DIGNITANA

Dignitana Live Session with Aktier – Småbolagsjakten on Facebook

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Aktier – Småbolagsjakten: Hi and welcome to this Live Session with Dignitana, I will be your host during this evening. Please give a warm welcome to CEO Bill Cronin, COO Jim McKinney and VP of Marketing and Investor Relations, Melissa Bourestom. The attendees will give all their answers through Melissa. Dignitana has hired Småbolagsjakten to perform this live Q/A. There is no conflict of interest between Dignitana and Småbolagsjaktens admins. The floor is now open for questions!

DIGNITANA: Hello everyone! I have with me Bill Cronin CEO, Jim McKinney COO and we are delighted to be talking with you today. We will start answering questions now.

Questions from members of Aktier – Småbolagsjakten begin below along with the Dignitana response.

1. When will we see the first male patient getting a treatment and why haven't we seen one yet?
DIGNITANA: We treated our first male patient several months ago - and in fact some men chose to use DigniCap prior to the FDA expanded clearance, at the discretion of the patient and their physician. Due to patient privacy, we do not post details of any patient treatment without their specific consent.

2. When will we see the first patient with a solid tumor other than breast cancer getting a treatment and why haven't we seen one yet?
DIGNITANA: Solid tumor answer -- same as male patients- this has happened many times already at the discretion of patient and physician but is not something we can disclose without their consent.

3. In a business presentation last autumn, you had a goal of taking a 25-30% market share with a total market of $700m in the US, could you put that goal within a time frame?
DIGNITANA: 25-30% market share - based on the current climate and that this is a new therapy option for patients, it very difficult to project how quickly this would occur. We would hope to see this milestone within 5 - 7 years.

4. Are the quality problems with the DigniCap fully solved? Do you see any risks with the new machine?
DIGNITANA: In the world of medical devices, Quality has a very different connotation and is an ongoing initiative for us and all device providers. We have addressed the production challenges that were encountered last year.

5. Will the new machine have to get approved by the FDA or can you just take it straight to the market?
DIGNITANA: Yes - any new device requires a FDA 510k, however we do not anticipate needing to provide any additional clinical data than what we have already collected and submitted in conjunction with our existing clearances.

6. Are there any risks that Dignitana could get sued by a dissatisfied patient or what kind of precautions do you have to prevent that?
DIGNITANA: Each patient signs a comprehensive consent prior to each treatment which outlines potentials risks and expectations.

7. How are you able to exhibit many systems when you charge a monthly fee while Paxman puts out their systems for free? Paxman has put out 96 systems in just 3 months, it's worrying fast pace!
DIGNITANA: Paxman's devices are single patient, while ours can treat 2 patients simultaneously, so there is an inherent discrepancy. We cannot comment on Paxman's business model, but for our company, we have in place several business models with a range of monthly fee structures to accommodate the unique needs of individual sites.

8. What is your USP (unique selling point) when a clinic will choose between DigniCap and Paxman?
DIGNITANA: Our primary differentiator is service. As this is a very new therapy option, the importance of ongoing interaction with our sites requires a high level of personal attention, as well as highly trained clinical specialists to provide immediate response to clinicians and patients.

9. When will the smaller machine come out on the market?
DIGNITANA: We anticipate that our next generation cooling device will be available to market by end of 2018.

10. Should the new machine undergo any tests and obtain approval from the FDA?
DIGNITANA: Yes - any new device requires a FDA 510k, however we do not anticipate needing to provide any additional clinical data than what we have already collected and submitted in conjunction with our existing clearances.

11. What do you think about Dignitana's market cap, given that Paxman is valued twice?
DIGNITANA: Our company is in transition from Sweden to America and we are in an aggressive product development as well as roll out. phase. If we execute on that plan, our market cap should look very different 24 months down the line than it does today.

12. 8th of March, ATENA will review its scalp cooling policy. What do you know about it and how fast can reimbursement be in place in case of change of policy?
DIGNITANA: Getting reimbursement for scalp cooling is an involved process that requires obtaining unique codes for billing to then collect from insurers vs. patients. These codes need to be issued by the American Medical Association, and values then need to be attached to the treatment codes. Until these codes exist, it will continue to be difficult for insurers to process patient claims, and patients will need to continue to pay for treatments.

13. Will there be studies showing the difference between results between Click-cap and Paxman's device?
DIGNITANA: No - we have separate devices, and thus it would be difficult to make a direct comparison in a clinical setting.

14. What's your vision for Dignitana. Where is Dignitana in 4-5 years?
DIGNITANA: We hope and anticipate that in 4 - 5 years Dignitana is a significantly larger and profitable entity, providing this treatment to many more patients here in the US as well as around the world.

