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ONVO - Q1 2019 Organovo Holdings Inc Earnings Call

EVENT DATE/TIME: AUGUST 09, 2018 / 9:00PM GMT

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PRESENTATION

Operator

Welcome to the Organovo Holdings Fiscal First Quarter 2019 Earnings Conference Call. (Operator Instructions) Please note, today's event is being recorded. I would now like to turn the conference over to Steve Kunszabo, Head of Investor Relations. Mr. Kunszabo, please go ahead.

Steve E. Kunszabo - *Organovo Holdings, Inc. - VP of IR & Corporate Communications*

Good afternoon,, and thanks for joining us. I would like to welcome you to our fiscal first quarter 2019 earnings call. Joining me on the call this afternoon, our CEO, Taylor Crouch; and our CFO, Craig Kussman. Today's call will begin with a discussion of the 2019 fiscal first quarter results, followed by Q&A.

Before I turn things over to Taylor, I'd like to caution all participants that our call this afternoon may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts and include statements about our future expectations, plans and prospects.

Such forward-looking statements are based upon our current beliefs and expectations and are subject to risks, which could cause actual results to differ from the forward-looking statements. Such risks are more fully discussed in our filings with the Securities and Exchange Commission.

During the call, we'll also be referring to certain supplemental financial measures. These supplemental financial measures are not prepared in accordance with generally accepted accounting principles. Please refer to today's earnings release for a definition of these supplemental financial measures.

With that, let me turn things over to Taylor.

Taylor J. Crouch - *Organovo Holdings, Inc. - CEO, President & Director*

Thanks, Steve, and good afternoon, everyone. Let me start by noting that we've refined and expanded upon our key clinical development and operating goals through calendar 2020.

The full weight of our financial and R&D resources is aligned behind achieving these objectives as we aim to treat a range of pediatric and adult liver diseases with our liver therapeutic tissue. The rare and often life-threatening conditions we are targeting, including single mutation, inborn errors of metabolism, urea cycle deficiencies, and acute and chronic liver failure, where at many cases, there are limited treatment options other than organ transplantation.

We believe our pioneering therapeutics approach has the potential to significantly impact patients within these group of diseases, and we are making important progress to that end.

As I look out over the next 12 to 18 months, let's quickly recap our goals. After recently concluding a detailed pre-pre-IND meeting with the FDA and listening to their valuable feedback and guidance, all of which is nonbinding, but gives us a sense of how they will view future submissions, we plan to hold a formal pre-IND meeting for our lead program in Alpha-1-antitrypsin deficiency or A1AT in calendar 2019. We expect to commence IND-enabling studies in the second half of calendar 2019, and ultimately, file for an IND in calendar 2020.

We also plan to nominate a second indication in the rare disease space in calendar 2019, which has the potential to closely follow our lead program into human clinical trials. We'll also likely pursue orphan drug designation with the FDA for the second indication in calendar 2019.

Our therapeutic solutions not only offer the promise of significant patient impact, but also represent an attractive revenue opportunity for Organovo. A1AT alone presents the potential to generate peak revenues approaching $1 billion, while the total group of liver diseases, I've outlined here, addresses a combined revenue opportunity that could exceed $4 billion.

As we consider our clinical development and regulatory pathway, we're moving forward with a strategy that allows our healthy NovoTissues to potentially address a broad range of target indications. The in vivo animal studies we conducted to-date, which have occurred in 2 different disease areas but utilizing the same implanted healthy tissue construct have shown good retention and robust functionality, including production of expected human enzymes often missing in the inborn areas of metabolism deficiencies.

In A1AT, we have also generated evidence of clearing some of the clogged cells known as globules, that when unchecked, can lead to liver failure. In our Type 1 Tyrosinemia studies, we have demonstrated improved health and survival in animals who have received our tissues. Certainly, we are encouraged by these growing body of proof-of-concept evidence as to the potential benefits of our therapeutic approach.

As we've done in the past, we'll continue to communicate our ongoing scientific and development progress at key industry conferences, such as The Liver Meeting in early November. Helping us lead these many important efforts, is our newly appointed Chief Medical Officer, Steven Hughes. Dr. Hughes is an industry veteran with significant experience directing clinical development and medical care teams at leading biopharma companies.

He distinguished himself at his most recent post as the Chief Clinical Development Officer at Ionis Pharmaceuticals, where he led a team that managed the global clinical development of 25 drugs across 10 therapeutic areas, including the rare disease space. We're delighted to have Steve on board as he brings an extensive track record of progressing novel therapeutics from the preclinical stage through to commercialization.

In addition, with many of the key steps we need to take for a successful IND filing, now coming into clearer view, we'll continue to work with leading hepatologists and transplant surgeons to refine and finalize our first-in-human clinical trial designs.

