

New Air

The Company

New Air Inc. US is the newly established parent company of Baby's Breath Ltd. Founded back in 2001 by a group of entrepreneurs and leading physicians. The company's main goal is to develop innovative inhalation technologies for children and adults.

Baby's Breath has completed the development of BabyAir[™], a special inhalation and drug delivery solution for babies under the age of 2 years, who suffer from asthma and other respiratory conditions.

BabyAir[™] is bringing to the market a unique touch-free inhalation and medication delivery device designed especially for infants and seniors.

The product efficiently overcomes the ineffective usage problem of Nebulizer systems, as well as the ENORMOUS resulting spoilage of expensive medication. With this definite competitive advantage, Baby's Breath Ltd. has already begun sales and believes it can capture a leading share of the market and create an extraordinary return for investors.

The Need

Respiratory diseases are among the most common chronic disorders in childhood and elderly communities, and rapidly growing from year to year. Aerosol therapy is commonly used in treating asthma, RSV, COPD, cystic fibrosis, upper respiratory infection, and other respiratory diseases.

- **Asthma** affects more than 9 million children under the age of 18 and 10.6 percent of adults in the US.
- **RSV** is the major cause of lower respiratory tract infection during infancy and childhood in the US. Almost all children are infected by RSV before 2 years of age, 75,000-125,000 require hospitalization. Each year there are 400 infant deaths from RSV in the US.
- **COPD** (lung disease) is the fourth-leading cause of death in the United States. More than 12 million adults in the United States have been diagnosed with COPD, and another 12 million are believed to be undiagnosed.

The common ineffective treatment: aerosolized medication delivery systems are effective only when used properly; an effective therapy typically requires 15 to 20 minutes to administer. However the facemask element turns the treatment into a very ineffective one.

Why? Simply put, babies and children despise the mask and fight from the moment the treatment starts often exhausting themselves in their weak state, therefore requiring more frequent treatments. In addition the treatment is given in an elevated position because of the position of the nebulizer itself and therefore cannot be administered while sleeping.

These difficulties can ultimately result in non-compliance due to the extreme discomfort. Studies show that hospitalization for more than 74% of patients admitted for asthma attacks could have been prevented by a nebulizer treatment¹.

In addition a glimpse into any pediatric emergency room will reveal a heart-wrenching scene of at least one screaming child with a frantic parent fighting to hold a mask over the child's face. This scene recurs every 4-6 hours in the hospital and continues at home each time the child has another attack.

The Problem

Inhalation devices' main adverse effect is the **enormous spoilage of medication** they cause: since the current popular method of inhalation is inefficient and requires additional repeated processes, a double usage of medication is required. Since the minimum monthly expense is approximately \$380 the economic damage for HMO, PPO and Medical Centers is huge (for a drug that is 75% reimbursed) assuming millions of inhalation procedures per annum in the US itself.

¹ General Practice Airways Group

The Market

Market size:

- During 2007 more than \$1.6 billion was spent on ventilators, oxygen therapy systems, and airway management accessories in the United States². Growing at an annual rate of 6.3%, sales of these products are expected to reach more than \$1.9 billion by the year 2010.
- Direct health care costs for asthma in the United States total more than \$11.5 billion annually.
- In 2006 approximately 180 thousands kits of portable nebulizers were sold throughout the US, 40 percent of them addressing the 0-3 year's old babies and toddlers. The average price for such a kit is \$88 (\$108 including a compressor).

Target markets trends:

- Children and elderly patients form the largest end-user segments that drive demand for nebulizers. The elderly population (50+ years) is likely to double by 2030 to approximately 70 million³.
- Portable compressor nebulizers have provided a major boost to the nebulizers market, by meeting patients' need for portability at a lower price. Portable compressor nebulizers are likely to continue to gain momentum due to high growth projections of the therapies market.
- Healthcare reimbursement systems have forced hospitals to shorten patient stays, resulting in an increase in home-based healthcare. Compressor-based nebulizers are especially complimentary to this market shift because of durability and efficacy.
- Additional market engine is the pharmaceutical and biotechnology companies' trend to develop new alternatives to oral drug delivery. This trend has increased dramatically in the last five years based on the belief that intranasal drug delivery may lead to greater drug efficacy, speed of action, safety, and patient compliance. Already several pipeline drugs are being developed for pulmonary (deep lung) systemic administration.