15. Will these answers be reported in future newsletter?
DIGNITANA: These answers will be archived here by the hosts of this group, but some of these topics may be explored further in future newsletters.

16. FDA cleared an expanded use of DigniCap to reduce hair loss during chemotherapy in august last year. How has this effected the demand for your product, in terms of clinics in the US?
DIGNITANA: The expanded indication has meant that we now are starting to get requests to install machines beyond just in the facilities for their breast cancer patients. In many cancer centers these are different buildings or even different campuses.

17. How does the company intend to develop its presence and exposure in social media and media in general? I would like to see an increased activity.
DIGNITANA: We have a dedicated social media team that posts patient-oriented content 1-2 times a day, and additionally run targeted digital advertising through social and other channels. In the near future we will be adding in a Dignitana Twitter specifically for shareholders. It would be correct to expect increased activity in the months to come.

18. Are there any clinical trials taking place at the moment or in the pipeline? Paxman recently announced that their System is currently being tested in a number of clinical trials in various countries.
DIGNITANA: We are constantly reviewing clinical trial opportunities with our partner sites. At the moment we have no active trials but anticipate initiating one or more new trials in the next 12 - 24 months with the next generation of our machine.

19. I am curious about guidance and plans for Europe and Asia, even though we know the company´s focus is on the US. Britain is a market where 90 percent of the clinics offer scalp cooling. The competitor Paxman is big there. Does Dignitana intend to compete in Britain in the long run?
DIGNITANA: Our international strategy is constantly under review; however, we have just completed a visit to each and every one of our sites in the UK to ensure their continued performance and expansion potential there. Once we have the next generation device, additional global markets will be added to our sales program incrementally.

20. Where are we in the cooperation with Konica Minolta. As I understand they are agents for big markets such as India/China and Japan. Can we expect a breakthrough soon on any of these markets? We have received clearance in China but from we know we have not seen any orders?
DIGNITANA: Conversations with Konica Minolta are ongoing. Once we have the next generation device, additional global markets will be added to our sales program incrementally.

21. Can you tell us a little bit more what differentiates Dignitana from Paxman and their products?
DIGNITANA: As the first scalp cooling system to receive FDA clearance in the United States, Dignitana is in a unique position to lead the effort to provide scalp cooling across the US for several reasons:
DigniCap is the only device to have an expanded FDA clinical indication to include solid tumors, allowing for treatment of alopecia in women and men with a wide range of cancers. Paxman clearance is limited to treating women with breast cancer.
DigniCap has superior results in the pivotal trial for FDA clearance with a 66.3% success with taxanes as opposed to Paxman's 59% success rate with taxane regimens.

In those same trials, the DigniCap treatment evaluation period was longer (more hair loss will occur with a greater number of treatments - DigniCap was evaluated one month after the end of the patient's chemotherapy, and Paxman was evaluated after just four chemotherapy sessions, not at the end of chemotherapy treatment.
Only DigniCap has patented sensors to ensure consistent, uniform cooling, temperature management and safety.
DigniCap offers 4 cap sizes, along with the DigniTherm Click Cap to provide a custom fit for a wide range of head sizes and shapes. Paxman caps are available only in 3 sizes.
DigniCap has an experienced, US-based clinical team that has been supporting the US market for 2 years providing ongoing support that has been well-recognized as a unique offering in this space. Paxman has a just a handful of staff in the US.
And finally, DigniCap provides local marketing support with robust national, regional and local media attention, providing facilities with an opportunity to easily showcase the availability of DigniCap.

22. Why didn't we see Dignitana in this [recent] press release?
DIGNITANA: It was Paxman's press release - Dignitana has been working with 2 of the top ranked cancer centers for over a year.

23. Scientific studies and publications. How does the company work with clinical studies? This is important not only for increased exposure and sales, but also for reimbursement.
DIGNITANA: We are constantly reviewing clinical trial opportunities with our partner sites. At the moment we have no active trials but anticipate initiating one or more new trials in the next 12 - 24 months with the next generation of our machine.

24. What is the most recent estimate for reimbursement and why will it happen at that date? Is reimbursement a gradual process or will we be able to say that we have reimbursement at a certain date? In the case we can say we have reimbursement at a certain date, what will trigger us to say that.
DIGNITANA: There will not be a set "date" for reimbursement. Coverage first requires a code which is up to the AMA, then valuation which is a different process. Then is up to insurers to determine whether they will cover the treatment in their many various plans.

25. Is it a problem for Dignitana that we do not have any "consumables", like the inner cap for Paxman?
DIGNITANA: The DigniTherm Click Cap utilizes a Custom Fit Kit which is provided to each patient as a part of their treatment.