While we are advancing our tissue platform in a broad range of in vivo animal studies, we'll also continue to opportunistically pursue revenue-generating projects utilizing our 3D bioprinting platform. The Organovo platform (inaudible) from our Samsara division, includes bioprinter placement and licensing opportunities and culminates in-service agreements and grants derived from a tissue-generating and disease-modeling capability.

In particular, we continue to explore with our clients the applications of modeling nonalcoholic steatohepatitis or NASH in our tissues, where we've demonstrated a fundamental ability to induce and modulate features of the disease.

As I shared before, we continue to expect the revenue profile for this part of our business to be unpredictable, partly due to the custom usage of our model. And I'd also like to note that we'll increasingly devote the majority of our scientific and platform resources to our primary therapeutic mission as we progress full -- progress forward into full IND implementation activities.

In closing, we're tracking against all of our goals with an increasing focus on advancing our therapeutics program to successful IND submission in calendar 2020, and the potential to enter human clinical trials shortly after IND submission.

With the addition of Dr. Hughes to our talented Organovo team and with an increasingly vetted development pathway, we are optimistic about our ability to achieve the milestones leading to the human testing phase as outlined today.

As always, updating you in the months ahead. And with that, I'll turn it over to Craig for a more complete financial review.

Craig Kussman - *Organovo Holdings, Inc. - CFO*

Thanks, Taylor, and good afternoon, everyone. I'll begin by reviewing our key profitability and balance sheet metrics for the fiscal first quarter, and we'll then recap our liquidity profile at-the-market or ATM financing strategy and future capital requirements. I'll conclude my remarks with a quick summary of our income statement trends.

We posted a fiscal first quarter net loss of $7.4 million, a 27% improvement over the $10.1 million net loss we reported in the year-ago quarter. Similarly, our net cash utilization improved to $7.1 million versus $10.7 million in the prior year period.

The material improvement in these bottom line figures is primarily due to a 26% reduction in total cost and expenses related to the streamlining of our operations and focusing of our research and development programs.

At the end of June, we had a cash and cash equivalents balance of $39.6 million, which included net proceeds of $3 million from the issuance of 2.1 million shares of common stock in ATM offerings. If circumstances and market dynamics permit, we'll continue to use our ATM facility opportunistically to extend the cash runway for the business as we successfully done during 2018. With approximately $47 million of funds available under our new ATM facility, we have access to $86 million in capital to carry out our IND development plans. We continue to estimate a net cash utilization rate between $22 million and $24 million for fiscal year 2019, and we believe we have sufficient funds to meet our operating and capital requirements well into fiscal 2020.

The significant and ongoing reduction in our net cash burn versus the last 2 fiscal years will continue to be driven by thoughtful management of our R&D programs and supported by revenue from our commercial opportunities.

Moving now to our income statement, and focusing first on operating expenses. Research and development expenses were $3.4 million, a 33% year-over-year reduction, primarily resulting from lower employee and lab supply costs related to our organizational restructuring and the prioritization of our research and development projects.

We reported $4.8 million in selling, general and administrative expenses during the fiscal first quarter. A 19% year-over-year decrease, largely, due to lower employee and noncash stock-based compensation expenses as we further streamlined our operations during the first quarter. SG&A also included approximately $0.5 million of restructuring and onetime CEO transition costs.

On the top line, Organovo generated fiscal first quarter total revenue of $0.7 million, which decreased 30% from the prior year period and was down 38% sequentially.

Total revenue declined due to fewer active contracts for liver tissue disease modeling research services in the quarter. As I previously shared, we're not forecasting any specific total revenue targets for fiscal 2019. Given the varying pace of exploration and adoption of our liver tissue disease model, and the evolving way we engage with prospective clients and partners, our revenue growth trajectory will continue to be uneven despite forward contributions from our Samsara business.

In wrapping up, we have several important clinical development and regulatory milestones in sight for our therapeutics program as we move ahead in fiscal 2019. We have an outstanding team at Organovo, bolstered by the recent addition of our Chief Medical Officer, with the ability to significantly impact liver health.

We look forward to updating you on our progress in the months ahead. With that, I'll turn things back to the operator for the Q&A portion of this afternoon's call.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question comes from Matthew Cross with JonesTrading.

Matthew David Cross - *JonesTrading Institutional Services, LLC, Research Division - Research Analyst*

Just had a couple about the work you're being -- that's being done on the therapeutic tissue to prepare for potential human trials, as you're talking about these pre-IND and pre-pre-IND meetings. So the first one was about liver tissue viability, and I was wondering if we can get an update on kind of the current status for how long these liver tissues last? And when you're transplanting in animal models? And how viable you think you need to get it? And how long it needs to last for use within this IM settings and in the transplant potential usage?

