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Belhaven Biopharma and Their Nasal Dry Powder Epinephrine Device Nasdepi® are Giving Patients a User-Friendly, Pain-Free Product to Use for an Anaphylactic Event

Scott Lyman
CEO/Chairman

Belhaven Biopharma

Interview conducted by:
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CEOCFO Magazine

CEOCFO: ***Mr. Lyman, what is the vision behind Belhaven Biopharma?***
Mr. Lyman: The vision for Belhaven is to bring innovation to emergency use medicines. We strive to develop new dry powder nasal devices to the market by leveraging our pharma R&D and formulation expertise to replace existing intramuscular injections and auto-injectors.

Our first product is for the treatment of life-threatening allergic reactions (anaphylaxis). It is a nasal dry powder epinephrine device called Nasdepi®.

We feel the advantages of a nasal dry powder device over the current standard of care, either the EpiPen or a manual intramuscular injection, are numerous. We have heard firsthand that patients, physicians, and insurance companies are looking for a better product that is both economical and user-friendly, and that is something we can deliver.

CEOCFO: ***What were the challenges with the type of product you are developing and what have you figured out about how to do it effectively?***
Mr. Lyman: Most of the previous research and innovation in the dry powder space has been working towards the development of very small particles for inhaled products. This research on dry powders has been devoted to medicines that can be delivered to the deep lung. We quickly realized that if you instead develop larger particles, it would be ideal for a nasal administration.

Our team's background and expertise are in formulation and spray drying. We are coupling that understanding to develop powders designed for quick emergency use when the nasal device is administered and absorbed by the nasal mucosal.

CEOCFO*: How did you develop nasal approach?*
Mr. Lyman: In general, we thought we could transition the emergency use medicine paradigm from an auto-injector in your leg to a nasal device. When we looked at a liquid nasal approach relative to a dry powder nasal, we quickly realized there were many advantages of dry powder over liquid nasal. By using a dry powder instead of a liquid, most medicines are more stable resulting in a longer shelf-life and better heat resistance. This results in a product that works with the patient's lifestyle; they can take it anywhere including a baseball game or to the beach.
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Our goal was also to overcome the need for the patient to be an 'active participant' in the administration of the drug, as required by the liquid nasal approach. With a liquid nasal product, you need to hold the liquid in the nasal cavity in order for the absorption of the medicine to occur properly. We are trying to overcome the need to be an active participant device, the dry powder nasal delivery allows for an involuntary process. Once a patient actuates our nasal device, the powder is deposited on the back of the nasal mucosa automatically, without any need for the patient to do anything. They could be unconscious and the dose will be delivered properly into the bloodstream which is key in an emergency use setting like anaphylaxis. The drug still gets absorbed regardless of whether they are upright or laying down. That is a big advantage.

With the dry powder nasal approach, our research suggests the variability of dose delivered goes down. For example, drawbacks of the liquid nasal approach is that when you pull the nasal device from the nostril, a portion of the liquid dose can come out the front of the nose. If the patient is leaning back, the liquid can go down the back of the throat. In general, it leads to a less precise dose when compared to the dry powder nasal approach. With something like epinephrine, you need an accurate dose, want the drug in the patient's bloodstream as quickly as possible, and the product to work whether someone is conscious or not.

We are trying to give patients who need to carry epinephrine with them, a user-friendly, pain-free product. If someone has an allergy to bees, wasps, food, or something else, you need to have the medicine with you in case you experience an anaphylactic event. We are confident that a dry powder nasal device is the best option for delivering these emergency medicines.

"Our first product is for the treatment of life-threatening allergic reactions (anaphylaxis). It is a nasal dry powder epinephrine device called Nasdepi®." Scott Lyman

CEOCFO: *Does it matter if someone has a cold or a runny nose?*
Mr. Lyman: In general, a key function of the nose and nasal mucosal is to act as a filter. The nose recognizes any foreign object, whether that is a piece of dust or in this case epinephrine dry powder, and rapidly tries to clear that. It will absorb certain things and leave the rest. That is how this passive way of drug absorption works. If a patient has a runny nose, which happens in some cases of anaphylaxis, we expect our dry powder device to deliver similar drug levels compared to a non-runny nose.

CEOCFO: *How do keep the powder dry and prevent heat problems?*
Mr. Lyman: Our background is in spray drying and formulation. Our team knows formulate epinephrine to make it stable as a dry powder. The spray dried powder is then filled into the device and assembled. By adding certain excipients, it protects the epinephrine from heat and humidity. To ensure the product stays stable, the device is packaged in a secondary vial with a desiccant liner that protects it from environmental pressures such as heat and humidity. These multiple layers of protection ensure that Nasdepi will not degrade over time. We are now seeking to confirm this stability in longer term studies and some of these are ongoing, but so far, so good.

