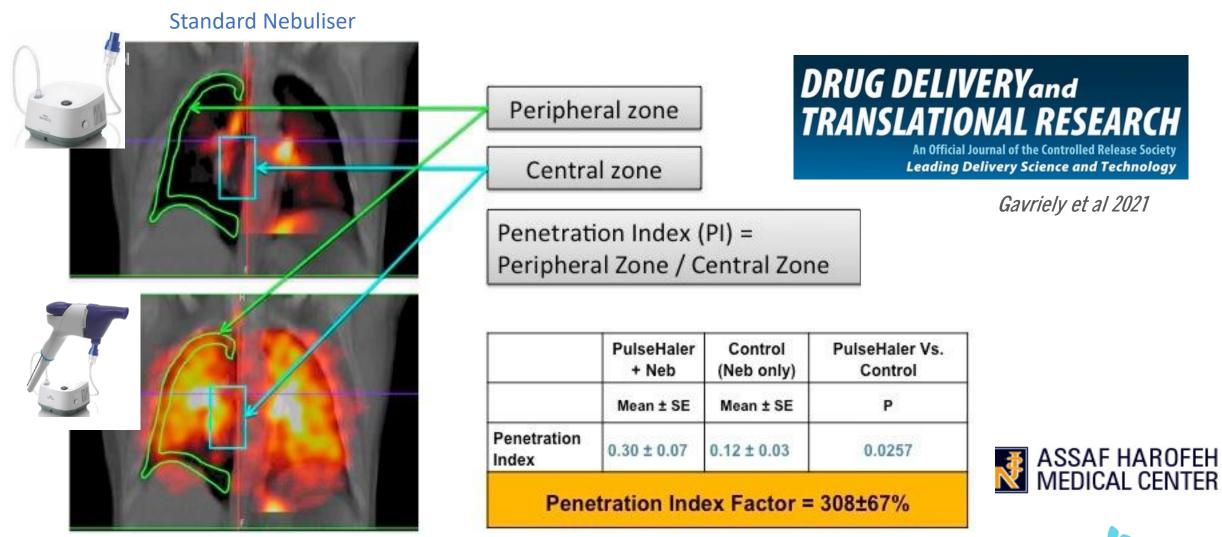




Pulsehaler™ Improves Deep Lung Drug Delivery

Pulsehaler[™] had <u>3x</u> the peripheral penetration ratio after only 1 treatment

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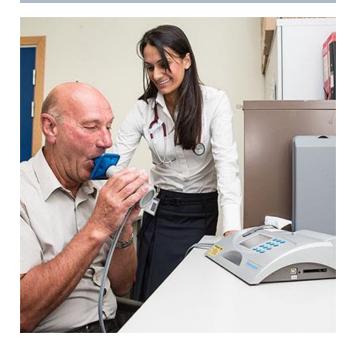
Nebuliser + Pulsehaler™

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PulseHaler™ Improves Drug Efficacy

Pulsehaler[™] for Drug Delivery

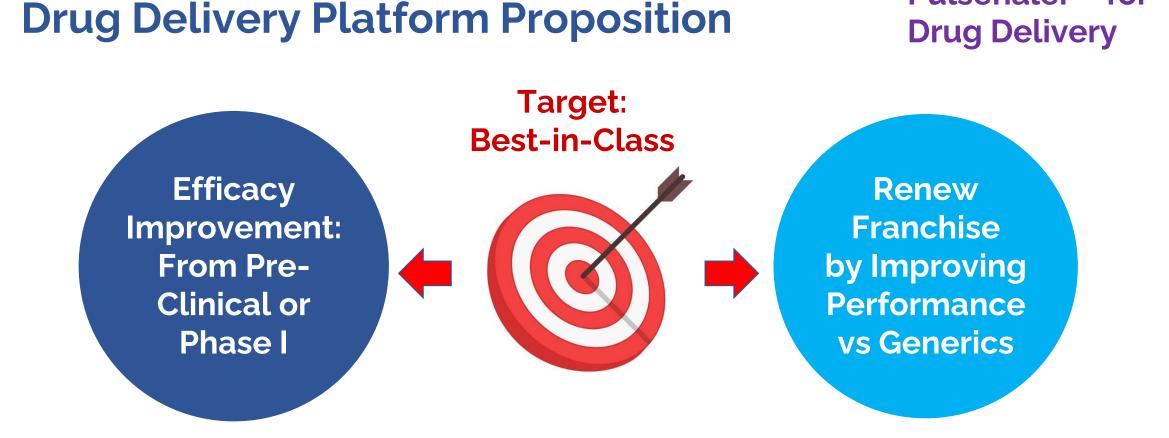
Spirometry Results



One Treatment of 20 Minutes!

