DESTINATION STARTUP

Respirogen, Inc.

One-Sentence Summary of What You Do: Respirogen technology delivers oxygen to the bloodstream independent of the lungs to reduce systemic hypoxia for lung disease patients.

Affiliated Institution: University of Colorado Boulder

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Angel Funding (including Self or Friends/Family)

Please describe your company and the problem you are trying to solve: Respirogen™ Micro-Oxygen (OMB) technology has been demonstrated to increase the oxygen saturation of the blood in hypoxia without the use of the lungs. This creates a new and novel strategy to augment oxygen management in emergency response and in ventilator protocols. RMO will provide capillary oxygen to cardiac arrest trauma patients, to hypoxic lung compromised patients in ARDS, in emergency resuscitation and transport, and other clinical situations where hypoxia causes organ damage.

Acute respiratory distress syndrome (ARDS) affects nearly 10% of all intensive care unit patients with a reported mortality rate of up to 40%. Oxygen microbubbles (OMB) are designed to provide rapid, non-invasive extrapulmonary oxygen to supplement the lungs. USAF sponsored research has shown that colonic OMB will increase mixed venous oxygen tension (PmvO2) and arterial oxygen tension (PaO2), and also reduce the corresponding carbon dioxide values (PmvCO2 and PaCO2) in a porcine model of smoke inhalation-induced ARDS. OMB treatment resulted in significant improvements in systemic oxygenation as demonstrated by an increase in PaO2 of 8-15 mmHg ($p<0.05$), and by an increase in PmvO2 of 4-12 mmHg ($p<0.05$), starting at 15 min and sustaining out to 150 min. We also observed a decrease in PaCO2 of 6.3-25 mmHg, and improvements in other blood gas parameters over the 3-hour post-treatment time period.

The technology is protected by 3 issued patents, 1 allowed patent, and mutliple filings for devices and methods of oxygen delivery. Patent license agreements are in place with Columbia University and The University of Colorado.

What is/was your go-to-market strategy? Customer acquisition is by identification of key opinion leader surgeons active in clinical studies for ARDS. Company Phase I and Phase II IND clinical trials will prove safety and efficacy in treating ARDS. Evaluation of relevant research publications, advisory boards of medical societies, and medical conference attendance will identify physicians and hospitals capable of clinical study enrollment and data management for study success.

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The medical need for an effective and safe treatment of ARDS is high, as the condition is life threatening with 40 % mortality rate and affects 200,000 patients in the USA, 170,000 patients in Europe, and 3,000,000 global patients annually. Currently there are no approved pharmacological treatment for ARDS by the regulatory authorities in the USA (FDA) or Europe (EMA).

How will/do you generate revenue? Respirogen customers will be physicians treating patients experiencing hypoxia from lung diseases which include COVID-19, ARDS, sepsis. pneumonia, smoke inhalation, chemical inhalation, near drowning, and influenza.

The initial clinical target will be patients requiring supplemental oxygen for hypoxia, being treated in the 486 trauma centers and 266 ECMO centers in the USA. The technology will increase the hospitals capable of lung injury care. Respirogen will sell sterile oxygen microbubbles (OMB) for therapeutic use in lung injury patients. Products will consist of single use catheter procedure kits for surgery, and dose volumes of sterile OMB for multiple infusions to the patient. Revenue and profitability will be driven by growth in procedure volume, with initial sales in COVID-19 and ARDS treatment. The therapy is adjunctive to ventilator therapy, adding revenue per ventilator procedure.

How will this showcase benefit your company or technology? The company is seeking $3,000,000 as a Series A preferred stock offering. Funding will support operations through pre-clinical animal studies, verification and validation testing, development of human use clinical protocols, and enrollment of the USFDA Phase I IND clinical trial.

Who are the members of your team and why is this the right team to get the job done? The management team includes: CSO Mark Borden PhD, inventor of the technology, Associate Professor at The University of Colorado; CEO Robert M. Scribner, experienced life science executive with successful management experience in new technology development from concept to market; Dir. of R&D Paul Mountford PhD, who holds his doctoral degree in microbubble science and has industry startup experience; and Dir. of Operations Robert T. Scribner, who trained in Quality System Management with Medtronic and has experience in life science technology startups.