The Product

BabyAir™ is based on a unique nebulizer which is mounted over a special hood constructed like an umbrella. It is designed to be placed over the head and upper torso of the child. The nebulizer can easily direct the aerosol to the nose and mouth of the child; therefore if the child wants to turn the parent simply readjusts the tube without troubling the child.

The medicine is placed in the nebulizer cup and is delivered to the area in front of the nose and mouth of the patient as a nebulized fine aerosol. This system enables the medication to be inhaled by the patient without any physical contact with BabyAir™. The hood is made up of a polycarbonate frame covered by plastic, which can be easily sterilized for re-usage, this is significantly important for hundreds of hospitals and clinics.



BabyAir™ is **significantly more effective** than traditional masks or any other solution out there since the baby does not resist treatment and due to the specially designed mechanism that enables receipt and absorption of an optimum dose of medication.

The Status

- BabyAir™ has gained the FDA approval for the United States and CE approval for the EU.
- Furthermore Baby's Breath Ltd. holds ISO 9001 certification from the European Union.
- Baby's Breath has been granted two patents for BabyAir™, in USA, EU, Israel and Japan.
- BabyAir™ is being sold in Italy, Portugal, Hungary, Germany, Taiwan and Israel.

Baby's Breath has completed the development of a second generation of BabyAir, and is in the late stages of development of an additional version, a disposable hood for hospitals, as well as versions for senior adults and for other applications (e.g. a product for use with oxygen in addition to medication).

² MedTech

³ U.S. census bureau

The Team

Prof. Michael Newhouse /Founder - considered among most leading pediatricians in the US and an expert in the field of respiratory diseases.

Yossi De Levie/Chairman – a successful entrepreneur, with over 35 years of vast experience in commercializing of mass market products. Yossi De Levie has participated in 3 exits of companies in which he was a shareholder; he sold his company to Gaon Holdings, had a partial exit in 2006 and assisted in an exit/deal of \$28 million to Suncoast in 2008.

Lior Carmeli/CEO- Mr. Carmeli offers extensive experience in various senior management positions in large leading organizations. Recently he completed 10 years at Makhteshim Agan Group, a USD 2.5 billion Chemical and Pesticides Group, mostly as a senior VP & Director of Finance in their US headquarters in New York.

David Kapon/CFO - Mr. Kapon has 15 years extensive financial management experience. He was the financial manager of Negev Ceramics (traded at TASE) for six years, and serves as a financial advisor to StarKist Food d'Or.

Guy Bino/VP BizDev&Sales – led and participated in strategic planning projects for large Israeli companies entering global markets at Rotem Strategy. Was a member of the economic team negotiating between Israel and the EU at the Israeli Finance Ministry

Jacob Bal/CTO – prior to New Air Jacob Bal was a senior director at Scitex Corporation, he also served as a senior project manager at IBM labs.

Scientific Advisory Board

Dr. Israel Amirav/founder - specialist of Respiratory Diseases at Ziv Hospital, Zfat, Chairman of the Association of Inhalation Physicians in Israel.

Asaf Halamish - extensive management experience in the development of new products, many years of experience in managing research and development projects in Israel and abroad. Mr. Halamish has special expertise in plastic products for medical applications.

Prof. David Groshar - associate professor at the Technion Institute in Israel, Head of the Nuclear Medicine Department at Bnei Zion Medical Center in Haifa, Israel.

Dr. Mandelberg Avigdor Director of the Pediatric pulmonary Unit, at Wolfson Medical Center, Holon, Israel.

Prof. David E. Geller associate clinical professor at Univ. Central Florida School of Medicine and assistant clinical professor at Florida State Univ. School of Medicine. Served as consultant and advisor of 16 companies among them Bayer, Novartis and Aerosol Research Institute (PARI).