Measure	Pre- SABA	Post- SABA	Diff	Pre- SABA + PH	Post- Saba + PH	Diff
FEV1 [L]	1.483	1.549	.066 (p=NS)	1.419	1.569	.151 (p = .008)
FEV1%	54.2	56.6	2.4 (p = NS)	51.8	57.0	5.2 (p=.005)
FVC [L]	2.975	3.121	.145 (p=NS)	2.841	3.079	.238 (p<0.02)
FEF ₂₅₋₇₅	.739	.746	.007 (p=NS)	.672	.802	.13 (p<0.02)
BORG Scale	2.1	1.3	-0.8 (p=.001)	2.2	0.6	-1.6 (p=0.00002)





Early Clinical

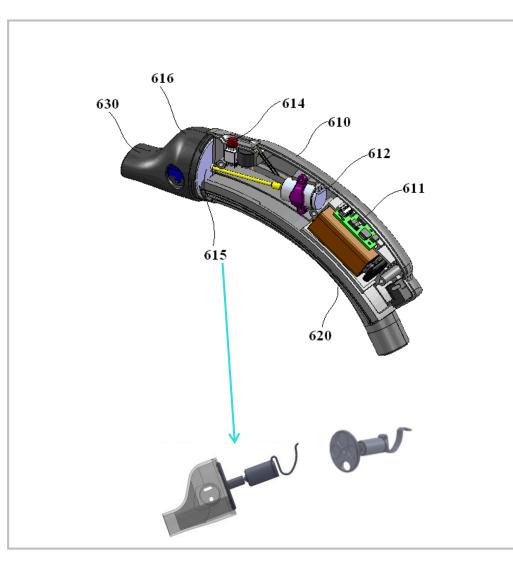
Declining Franchises

Pulsehaler[™] for

Strategy: 1. Platform Technology for Multiple Products 2. Partner for Co-Development



Intellectual Property



- 6 patent families with 24 applications filed covering device, methods, protocols
- 17 patents granted in Europe, US, Canada, Eurasia, Israel and China
- USA, Europe, China, Japan, Canada and Israel, India
- Encrypted Pulse Frequency / Pressure Protocol Software

"

Respinova's IP is a highly grantable monopoly encompassing a device for producing controlled combinations of periodic sequences of pressure pulses (BURSTS OF AIR, or AIR PACKETS) in any sequence. The device provides any protocol, characterized by the sequence, pressure, oscillations, vibrations, amplitude and intensity of the train or trains of air packets. These are provided to physiological tissues to bring about a therapeutic effect and/or to facilitate drug delivery for the relief of lung diseases.





Team with Over 125 Years Experience

Scientific Advisors



Dr. Richard

Casaburi, UCLA





Prof. Gershon Fink, **Kaplan Hospital**



Business Advisors



Florence Joffroy-Black Device Marketing Exec







Seema Chaturvedi Capital Markets / Entrepreneur





Rachel Behar Finance Manager



Ran Amos **Director of Quality**



Ariella Ascher **Clinical Coordinator**

John Lipman Respiratory Marketing Expert

Dr. Barry Make,

National Jewish Hospital



Dr. Eddo Dinstein, LLB, SJD

Director and Founder

Hans Brocker

Director and Founder

Directors



Otto To Director





UCLA



Cliff Ansel

CEO

Dalia Givony Head of Clinical Affairs

Ariel Shvager VP Mech. Eng.

Yuval Avni



Drew Miller

Prof. Noam Gavriely

СМО









Dr. Ishay Ostfeld

Lilach Bar-El CTO & Founder **COO**

Series B: €10M



- European Commission EIC / EIB committed investment of €5M as part of Horizon 2020 EIC Pilot Win
 - > Seeking of €5M Lead Investor
- First Tranche of €1.7M via Convertible Note (€850K) from EIC)
 - Seeking balance of €850K
- Use of Series B Funds:
 - > Complete CE Mark
 - Multicenter Clinical trial
 - Production Rampup
 - ➢ Pulsehaler™ Launch in Europe , USA
 - plus Japan and China via Strategic Partner



Two Time Horizon Winners H2020 SME Phase II + EIC Pilot



Winners – Startup.Battle



Finalists









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