Q&A ZEALAND PHARMA

29TH OF MAY 2019
WITH EMMANUEL DULAC

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Transcript Live Q and A Zealand Pharma with Emmanuel Dulac, the 29th of May 2019

Helge Larsen/PI-redaktør	This session start at 16.
Helge Larsen/PI-redaktør	Emmanuel Dulac, are you online?
Emmanuel Dulac	Yes, hello!
Emmanuel Dulac	Thank you for having me.
Helge Larsen/PI-redaktør	Good afternoon, Emmanuel Dulac and welcome to your first Q&A with us here on ProInvestor.com. We are very happy to have you with us today - ready to answer a wide variety of questions from our investors.
Helge Larsen/PI-redaktør	Can you please give us a short-term update on key figures and of important events for Q1 in 2019?
Emmanuel Dulac	Thank you. I appreciate this opportunity to introduce myself to the Danish investment community and continue ongoing dialogue about Zealand Pharma..
Emmanuel Dulac	Zealand is off to a strong start in 2019. The agreement with Alexion signed in March has had big impact by validating our peptide platform and establishing partnership with the global leader in complement mediated diseases. The upfront payment also helped boost our overall cash position to about DKK 1.3b..
Emmanuel Dulac	We initiated three Phase 3 studies so far this year. Glepaglutide for SBS remains on track. We received a second set of Phase 3 results demonstrating dasiglucagon HypoPal as the fastest potential treatment of severe hypoglycemia. The first children with congenital hyperinsulinsm were dosed in the pivotal Phase 3 trial, with at least one already transitioning into the Phase 3 long-term study..
Emmanuel Dulac	It was a busy time to join Zealand Pharma! Yet it has also demonstrated to me the knowledge, capabilities, and reliability of the team.
Helge Larsen/PI-redaktør	What is the guidance for 2019? - and which important events do you expect this year?
Emmanuel Dulac	At this stage in our development, we guide only on net operating expenses. We do not guide on revenue, but expect to receive some from new potential partnership agreements, and milestones from existing license agreements..
Emmanuel Dulac	For key events through the rest of 2019, we look forward to completing the clinical program for dasiglucagon HypoPal and preparing the NDA for submission next year. With dasiglucagon for dual-hormone artificial pancreas, we expect results from the

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	Phase 2 home-use trial. We also expect to have an interim readout of results from the CHI pivotal Phase 3. For treatment of short bowel syndrome, we will update on recruitment in the pivotal Phase 3 study of glepaglutide, plus expect to move ZP 7570..
Emmanuel Dulac	into Phase 1. In our partnered programs, we expect advancement in the early clinical programs with Boehringer Ingelheim and Alexion.
Helge Larsen/PI-redaktør	Can you please give us an overview of the present Zealand Pharma pipeline?
Emmanuel Dulac	We aim to establish leadership in treating short bowel syndrome, first by bringing glepaglutide to market as a best-in-class GLP-2, then follow it with ZP7570 as a next generation dual-agonist treatment option to benefit even more SBS patients. The pivotal Phase 3 trial for glepaglutide is on track to deliver results in 2020. ZP7570 is expected to begin Phase 1 this year, as just mentioned..
Emmanuel Dulac	With dasiglucagon, we are working with three areas of high unmet medical need, and under developed markets. For severe hypoglycemia, we aspire to deliver a rescue treatment that will see much greater adoption than today's solutions. We will conclude the HypoPal clinical program this year and plan to submit the NDA early 2020..
Emmanuel Dulac	For children born with congenital hyperinsulinism, we are developing dasiglucagon for chronic infusions to reduce or eliminate the need for intensive hospital treatment and or pancreas removal. The first pivotal Phase 3 study initiated (children 3 months to 12 years), and the first child already transitioned into the extension study. We expect the second phase 3 study (children up to 1 year) to begin yet this year..
Emmanuel Dulac	we are seeing steady progress with partner Beta Bionics to develop the dual hormone artificial pancreas, which combines insulin and dasiglucagon injections to transform the lives of people with diabetes. A Phase 2 home-use trial just initiated and we expect results already this summer..
Emmanuel Dulac	Our pre-clinical pipeline is also worth noting. We have two programs with Boehringer Ingelheim to develop novel treatments for obesity / type 2 diabetes. This year, we expect the GLP-1/GLU dual agonist to conclude Phase 1 and advance to Phase 2, and the Amylin analog should initiate Phase 1. We are establishing working teams and processes with Alexion, and hope this year to announce the lead complement-inhibitor candidate to begin Phase 1.
Stroka	Emmanuel Dulac ... From here congratulations with the exceptional increase in the share price for Zealand Pharma. The media cites you for stating, that the rise is due to the american investors buying into the story about Zealand Pharma. This is due to which part of the story? – and what makes this happen now and not earlier?
Emmanuel Dulac	It is a bit difficult for me to comment on "earlier" as this is only week 6 for me at