26. What is the current status on the contract with Memorial Sloan Kettering? Paxman writes in their financial report that they installed their product "after change from a different distributor" (the quote is translated from Swedish in the report). Is that true?
DIGNITANA: We continue to provide service to Memorial Sloan Kettering and have an excellent relationship with their leadership and clinicians.

27. In how many facilities have the Click Cap been implemented to date?
DIGNITANA: The Click Cap has now been implemented in a majority of the US sites and will be in all U.S. facilities by end of Q1 2018. It is now the standard that is sent out to all new installations.

28. Is the main benefit of the Click Cap improved results or to be easier to use? Is it possible to quantify the improvement of the result? Will there be new studies to estimate how much the results improve?
DIGNITANA: Both - the expanded indications increase the opportunity for utilization at existing sites, but also provides opportunity for placement at new sites that do not treat only breast cancer.

29. For MSK, are we still treating breast cancer patients or only patients with solid tumors?
DIGNITANA: Breast Cancer patients

30. How many of the hospitals where DigniCap is available have the capacity to also treat solid tumors as opposed to only breast cancer?
DIGNITANA: We don't have an exact number at this time, but some of the facilities with DigniCap are Breast Cancer or Women's Health Centers – typically this is in conjunction with a larger medical institution, but it may be in a separate location. We are now working with these facilities to provide DigniCap machines to the wider patient group.

31. Do you expect the major effect of the extended clearance to be increased usage of the currently placed DigniCap systems or is it more of a market opportunity to place more DigniCap at new facilities?
DIGNITANA: Both provide opportunity. The core market for scalp cooling continues to be female breast cancer patients but the expanded clearance allows us to provide this to a wider group of men and women with solid tumors and it is therefore of interest to a wider number of clinics and patients.

32. Are there any ongoing studies of permanent hair loss when using scalp cooling?
DIGNITANA: Not that we are aware of at this time

33. What is the status on Memorial Sloan Kettering? I am aware of your recent statement "In October 2017 Dignitana announced that Memorial Sloan Kettering had renegotiated its long-term agreement and replace it with a short-term agreement. Dignitana continues to provide service to Memorial Sloan Kettering." But I feel that this is still a bit vague for us shareholders. Do you still have a deal/partnership with them? What was the reason for the renegotiation? How do you assess the chance of securing further installments on MSK sites?
DIGNITANA: We continue to provide service to Memorial Sloan Kettering and have an excellent relationship with their leadership and clinicians.

34. Dignitana has been granted clearance by the FDA for a wider indication for the use of DigniCap. How does this affect your market position in the US?
DIGNITANA: The expanded indication grew our potential market from 255,000 patients to 800,000+

35. Do you have enough resources to address these new market segments?
DIGNITANA: We continue to add additional resources as we grow market share.

36. From a market cap point of view; Over a period of 12 months, Dignitana has lost more than 80 percent of its market cap. What do you consider will be the most important part to regain the investor's confidence in the company?
DIGNITANA: As the transition of operations from Sweden to the US progresses we are looking closely at every aspect of the company. Maintaining effective and efficient operations are critical to our success and providing transparency to the market through clear and consistent communication we believe will provide investors with the confidence they need to support the company.

37. What is your vision of the future and how big are your dreams with Dignitana?
DIGNITANA: We continue to focus on our product development with a goal of optimizing clinical outcomes and constantly increasing market share and utilization.

38. Are you working on other products than scalp cooling?
DIGNITANA: We are not currently working on products other than scalp cooling.

39. Can the business model in US be applied in other big markets? Which?
DIGNITANA: Business model in new markets requires detailed analysis of that market which we will address on a case by case basis.

40. What is your strategy to keep up with the aggressive Paxman in US market.
DIGNITANA: The market potential in the US is huge - there is plenty of opportunity for both of us.

41. Break even in Q4 is the goal, last time the promises were not kept. Is this guess more realistic and what strengthens that argument?
DIGNITANA: The transfer of operations to the US has necessitated a close evaluation of all aspects of our business and we are now well-positioned for growth and effective utilization of resources.

42. How do you prioritize your markets? Is Europe and other regions not as highly prioritized since you've moved your key operational activities to the US?
DIGNITANA: We have identified the US as the market with the largest potential and growth opportunity. We continue to evaluate potential in global markets and will act accordingly.

