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Transcript of
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Participants

Luke Zimmerman – Senior Associate, MZ North America
Francois Michelon – Chief Executive Officer
Michael Thornton – Chief Technology Officer
David Wells – Chief Financial Officer

Analysts

Brooks O'Neil - Lake Street Capital Markets
Michael Entredor - Private Investor.

Presentation

Operator
Good day, and welcome to the ENDRA Life Sciences Second Quarter 2018 Conference Call and Webcast. Today's conference call is being recorded.

At this time, I would like to turn the conference over to Luke Zimmerman, Senior Associate at MZ North America, ENDRA Life Sciences' Investor Relations firm. Sir, please go ahead.

Luke Zimmerman- Senior Associate, MZ North America
Thank you, good afternoon. I'd like to thank you all for taking time to join us for ENDRA Life Sciences Second Quarter 2018 Conference Call. Your hosts today are Mr. Francois Michelon, Chief Executive Officer; as well as Mr. David Wells, the company's Chief Financial officer; and Mr. Michael Thornton, the company's Chief Technology Officer.

Francois and Michael will provide a business update which will cover partner announcements, product updates and operational milestones, while David will discuss the financial results. A press release detailing these results crossed the wires today and it's available on the company's website, endrainc.com. Following management's prepared comments, we will open the floor to questions for those of you who are dialing in for today's call.

Before we begin the formal presentation, please take note of the Safe Harbor paragraph that appears at the end of the release covering company's financial results, and that any forward-looking statements that we make only apply as of the date made and are subject to inherent risks and uncertainties, including those described in the company's SEC filings and should not be unduly relied upon.

Except as otherwise required by federal securities laws, the company disclaims any obligation or undertaking to publicly release any updates or revisions to any forward-looking statements. We would also refer you to the company's website for more supporting industry information.

At this time I'd like to turn the call over to Francois Michelon. Francois, the floor is yours.

Francois Michelon
Thank you, Luke. Welcome everyone to ENDRA Life Sciences Second Quarter 2018 Conference Call. The second quarter of 2018 demonstrated progress on the development of our first thermoacoustic enhanced ultrasound product, growth of our intellectual property portfolio and positive progress on our Health Canada human study application.

Before I go deeper into our Q2 and subsequent achievements, I'd like to briefly provide listeners who are new to the ENDRA story with a brief summary of our disruptive ultrasound technology. ENDRA is currently developing a next generation thermoacoustic enhanced ultrasound, or TAEUS as we call it, to enable clinicians to safely visualize human tissue composition, function and temperature in ways previously possible only with a CT or MRI, but at 50 times lower cost and at the point of patient care.

TAEUS is a platform with multiple potential clinical applications and revenue streams including hardware, software, disposals, service and licensing. Our first TAEUS application is focused on the assessment of fat in the liver for early detection and monitoring of nonalcoholic fatty liver disease, also known as NAFLD. NAFLD is a condition closely associated with obesity, diabetes, hepatitis C and certain genetic predispositions in which fat accumulates in the liver. It affects over a billion people globally and is estimated to cost the US healthcare system alone over $100 billion annually.

NAFLD is often asymptomatic, and if left untreated NAFLD can progress to inflammation, also known as NASH; tissue scarring, known as fibrosis; cell death, known as cirrhosis; and liver cancer. By some estimates by 2025 NAFLD is forecasted to be the greatest root cause of liver transplants.

Critically for patients, clinicians and insurers the only tools currently available for diagnosing and monitoring NAFLD are really impractical; either an expensive and time-consuming MRI, which most people on a global basis don't have easy access to, or an invasive, painful and risky surgical biopsy of the liver. This is why ENDRA is focused on early-stage liver disease. It's an enormous healthcare problem affecting a lot of people with no practical diagnosis and monitoring tools.

Viewed from a broader perspective, the TAEUS platform has the potential to address two of the most pressing needs of global healthcare. First, broadening access to better healthcare. TAEUS does this by leveraging cost-effective, broadly available ultrasound. Second, by improving safety. Again, TAEUS leverages ultrasound which is non-invasive and which doesn't depend on potentially allergenic intravenous contrast agents. ENDRA's goal is to bring multiple new TAEUS capabilities to ultrasound starting with the liver, but overall a $13 billion global market opportunity.

Now let's turn our attention to our progress in the second quarter of 2018 and subsequent months. We completed the TAEUS liver system and safety testing, and are awaiting with some delay Health Canada's investigational testing authorization, also known as an ITA, to commence recruiting for the clinical study. We believe applications to Health Canada for human studies have seen longer than normal review times due to elevated application volumes. As you can imagine the ENDRA team shares everyone's frustration in the overall processing time of this application, but we remain confident that Health Canada will approve our study for two reasons.