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	Zealand. I will say that there is a red thread of continuous progress, tying together bigger achievements that make Zealand appealing to investors. The Zealand Pharma story became much clearer when the Sanofi relationship ended with the sale of related product royalties. That allowed space to focus on the strategy for Zealand to bring its own products to market..
Emmanuel Dulac	After the Alexion deal, we gained attention of American healthcare investors. Aside from partner-related events -- and highly critical to success -- is that Zealand's pipeline continues to deliver strong clinical results.
Stroka	What is Zealand Pharmas present cashburn and for how long do you expect to be able to keep going at the present rate?
Emmanuel Dulac	In Q1, our net operating expenses were DKK 135.9 million. This amount represents the high activity of running three phase 3 programs. We expect clinical expenses to taper down in 2020 as these late stage clinical programs conclude while we ramp up our US commercial readiness..
Emmanuel Dulac	That said, we also have a very solid cash position of DKK 1.3 billion, with potential development milestones coming in from partnered programs. We have sufficient funding to bring our late stage programs to market, while continuing to support early research and discovery.
HanneP	Takeda have had Gattex in treatments of children suffering of the disease Short Bowel Syndrome (SBS) – this also for patients no more than one year of age. How far are Zealand Pharma with the indikation SBS for young children?
Emmanuel Dulac	We intend to offer glepaglutide to pediatric SBS patients. We are planning the clinical program and expect it to be a part of the NDA submission package.
HanneP	Taking into account the slow and conservative mode of the worlds health systems: How quickly do you expect glepaglutid to achieve a satisfying penetration of the market once it eventually has been approved?
Emmanuel Dulac	Of course we need to consider, completion of the studies, registration, approval and access before we can envision commercialization. However, it is fair to predict that access will be easier on the back of an existing product than in a totally new market : awareness for these treatments is high, value and prices are already set,… but the unmet medical need in these patients is so big, that I believe the best treatment will be adopted fast.
Stroka	How large is the economical potential for glepaglutid?
Emmanuel Dulac	For a treatment that would offer strong efficacy, improved safety/tolerability and fit better with SBS patient's life, we estimate total market potential of more than USD 1.5 billion in U.S. and select European markets by 2030.

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B.Andersen	To which extend will Zealand Pharma conduct the marketing of dasiglucagon og glepaglutid in the United States and other countries?
Emmanuel Dulac	We believe that glepaglutide (SBS) and dasiglucagon (in CHI) are ideal opportunities to establish Zealand as a fully integrated biotech company with commercial operations. For dasiglucagon HypoPal rescue pen and dual hormone pump, we believe that the market can be developed further and we are examining various scenarios for getting the most value.
Jakob440	First of all welcome til Zealand Pharma Emmanuel Dulac. My first question is: In Q1 I see that Zealand expect to enter into more than one partnership in 2019, can you tell us in which areas you expect this. Is't the clinical trials or Gleplaglutide or Dasiglucagon Hypopal?
Emmanuel Dulac	Thank you for the kind welcome. We are examining multiple opportunities for partnership throughout 2019. We have been in ongoing discussions with potential partners to help commercialize the HypoPal, dasiglucagon in general, or support glepaglutide for SBS ex-US, and in response to interest from different parties regarding assets in our pre clinical pipeline..
Emmanuel Dulac	At the same time, we also have honest internal dialog about our own capabilities and how to deliver on Zealand's ambition of becoming a fully integrated biotech company with commercial operations. While we are not changing our strategy, I am also exploring all opportunities thoroughly to ensure we get the most value from our programs.
Jakob440	In your collaboration with Beta Bionics, will Zealand in the future be tied to make more investments in beta bionics? And is there any agreement on the use of Zealands Dasiglucagon with Beta Bionics, or has Beta Bionics the full opportunity to pick another glucagon candidate from another company? ?In case of approval, will it then be necessary to jointly enter into a partnership with a third company that can bring the product to the market?
Emmanuel Dulac	Beta Bionics secured 65m USD in their last financing round and are well funded to sustain development. Our partnership is very strong, although it is not an exclusive agreement. We are evaluating scenarios for how to best commercialize our dasiglucagon cartridge.
lassevedel96	Last year, Eli Lilly demonstrated impressive results with their novel GLP-1/GIP dual agonist in phII settings for T2D. Have there been any interest in the preclinical GLP-1/GIP candidate from ZP? Is a partnership on this candidate likely to happen before phase I trials?
Emmanuel Dulac	There is high interest in our GIP portfolio and Lilly results certainly contributed partially to that renewed interest. I cannot speculate about if or when a partnership agreement

