DESTINATION STARTUP

Nob Hill Therapeutics

One-Sentence Summary of What You Do: Nobhill Therapeutics (NHT) is commercializing a first of its kind, dry powder nebulizer technology, DryNebTM, by developing effective inhalation therapies to treat deadly lung infections.

Affiliated Institution: University of New Mexico

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Direct/Indirect University Support, Angel Funding (including Self or Friends/Family)

Please describe your company and the problem you are trying to solve: There are 250 million people that suffer from lower respiratory infections every year and is the 5th leading cause of death in the world. Multidrug resistance infections are difficult to treat, require long treatment periods and large doses of antibotics, which can lead to severe and intolerable side effects. The COVID-19 pandemic has highlighted the urgency for effective respiratory therapies. Inhaled antibiotics dramatically improve the targeting of therapies to the site of respiratory infections, while simultaneously minimizing systemic exposure and associated toxicity. The high local concentrations of antibiotic may enable more effective treatment of multi-drug resistant pathogens. There is a great and unmet need to provide targeted therapies, inhaled to directly deliver drugs to the infected area, for fast onset of action and reduced toxicity. NHT has a patent protected inhalation device technology that is advantageous in the delivery of therapeutic doses directly to the infected area in a manner that is suitable for patients of all ages and inhalation capabilities. These factors are critical to ensure treatment efficacy when a patient has limited inhalation and coordination capability. NHT is first planning to repurpose FDA approved drugs, we are developing our first therapy using a combination of both private and NIH funding. NHT is currently conducting preliminary animal safety study and hope to move into the clinic by late 2021.

What is/was your go-to-market strategy? In 2018 the inhalation therapeutics market was approximately $25B and is expected to expand at a CAGR of approximately 6 % through 2025. Market growth is being driven by the continuing rising of respiratory diseases. NHT has two market objectives: First, position DryNeb as the method of choice for dry powder inhalation drug delivery through partnership or licensing. Large Pharma companies are constantly looking for new and effective therapies to address lung infections, which includes but is not limited to Vectura, Novartis, Pari, Teva, and GSK. The progress in the drug development process is greatly hindered by lack of effective drug delivery devices and NHT is well positioned to be the device partner for these companies. Second, take our lead drug-device combination antifungal therapy using DryNeb's

platform through the FDA and build a therapeutic pipeline. To expedite time to market, the first therapy will seek the Limited Population Pathway for Antibacterial and Antifungal Therapies for relatively rare but life-threatening infections. We have selected our lead therapy based on the initial efficacy data gathered through clinical off-label use. The SBIR-supported animal study will move the lead product towards Investigation of New Drug (IND) application. In the meantime, we have strategically positioned our product development pipeline to address other unmet needs and to attract follow-on funding and development partners. NHT is pioneering dry powder nebulizer drug delivery. Currently, there is no inhaled antifungal therapy on the market. Inhaled Tobramycin, Aztreonam, and Amikacin are the only approved inhaled antibiotics on the US market.

How will/do you generate revenue? NHT will generate revenue through two paths. First, NHT plans on repurposing approved drugs for the treatment of respiratory orphan diseases. The company is seeking grants from The National Institute of Health and Cystic Fibrosis Foundation for our therapy development effort that addresses the needs of orphan diseases. We have been awarded a $299K Phase I SBIR and we will be seeking Phase II SBIR-NIH grant which will take the therapy development through preclinical development, animal toxicology and IND filing. Second, as our device platform is fully developed in the next two years, we will first seek business and revenue generating opportunities through licensing and co-developing proprietary drug inhalation therapies. For example, CF-related non-tuberculosis mycobacterium has led to the recent partnership of Pulmatrix's Pulmazole (inhaled itraconazole) by Cipla technologies, which received $22M plus milestone payments (Phase I clinical asset). We understand the challenges in taking a drug-device therapy through FDA clinical trials, but with orphan disease designation, we can expect to go to market sooner. A therapy for orphan indications can generate substantial revenues. For example, Insmed's inhaled NTM antibiotic, Arikayce has current sales of approximately $200M annually and was approved in 2018 under the Limited Population Pathway for Antibacterial and Antifungal Drugs (21st Century Cures Act) to advance novel drugs for relatively rare but life-threatening infections.

How will this showcase benefit your company or technology? We are seeking series A $6M funding to expand our team's clinical and FDA regulatory expertise (0.5M), and complete the clinical DryNeb device design, build and test ($2M), IND application and complete IND enabled pre-clinical safety study ($2.5M), and set stage for clinical phase I trial (1 M) in two years.

Who are the members of your team and why is this the right team to get the job done?

We have assembled an knowledgeable team and advisors that have a combined 60 plus years of inhalation drug delivery experiences and startup business development. The teams members have diverse background and experiences in taking startups from company formation to crossing the valley of death into the VC stages. We are passionate of what we do, and determined to develop the effective lung infection therapies to save lives.

DESTINATION STARTUP

- Dr. Yun Li, CEO, entrepreneur and physicist, has been a startup/commercialization executive for over a decade. She has assisted a handful startups from starting-up to VC funding stages, MesaBio, Innothium, Integrated Deposition Solutions, mPower.
- Mr. Carmine Durham, the chief strategic officer of NHT, entrepreneur, is an experienced pharma executive in startup and large pharma companies, Zurex Pharma, BoneCare International, Abbott, Knoll - BASF Pharma. He founded Zurex Pharma, and have raised $10M for clinical stage of development.
- Dr. Matt Reed, the chief science officer, is a renowned inhalation toxicologist, experienced in clinical study development and inhalation toxicology with over 30 years' experience at the Lovelace Respirotory Research Institute.
- Dr. John Pritchard, the business advisor has made a life career in inhalation therapy and business development at Philips Health Care, AstraZeneca, 3M Health Care, GSK.
- Dr. Chuck Daly is the country's leading respiratory disease clinician at Jewish health.
- Dr. Hugh Smyth is a tensor professor at UT Austin, a serial innovator, with one delivery invention in clinical Phase II trials.