43. Paxman was mentioned before within the area of scalp cooling. What companies do you regard as your biggest competitors and what makes Dignitana's products better than theirs?
DIGNITANA: The only other company to currently provide a scalp machine is Paxman. There are several manual gel cap companies that offer scalp cooling services directly to patients - Penguin, ChemoColdCaps, Arctic, and WishCaps are the main providers and none have FDA clearance. Manual gel caps are a labor-intensive process for the patient involving dry ice, frequent cap changes, and additional discomfort from the colder temperatures. Although the scalp cooling science is similar, there is a significant difference in a patient supplying and managing their own treatment as opposed to a trained professional supervising the treatment.
As the first scalp cooling system to receive FDA clearance in the United States, Dignitana is in a unique position to lead the effort to provide scalp cooling across the US for several reasons:
DigniCap is the only device to have an expanded FDA clinical indication to include solid tumors, allowing for treatment of alopecia in women and men with a wide range of cancers. Paxman clearance is limited to treating women with breast cancer. DigniCap has superior results in the pivotal trial for FDA clearance with a 66.3% success with taxanes as opposed to Paxman's 59% success rate with taxane regimens. In those same trials, the DigniCap treatment evaluation period was longer (more hair loss will occur with a greater number of treatments - DigniCap was evaluated one month after the end of the patient's chemotherapy, and Paxman was evaluated after just four chemotherapy sessions, not at the end of chemotherapy treatment.
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44. Where is Dignitana in 3 years?
DIGNITANA: We hope and anticipate that in several years Dignitana is a significantly larger and profitable entity, providing this treatment to many more patients here in the US as well as around the world.

45. From an investors perspective it's important to me that management is also a big shareholder so that you can be seated in the same boat. What does it look like for your part Bill, are you a proprietor, i.e. also a major shareholder in Dignitana?
DIGNITANA: Shareholdings are addressed in the Year End report published last week.

46. What is the current total number of clinics? What is the total number of units installed?
DIGNITANA: As of 22 February 2018, in the U.S. there are 111 sites in 23 states representing 135 machines.

47. Are you still going break-even at 200 units installed? Considering the estimate cost savings of approximately SEK 15 million on a yearly basis, starting in the second quarter of 2018, to be fully reflected in mid-year 2018, I would say that this figure could be lower?
DIGNITANA: Break even depends on multiple factor including number of sites and utilization in the US.

48. Out with the old, in with the new. "New" CEO, operations handled from the US and new board members. All good things for a company that haven´t performed as well as I think it could/should have done with the first mover advantage in mind. Can we as shareholders expect to see any differences in the way the company is run?
DIGNITANA: As the transition of operations from Sweden to the US progresses we are looking closely at every aspect of the company. Maintaining effective and efficient operations are critical to our success and providing transparency to the market through clear and consistent communication we believe will provide investors with the confidence they need to support the company.

49. If treatment success among patients increase with the new BOA click-cap and later with the new system will that be visible in the the CHILL registry?
DIGNITANA: CHILL Registry is still in development in terms of their ability to collect data from facilities worldwide. We will continue to support their efforts as we move forward with our product innovations.

50. How is the demand for DigniCap outside of USA?
DIGNITANA: Demand for DigniCap is strong. We have identified the US as the market with the largest potential and growth opportunity. We continue to evaluate potential in global markets and will act accordingly.

51. I would like to know more about the "reimbursement deal", how likely is it that you will get an 'approval' and assuming you do get an approval, how long will it take before the outcome of the deal will reflect your financials? And what are your estimates both unit wise but also in terms of revenue?
DIGNITANA: The financial impact of reimbursement is highly dependent on the valuations that are assigned to scalp cooling treatments by the insurers after the coding is obtained. Thus, it is difficult to predict financial implications.

52. What is the average use of today's installed base of DigniCap machines? How many sessions a day/machine are possible? Do you see an increase of usage/machine or is the increase in turn-over mainly due to increased installed base?
DIGNITANA: Due to the competitive nature of business we do not publicize specific treatment numbers but can say that our treatment numbers have consistently grown month over month.

53. Do you have plans to make a IPO in the US instead of Sweden to attract more international investors?
DIGNITANA: Not at this time

54. I think Dignitana would get much more attention if the company was listed on the US stock market. what do you think? And are there any plans for that?
DIGNITANA: There are currently no plans to list on the US stock market.

Aktier – Småbolagsjakten: We round off today's Live Session with Dignitana. Our special thanks goes out to Bill, Jim and Melissa for their participation. Many thanks for all the members who asked very good questions. Dignitana is a very interesting and innovative company which many of our members will follow in the future. For more information regarding Dignitana please visit http://www.dignitana.se

DIGNITANA: Thank you all for your time and support. Feel free to email us at investorrelations@dignitana.com anytime and we will reply. And watch for our new IR website coming very soon.