First, we very recently received comments from Health Canada requesting clarity on two straightforward matters related to labelling and ENDRA's study duration. These comments are consistent with the normal application process. We expect to address their questions by the end of the week. We need to remind ourselves that TAEUS is new technology combining elements of MRI and ultrasound. While TAEUS has the potential to radically change healthcare because it's so different from existing imaging technology, it also needs to be

carefully explained, tested and understood by organizations like Health Canada. In view of this, Health Canada's comments were straightforward.

The second very encouraging signpost is that we were notified that our application is being reviewed as a Class 2 device under the investigational testing pathway. The reason that Class 2 is encouraging is that it reflects a low to medium-risk device similar to MRI's classification. Conversely, a Class 3 designation would have required a higher burden of documentation and potentially extended the application review process. So we're very happy to have received the Class 2 designation, both as an encouraging indicator for our Canadian study and because all the testing, safety analysis and documentation that we prepared for the Canadian application will go into the technical file submission for our planned European CE Mark application.

While we acknowledge that the delay in the Canadian clinical study and the human factors data it will yield will contribute to a pushback of our CE registration from our target in the second half of this year into the first half of 2019, we believe that the Canadian clinical study will directly support our CE application and our subsequent success in Europe. Naturally, we'll announce the Health Canada approval once we receive it. Investors should also remember that once we receive Health Canada approval we expect it will only take about three weeks to recruit volunteers and perform this study which will encompass 20 patients scanned in an MRI for 20 minutes followed by an ultrasound liver scan and TAEUS liver fat measurements, each of which only takes a few seconds. It's also important to emphasize that the ENDRA team and our technology haven't been sitting still simply waiting for the human study.

We've used the time to continually improve our TAEUS product, refine our software algorithms, advance our understanding of work flows with our clinical advisors and improve our engineering materials. In fact, on this last point we've been collaborating with a Duke University professor to engineer high performance ceramic elements that we believe have the potential to improve certain performance parameters of our commercial TAEUS system by over 30%. Our goal is to fully launch our TAEUS liver device in Europe in the first half of 2019. We're ramping up commercial activities accordingly ahead of the CE Mark. For example, building on our meetings in April in Paris with the early adopters at the European Association for the Study of the Liver we secured exhibit space at notable liver disease and ultrasound industry events in Basel, Geneva, San Francisco and Chicago in the second half of 2018.

Our goals at these meetings are twofold. First, raise awareness for ENDRA's TAEUS technology and our Canadian human study with ultrasound radiologists and hepatologists, collecting their feedback and further building our Rolodex of potential sales prospects. Second, develop a recruiting pipeline of potential European ENDRA sales candidates to complement our GE partner and distributor channels. As I previously mentioned, ENDRA's plan is to hire three to four sales people in Europe to train, co-sell and support our channel partners and customers.

Complementing these industry events and the eventual publication of our Canadian human data, we're creating marketing materials including clinically focused white papers and videos on the technology of TAEUS. Naturally, until we receive full regulatory approval, all these marketing materials will clearly note that our TAEUS technology is not yet approved for sale. It's critical for investors to understand we're parallel processing and certainly ramping up the commercial activities and not waiting for the data.

In summary, for Q2 and the balance of 2018 we remain committed to the five goals that I emphasized on previous calls. First, attract, develop and retain top quality talent. Second, execute our operating plan. Third, protect and grow our intellectual property. Fourth, adhere on asset light business model by leveraging partnerships in engineering and for commercialization to minimize overhead and preserve cash. Fifth, to grow investor awareness and trust through active, outbound investor relations activities and ENDRA transparency.

I'll now turn the call over to our Chief Technology Officer, Michael Thornton, who will provide a deeper update on our IP portfolio and product development of our TAEUS clinical product targeting NAFLD. Michael?

Michael Thornton – Chief Technology Officer
Thank you, Francois. On the IP front since we last talked to you ENDRA was granted a total of four US patents, three of which are directly related to our non-invasive fat assessment TAEUS technology. This brings our intellectual property total as of today to 39 issued patents, filed patent applications and prepared disclosures up from 33 at the end of 2017.

Two of the newly issued patents cover applications for correcting fat-induced aberrations and imaging biological structures. Another one of our issued patents protects our methodology for improving safety in magnetic resonance imaging, or MRIs as more commonly known. The fourth patent that issued was for the non-invasive assessment of fat to support our TAEUS clinical product. These patents support ENDRA's proprietary approach to assessing fat content in tissue and support the company's commercialization of a clinical application for non-invasive assessment of liver fat, and other fat-related applications.

