Interleukin 1-beta Inhibitor Drug entering Phase II/III Clinical Trials Showing the Ability to Suppress Inflammation in Treating Epidermolysis Bullosa Simplex (EBS)

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“We are building an amazing company that has a portfolio of innovative products targeting diseases of high medical need in areas that are not used to seeing innovation. We already have two late stage programs and will be adding to the portfolio, with the aim of building a substantial enterprise in our core segments.” - Michael Derby

CEOCFO: Mr. Derby, Life-Changing Impact is the tagline on your website. Would you tell how that describes Castle Creek Pharma?
Mr. Derby: We are a specialty pharmaceutical company that focuses on diseases and medical conditions with tremendous unmet medical needs. We focus on patient populations, many of them orphan populations, where there are either no treatment options available or only inferior treatment options available. We are developing innovative products to serve these patients.

CEOCFO: Many conditions fall into that category. What is it that you look for when choosing a technology or an area?
Mr. Derby: Therapeutically we are focused in the specialty dermatology and ear, nose and throat spaces. Within those categories, we look for products that has shown some clinical proof of concept. Oftentimes there have been small pilot studies or other clinical studies that have been conducted to demonstrate preliminary safety and efficacy in the designated populations. We look to build upon these data and design pivotal clinical trials or make product improvements that lead into the later stages of development to get these products approved and ultimately commercialized to serve the patients’ needs.

CEOCFO: What are you working on right now?
Mr. Derby: Our lead development asset is a drug that is entering a Phase II/III clinical study for the treatment of Epidermolysis Bullosa Simplex (EBS). Epidermolysis bullosa is a rare genetic dermatologic disease where patients develop blisters in multiple parts of their body. It is a disease that is diagnosed at childhood and it is largely a pediatric disease although it does continue into adulthood. There are no treatment options currently available for these patients. It has a high degree of morbidity and the more severe forms of the disease can even lead to mortality. It is a prototype of the kinds of conditions that we like to treat.
We have a drug that targets the underlying disease mechanism for the Simplex form of the disease and has established clinical proof of concept in both Phase I and Phase II studies. We are excited about this product and we think it will be a tremendous asset for patients with this devastating disease and potentially one of the first drugs available for the disease.

CEOCFO: How does the drug work?
Mr. Derby: The drug is an inhibitor of Interleukin 1-beta, which is pro-inflammatory cytokine that has been shown to mediate the inflammatory cascade that is present in the Simplex form of Epidermolysis Bullosa. Our product is a potent inhibitor of the Interleukin 1-beta signaling and has been shown both in vitro and in early clinical trials to inhibit the Interleukin 1-beta signaling cascade present in the disease.

CEOCFO: When you are working on a drug where there is a limited population, how do you find people for the trials?
Mr. Derby: You have to align yourself closely with the patient groups as well as the physicians that treat these patients. For rare diseases, oftentimes there are close knit patient advocacy groups or other patient organizations that are active in the community and actively looking to advance the science, the understanding of their diseases, and looking to support new treatment options that might be beneficial to the population. Likewise, the key opinion leaders and other leading physicians that treat these conditions are relatively few for these rare diseases and they are experts in the field and tend to see a lot of the patients. We work closely with both of those groups for this condition and for other conditions that we target and that helps us find the patients.

CEOCFO: Would you tell us about the license agreement for Arlevert®?
Mr. Derby: That was an agreement that we closed in December. That is not a dermatologic product but a drug for the treatment of vertigo which is the first in the ENT space for Castle Creek. That is a drug that is approved in Europe, was initially approved in Germany and subsequently in a number of other markets in Europe. It has been around for some time and has some very compelling clinical data to support the safety and efficacy of the drug in the treatment of vertigo. Vertigo is not an orphan condition but is an area of high unmet medical need. The last drug to be approved in the United States for vertigo is Meclizine, which was approved almost fifty years ago and has a number of limitations both on the safety and efficacy side. We are excited about Arlevert®. It is a drug that is supported by eight different randomized clinical trials, several of which are pivotal that we will look to leverage to expedite the development of the product in the United States. This will probably be one of the first drugs approved for vertigo in decades and will be an important drug for treating patients with this debilitating condition.

CEOCFO: Were you looking to get into the ENT arena and hence Arlevert or was it opportunistic?
Mr. Derby: There is some crossover between dermatology and ENT in the approach to treatment, the way the physicians think and some of the development opportunities that are afforded through topical treatments and the like. We like ENT as well as derm because these are areas that historically have not had a lot of innovation. Because of that we were specifically looking for products that lent themselves well to our business model in the ENT space. Arlevert will be a very nice flagship product for Castle Creek in the ENT arena.
CEOCFO: **What else is in the pipeline?**
Mr. Derby: These are our two lead products, the topical form of Diacerin for the treatment of Epidermolysis Bullosa Simplex, and then Arlevert for the treatment of vertigo. Each establishes a cornerstone of growth for our business in the derm and ENT spaces, respectively. Beyond that we are looking to build a substantial enterprise in those two core areas. We have some earlier stage programs that we have not yet said too much about publicly, one of which is in the specialty derm space for another rare genetic derm condition and one that is in a broader ENT condition. There are also a number of additional product opportunities that we are evaluating and I expect we will be announcing further acquisitions or in-licensing arrangements later this year.

CEOCFO: **Is the team in place now?**
Mr. Derby: The core management team is all in place, including a full development team and commercial team that positions us well to execute on our near term plan. We are very fortunate to have an outstanding team leading the business. We will be selectively adding to the team based on additional deals that we may do or as our business expands.

CEOCFO: **How were you able to get funding since it has been difficult times for companies in your industry?**
Mr. Derby: We have unique business model in that we are pursuing areas of high unmet medical need in the categories of dermatology and ENT, which historically have been overlooked in many respects. That makes for a rather unique value proposition. We focus almost exclusively on product opportunities that have some early clinical data that have already established proof of concept. From that perspective, we are a late-stage company with specialty products that are treating patients with high medical needs in categories that have not historically not had a lot of innovation. And we have a first-rate management team – by all measures, the best in the business. This value proposition was attractive to a number of investors. We have been fortunate that we have been able to close on a substantial round with Fidelity in September.

CEOCFO: **What have you learned from previous experience, what to do and what not to do?**
Mr. Derby: The things to do are probably are self evident. You need to have large markets, break-through products that will attract a lot of interest and serve the needs of patients. That is the key to success in any pharmaceutical venture. What I have learned not to do is chase every opportunity that sparkles. You have to be disciplined in this business and you have to prioritize, you have to understand what is worth pursuing and what is not and not be afraid to make difficult decisions early on.

CEOCFO: **What surprised you so far about the products you have looked at and the products you are working on?**
Mr. Derby: I guess I am surprised at the kinds of opportunities that are available if you dig below the surface. There are so many companies that grow through product acquisition and do so by competing in auctions, trying to buy products that are being shopped and these products tend to get bid up. There are many successful companies that have built themselves along those lines. We have been quite fortunate, and it is perhaps surprising, that we have been able to find interesting and high potential products that are a bit off the beaten path, that have clinical data and sometimes come out of academia or are products that are not being prioritized by other companies. That is the business model that we have forged as we have built the business.
CEOCFO: Why pay attention to Castle Creek Pharma?
Mr. Derby: We are building an amazing company that has a portfolio of innovative products targeting diseases of high medical need in areas that are not used to seeing innovation. We already have two late stage programs and will be adding to the portfolio, with the aim of building a substantial enterprise in our core segments. We look forward to having more to say on our growth strategy and portfolio in the coming months.