CEOCFO: *Where will your initial markets be for the release of Nasdepi?*
Mr. Lyman: The vision is this product will not only be used in the US, but also worldwide. We would like to see this product launched globally. As we talked about earlier, we expect Nasdepi to be heat resistant, have a longer shelf life, and be small – all keys to a successful worldwide product. You can carry Nasdepi with you at all times. Quick access to medicine is one of the biggest issues with anaphylaxis. People have serious emergencies because they don't have an EpiPen with them. Besides autoinjectors being big and cumbersome, patients know that extreme heat can cause them to go bad. By having the drug with you at all times and feeling comfortable that it is not going to degrade because of heat, we feel we can get more patients to carry their medicine with them at all times.

CEOCFO: *How often is the injector pen needed?*
Mr. Lyman: It is not needed very often. I think the statistic is less than 1% of the autoinjectors are used. This is one of the pain points that we would like to solve because the effective expiration date for the EpiPen is about twelve months for the patients after it sits at a wholesaler and then at the pharmacy. On average, patients have about twelve months of expiration dating before they must replace it. Since most epinephrine autoinjector do not get used, we would like to

extend the expiration date so that patients do not need to go back to the pharmacy every year and get a new device. Each Nasdepi device is single use, just like the EpiPen.
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CEOCFO: ***Where are you today with regulatory issues?***
Mr. Lyman: From a regulatory perspective, we have had a pre-IND meeting with the FDA and received valuable feedback on our development plan. I would say the FDA is learning more and more about nasal products and giving good advice to companies like Belhaven on what is needed for an FDA approval. We just completed our first in-human clinical study. That data should read out in mid-January, and we closed our latest round of funding in early January. In terms of patent coverage, multiple patents have been issued to date and we've filed for international protection as well. We continue to add more patents as we continue to develop Nasdepi. We feel strongly about our intellectual property protection.

CEOCFO: ***How might a nasal spray affect the injector suppliers?***
Mr. Lyman: We commissioned a survey through the Asthma and Allergy Network for 3700 patients and physicians to get some preference data. The results were pretty clear that the allergy community wants an EpiPen alternative. Beyond wanting something without a needle, they also want something with a longer shelf life and a product they can trust in heat and humidity. We know there is a huge opportunity here for a better product for these patients. I think some of the headlines in the news over the last ten years about EpiPen, maybe have helped in this particular case. These include large price increases and product stockouts when kids are going back to school, it feels like the community is ready to make a change. The feedback we have gotten from our medical advisors confirms this sentiment.

CEOCFO: ***Development and commercialization is always expensive; are you seeking funding, investment, or partnerships today?***
Mr. Lyman: We are looking to find a commercialization partner. Our expertise in developing new, innovative, pharma products with novel formulations. It is expensive to build a salesforce and a team and I know this first-hand from my time at Amgen and GSK. Therefore, getting our products in the hands of a established company with leverage with insurance companies and PBMs to insure Nasdepi is widely available to the patients is key, both in the US and worldwide. We want to not only develop a simple product that patients are going to love, but they need to have access to it and that is what a pharma partner brings to the table.

CEOCFO: ***Have you started looking for a pharma partner or put out feelers; do you have a plan for how to get their attention?***
Mr. Lyman: Yes, it has been baked into our plans all along. We are actively talking to not only companies that work in the allergy space and have an existing sales force, but also pharma companies that have been out of the allergy space and might want to jump back in with a product like Nasdepi. Ongoing discussions are taking place and hopefully, we will have something to share in the next six to twelve months.

CEOCFO: ***How do you deal with some of the frustration when you are developing a product that could have a big and immediate effect on people and yet it is a long process to develop and when you have it ready, to get it in use?***
Mr. Lyman: Part of that is our business model. We are an outsourced virtual pharma company, so we rely heavily on our development partners whether that is our spray dry partner, our filling and assembly partner, or even our device partner. We must walk lockstep with those external companies and that can be a difficult process for teams that are not used to contract manufacturing. In general, this model works well for us, and we make decisions quickly, we are nimble. I have seen bureaucracy and governance get in the way of development at big pharma, so it is nice that we are able to streamline the process as much as we can.

CEOCFO: ***With so many new ideas, particularly in the health field, why pay attention to Belhaven Biopharma? Why should Belhaven and Nasdepi standout?***
Mr. Lyman: I am a problem solver by nature. The beauty of the bioequivalency approach is we are dealing with medicines where the efficacy is known, the safety is known, and we are just trying to change the route of administration. This is more of an engineering problem to solve, and we have to show operational excellence to get it done as efficiently as possible. If we do that, we can do each of these programs with minimal capital required, and the timeline to get a product approved is much shorter than a traditional pharma product. I jokingly tell people that what we are doing is "pharma lite," so they understand that we do not have to go through all of the development steps as a traditional pharma product. We think that if Belhaven can get these products developed, there will be a real impact on patients and physicians, even insurance companies, and the overall cost and burden of healthcare.