Our four new patents, along with several filed applications, directly support our plans to commercialize a transformative clinical application focused on non-alcoholic fatty liver disease. With two registered patent agents on our staff, ENDRA maintains a strong focus on protecting key enabling methodologies and technical innovations related to our TAEUS fatty liver application.

Moving on to the development front, since we last spoke we continue to work with our engineering, manufacturing and regulatory service providers, which we believe is the most capital efficient model for ENDRA while providing the shortest time to market. With some supplier and engineering issues resolved, we're making good progress toward implementing our procedures and quality management system as we work toward achieving ISO 1345 certification, which is a requirement for the CE technical file submission of our first product. We are working toward a first half 2019 target for CE clearance, followed by a planned FDA submission for the US market.

In addition to what Francois mentioned earlier, we are in active discussions with US sites to organize clinical studies with our fatty liver TAEUS technology. While we do expect to have Health Canada approval imminently, we will continue to engage the US clinical sites to support our stated commercialization timeline.

I'll now turn the call over to our Chief Financial Officer, David Wells, for his financial summary. David?

David Wells – Chief Financial Officer
Thank you, Michael. I will now provide a summary of our reported second quarter 2018 financial results. We did not generate any revenue for the three months ended June 30, 2018, as compared to $57,772 of revenue for the comparable period in 2017. There was no recognized revenue for this quarter as compared to the same period in 2017 when we had earned revenue from service fees on our installed base of legacy Nexus 128 units.

Our operating expenses increased to $1.8 million in the second quarter of 2018, up from $1.1 million for the same period in 2017. The increase in operating expenses was due primarily to increased research and development expenses related to the development of our TAEUS product, as well increased general and administrative costs related to our increased head count.

Our net loss for the three months ended June 30, 2018, was $1.8 million, or $0.47 per basic and diluted share as compared to a net loss of $1.4 million in Q2 of 2017. Noting that approximately $750,000 of the 2018 loss was due to non-cash compensation expenses related to prior option and warrant issuances.

Our cash balance as of June 30, 2018 was approximately $2.2 million, as compared to approximately $3.2 million as of March 31, 2018. We strengthened our balance sheet with a private placement of $1.1 million of convertible secured notes and warrants in June of 2018. Management and existing investors participated in the transaction and the funds will extend our operational runway into Q4 of this year. During the quarter we used approximately $1.9 million in cash, which again was due mainly to continued development of the TAEUS product.

Our spending remains on budget and on track with our internal projections. We are continually evaluating our capital needs in real time to ensure adequate capital to support our clinical, regulatory and operational activities and will continue to do so as we prepare for EU commercialization.

As has been emphasized before, and in summary, we believe the combination of our asset light operating model, clean capitalization structure and continued effective and efficient use of cash will position ENDRA to commercialize our TAEUS liver product in the European Union as scheduled.

I will now turn the call back over to Francois. Francois?

Francois Michelon
Thanks, David. In summary, here are the six key points I'd like our listeners to take away from today's call. First, we're still waiting for approval of our human study, but based on recent communications from Health Canada, and our device being classified as Class 2 for investigational testing authorization pathways, we remain confident that ENDRA's study will be approved shortly.

Second, much of the documentation that we've prepared for the Canadian study application will directly support our planned European CE Mark application. Third, our commercial activities are ramping up with new marketing materials, a growing list of target clinicians in Europe, and a formal ENDRA presence at key global clinical conferences in the second half of 2018.

Fourth, continue to actively manage our cash burn, leveraging partnerships, minimizing overhead as we shift gradually from R&D to commercial activities. Fifth, we remain committed to growing and protecting our IP and have secured four issued patents in recent months. Finally sixth, the ENDRA team remains committed as ever to realizing the potential of the TAEUS platform to change the game of the epidemic of non-alcoholic fatty liver disease.

At this time I'd like to open up the call to questions from our listeners. Operator?

Operator
Thank you. [Operator instructions]. Our first question comes from Brooks O'Neil, Lake Street Capital Markets. Please proceed with your question.

Q: Hi, Francois. How's everything?

Francois Michelon
Great, thank you for joining call and your continued interest.

Q: Sure. I'm curious if you can talk a little bit about the pending spinoff of the GE Healthcare business and whether you see that as a positive or a negative for your business.