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	will be made but we are also having discussions there.
lassevedel96	You have recently initiated a phase IIb trial testing dasiglucagon in a dual pump system. What are the plans after a, hopefully, succesful trial? Can ZP take the drug to phaseIII alone in this setting/indication (With Beta bionics) or do you need an external partner for this?
Emmanuel Dulac	Beta Bionics and Zealand will continue working with each other for the foreseeable future. Their dual hormone device is the farthest in development, just as dasiglucagon is the farthest in development for a glucagon analog in such use..
Emmanuel Dulac	We don't plan to get involved in the commercialization of the device. We will only sell the dasiglucagon, which is the only liquid glucagon analog advancing in this use today.
lassevedel96	What are the timelines for your program with peptide Ion channel blockers? Have there been any interest towards this program, as we saw with complement inhibitors? Would it be possible to make a similar deal as the one with Alexion?
Emmanuel Dulac	We have identified novel peptides that are potent and selective blockers of ion channels, but further optimization is required. We expect these programs to contribute to our clinical pipeline in the future. This is too far to estimate if we want to partner these programs.
lassevedel96	How many patients would be required in a phase III trial testing dasiglucagon in a dual pump system?
Emmanuel Dulac	Once we have results from the ongoing Phase 2 trial, we will meet with the FDA to understand their position and discuss what needs to be demonstrated in Phase 3, which is anticipated to initiate in 2020.
Jakob440	Will there be opportunities to achieve orphan drug designation on other of your products in the future?
Emmanuel Dulac	Zealand has high focus on rare diseases with unmet medical needs. While it is a challenging exercise to forecast what will come via research and the preclinical pipeline, we will certainly continue to leverage our peptide platform within rare diseases and thus orphan drug opportunities.
Investorbro	What is the status on Elsiglutide? Is there an investigator sponsored phase 2 trial coming up?
Investorbro	When can we expect the first pre clinical data from the collaboration with Alexion?
Emmanuel Dulac	First, the discontinuation of elsiglutide was announced in March 2019, along with the selection of ZP 7570 as a new clinical candidate..

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Emmanuel Dulac	Second, the Alexion-Zealand working teams are off to a good start. We hope to have data on the C3 complement inhibitor by the end of 2019 so that Phase 1 initiation could be possible next year. But there are three more candidates to this deal and more milestones attached to advancing them..
Emmanuel Dulac	And third, Boehringer Ingelheim will decide on development progress for GLP-1/GLU. We expect results from Phase 1 this year, which of course will inform if development will continue into Phase 2.
Stroka	Zealand Pharma has yet not found a new CFO. When do you expect to be able to announce this position occupied?
Emmanuel Dulac	Filling the CFO position has been one of my immediate tasks upon starting at Zealand, as well as a priority for the Board of Directors. We are in discussion with several candidates and hope to make an announcement as soon as possible .
Jakob440	Finally, does Zealand Pharma participate in Investordagen in Aarhus June 11th?
Emmanuel Dulac	Unfortunately, we will not participate in the June event this year. We are hoping to join Investordagen in Copenhagen this September.
Helge Larsen/PI-redaktør	Emmanuel Dulac..Thank You for joining us and thank you for the many fullfilling answers to our questions. We look forward to to seeing you back here on ProInvestor.com after Q2.
Emmanuel Dulac	Thank you again for having me. I look forward to our next discussion.
Helge Larsen/PI-redaktør	This session is ended.