Taylor J. Crouch - *Organovo Holdings, Inc. - CEO, President & Director*

Matt, it's Taylor, and thanks for that question, which is a really important point. So in our animal studies, we've been able to demonstrate functionality well past 90 days and in our longest study up to 125 days. That, in and of itself, would be a meaningful duration for any kind of acute in that -- and on a number of diseases, for instance, a bridge to transplant or just a boost or delay in deterioration of function. What we don't know and may not know until we actually going into humans is how much longer the effect of our tissues will be once we're in a same species environment, where we would expect ourselves to have the opportunity to regenerate and have a longer-lasting effect. So we'll certainly be studying this in any mouse we can get a hold of. And particularly, we'll look forward to answering that question once we're in humans. That said, the acute effect that we're seeing, certainly, would provide a meaningful medical benefit we believe to a number of patient populations we're looking at.

Matthew David Cross - *JonesTrading Institutional Services, LLC, Research Division - Research Analyst*

Got it. Okay. No, that's very helpful. And I'll look forward to any additional data on that as you progress. The other question was just about, I'm not sure if you've seen, but there was this short report out on you guys recently that was raising some concerns about the sickness of the liver tissue, and that's preclinical stage. And so I was wondering if you got any commentary you could offer around how important you believe that characteristic is relative to something like covered surface area in supplementing liver function with your therapeutic tissue patch. I mean you're already reporting circulating levels of albumin and other functional proteins and enzymes in transplanted mice. But I wanted to get a sense for how these designed elements may play a role in further development of the tissue?

Taylor J. Crouch - *Organovo Holdings, Inc. - CEO, President & Director*

Sure. Well, at the heart of our strategy or the drivers for why we're even trying this is that there is a dramatic shortage of transplantable livers. So any strategy one contemplates should try to be as sparing as possible of this precious resource and the sales that we derive. And what we're working to identify is, what is that balance between smaller scale, which we certainly can generate versus what level of functional boost would be meaningful in an acute phase or, as you mentioned in your first question, in a longer phase. The thickness that we've chosen has a number of properties and rationale behind it related to speed of engraftment, thrivability if you will outside of humans before implantation. And hopefully, speed of acceptance and engraftment. So we are concerned by the thickness and the scalability we've chosen, and we certainly are going to look forward to seeing what that impact can be in the human setting.

Operator

(Operator Instructions) The next question comes from Ed Arce with H.C. Wainwright & Company.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

So I had a couple. First is on your lead therapeutic programs with A1AT out in front. Just wondering, as you are progress your discussions with the agency, perhaps you could enlighten us on some of the key issues that are being discussed, and what kinds of design parameters you think are at issue here that need to get addressed and worked out before you can feel comfortable that you've got a right package to submit for an IND? And then the second question is sort of related just to have a sense for where you're going a bit longer-term? You had mentioned that there is a second indication that you're looking to nominate in the rare disease space. And I am a bit confused because I think you had HT-1 in that second slot. Is that separate than those 2 programs?

Taylor J. Crouch - *Organovo Holdings, Inc. - CEO, President & Director*

Sure. Ed, this is Taylor again. So with regard to the interactions with the FDA, this is a formal and confidential process, so -- one that I can't comment on directly. However, the fact that we are maintaining our guidance to move forward to an IND submission in 2020, and also that as priority that we would expect to submit for a pre-IND meeting in 2019 suggest that we feel increasingly comfortable that we have a CMC or design approach that will be appropriate to clear those important hurdles. And certainly, we're driving on 10 years of our platform experience in designing tissues from cells on us and all the processes and rigor one might hope to have in place as one approaches a clinical setting. So I would say on the tissue design side, we're very comfortable with our trajectory to complete that process in the timing that I outlined. The next step that we certainly will focus on, and this is a critical part of the pre-IND meeting process is to submit a final proposed protocol for the first-in-human studies, in this case, in A1AT. And that's where we'll be turning a lot of our focus over the next month to sort of fine-tune our strategy, the risks benefits to patients and the rationale for patients as well as the controllability of goals that one would have in a rare disease area like this. And with Dr. Hughes joining us and his deep expertise, and we are achieving workable, practical and intelligent designs through clinical trials, I think we'll be in good hands with the timing of getting those considerations in place for the pre-IND meeting.

To your second question, we've outlined that our single patch construct provides a broad range of functionality in theory of relevance across the 3 groups of disease areas that I mentioned the IEM, inborn errors of metabolism; group of diseases, the urea cycle management, groups of diseases and certain conditions associated with acute-on-chronic liver failure. We have -- we will be increasing our animal model studies in cherrypicked areas across that group of indication areas. We've already announced promising animal results in one of those areas, Type 1 Tyrosinemia. We'll be looking at multiple other opportunities. And from that basket, we'll again choose what we think would be the most logical second indication area to file probably under the initial IND, and taking into the consideration the same design amongst I mentioned for the first-in-human study on the A1AT side.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Great. That's very helpful. And congrats to Dr. Hughes.

Taylor J. Crouch - *Organovo Holdings, Inc. - CEO, President & Director*

Thanks, Ed.

Operator

This concludes our question-and-answer session, and the conference is also now concluded. Thank you for attending today's presentation. You may now disconnect.