Francois Michelon
That's great. Great question. I wish I knew and obviously I can't speculate on GE's behalf, but my perception of what's happening at GE is a clear centralizing of common businesses, industrial businesses in particular. As you

can see from the recent quarterly announcements, GE Healthcare has been doing very, very well, so I don't believe that the potential spinoff of GE Healthcare has any relationship to its performance. I think it's probably just getting back to basics and keeping like business, like aircraft engines and energy and power supply into a common pot.

My sense from what I've known at GE Healthcare, having worked there almost eight years and being obviously in close contact with them regularly is the culture of GE Healthcare is phenomenal, it's very execution oriented and a market leader; certainly the ultrasound business is dominated by GE. I believe that whatever happens to GE Healthcare, be it a standalone spinoff, an acquisition, that they will likely benefit from the greater independence and collaboration in the healthcare space in terms of nimbleness versus continually being associated with the more industrial businesses.

That's really my view on it, and I can say that I've sensed no distraction in our relationship with GE and it remains quite strong. In fact, we just took possession of two more ultrasounds from them last week. So, a great business; we're thrilled to be associated with them. Whatever happens to GE Healthcare I believe will be a good thing for it, and I don't believe it will have any effect on ENDRA's relationship. I hope that helps answer the question.

Q: No, that's perfect. I really appreciate it. Thank you very much.

Francois Michelon
Thank you.

Operator
[Operator instructions]. Our next question comes from Michael Entredor [ph], private investor.

Q: Hi, good afternoon. Does the market size of $13 point-something billion, does that include the software and the accessories?

Francois Michelon
Yes, so great question, Michael. Thanks for joining our call. The $13 billion as you have in our investor presentation really includes the potential of the five clinical applications that we've demonstrated so far with our TAEUS platform. They extend beyond just the liver and composition of fat. They also include tissue temperature and some vascular applications.

In terms of deployment, to answer your question, they include the hardware and software elements. They do not include the licensing opportunity, which we view as upside. Nor does it even include the potential disposables of some applications that we've started working on. My takeaway, because I'm also very sensitive to not overstating these enormous numbers, is when we did our assessment of an addressable market we said look, there are about a million ultrasounds in the world today.

Which ones of those do we realistically think we could sell an accessory with some hardware to in the future? We carved the mobile ultrasounds because although technically it works with our product, customers buy mobile ultrasound for mobility and we thought it would be disingenuous to keep them as a viable target, so we carved them out of the million. We also carved out the prenatal ultrasound users because although we don't have any current applications—we may have some applications in the future—we don't currently have any prenatal applications.

We thought, again, let's not fool ourselves into thinking that an Ob-Gyn is going to buy something from TAEUS as we know it today. That left us the roughly 300,000 cart based non-prenatal ultrasounds in global use today,

Michael, that we think are a very reasonable target for both the liver applications, both hardware and software, as well as some of the future TAEUS applications.

I want to also make it very clear that the accessory that we are bringing to market next year is really just a vehicle for the software. Long-term, there's an opportunity of course in the installed base of ultrasound users, but long-term I don't want to be in the hardware business. I want to be in the software and licensing and service and disposables business. As a first step to get into this market we're going to put a small box that plugs seamlessly into a GE ultrasound; it'll have the software. Then, a year or two later we aspire to selling another software that would go on that same box, but charge some money for that.

That's what gets me so excited, Michael, is the liver the space is huge; there's a large unmet need. The ultrasound space is growing and there's a great opportunity. We're just starting with this TAEUS platform and so I'm very eager for that. I hope that's an energetic and positive and convincing answer to your question.

Q: Well, I want to understand what's the size for the disposables portion of the market and the licensing portion relative to the device and the software.

Francois Michelon
Right. Yes, yes, yes. We have not even communicated the potential of the licensing, which would be including our TAEUS technology into new ultrasound systems from GE and potentially other ultrasound manufacturers. I don't want to step beyond what we've carved out and identified, but I view it as substantial and incremental to that large addressable market that we've discussed just on the ultrasound hardware and software basis alone. I hope that's helpful.

Operator
This concludes our question and answer session. I'd now like to turn the call back over to Mr. Francois Michelon for closing remarks.

Francois Michelon
Great. Well, thanks everyone for joining our call today. As always, I'd sincerely like to thank our hard-working team of ENDRA engineers, scientists and pat specialists who keep our technology evolving; couldn't do it without you. Lastly, if we weren't able to address all of your questions on today's call, please feel free to contact our investor relations firm, MZ Group, who would be happy to answer them.

We look forward to speaking with you on our upcoming Q3 call. I appreciate everyone's time today. Good-bye.