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ONVO - Q2 2017 Organovo Holdings Inc Earnings Call

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PRESENTATION

Operator

Good day, and welcome to the Organovo 2017 fiscal year second quarter earnings conference call and webcast.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference over to Mr. Steve Kunszabo, Investor Relations. Please go ahead.

Steve Kunszabo - *Organovo Holdings Inc*

Good afternoon and thanks for joining us. I'd like to welcome you to our fiscal second quarter 2017 earnings call. Joining me on the call this afternoon; our CEO, Keith Murphy, and our CFO, Craig Kussman. Today's call will begin with a discussion of the 2017 fiscal second quarter results, followed by Q&A.

Before I turn things over to Keith, 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 fact 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. Our remarks today should be considered in light of such risks. Any forward-looking statements represent our views only as of today, and while we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our expectations or views change.

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 Keith.

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

Thanks, Steve, and good afternoon, everyone. I'll begin by emphasizing that we more than tripled total revenue year-over-year in our fiscal second quarter, and affirmed our recently updated guidance across the board today. In fact, our total revenue for just the first half of fiscal 2017 was 53% more than what we recorded in all of fiscal 2016. These gains represent a significant inflection point in our growth trajectory, putting us on solid

footing to execute against our financial and operating targets in the months ahead. Craig will cover these financial updates and trends later on his remarks.

Before I take you though my customary business update, I'd first like to recap our recently concluded $26 million equity offering. In short, we strengthened our balance sheet and successfully closed this round of financing in three days with meaningful participation from long term, fundamentally oriented institutional investors. In addition, we continue to engage leading analysts in our space, which we believe will yield increased research coverage and exposure for Organovo. More importantly, let's step back and evaluate the big picture around how we'll put this capital to work and maximize the value created by our enterprise.

Let me be clear in stating, while we could just stop at scaling our preclinical tissue testing business and focus on profitability, that approach wouldn't allow us to take full advantage of our platform technology. As we've shared in the past, the true power and versatility of our platform is showcased by working across multiple disciplines with multiple tissue types in multiple markets and applications. Our investments don't end with our ExVive of human liver and kidney tissue services, although we'll certainly focus on accelerating adoption of our existing commercial products.

Allow me to describe a few examples of our compelling growth opportunities. First, we believe we can double the addressable market for liver and kidney tissue services by adding metabolism studies to our menu of services. This requires near term investment in equipment, such as a mass spectrometer and personnel. But the pay back could be substantial. We are now pursuing the development of a metabolism service offering for both liver and kidney.

Second, it's important to foster product development initiatives around new tissues and new markets. As evidenced by the milestone payments we've achieved with our collaborative research partners, Merck and L'Oreal, we're making excellent progress in these areas. We also continue to promote an active business development pipeline in the oncology sector.

And third, we intend to pursue a formal pre-clinical development program for bio-printed human liver as the first candidate in our therapeutic tissue portfolio. As we continue to advance this tissue, we'll evaluate whether to pursue this project alone, or to partner with another company to help cover the cost of pre-clinical development, which can often run into the low tens of millions of dollars for a novel therapy to advance to IND. As a reminder, we have demonstrated strong results in animal models to date, including showing tissue engraftment, vascularization and sustained functionality.

Our total spend on this program has totaled approximately 15% of our annual R&D budget in the last couple of years, and we expect this amount will increase as we aim for future milestones. We believe this opportunity is certainly work pursuing as the initial indication areas alone represent a total addressable market exceeding $3 billion.

In regards to our progress in key areas; in the pre-clinical safety segment, the adoption of our liver research services continues to be our primarily source of growth. As we are engaging with pharma and biotech companies of all sizes and disciplines to address their needs and solve their problems. In the influential global top 25 pharma group, defined based on their full-year revenue for calendar 2015 ,we've added three new customers recently to reach 10 within this segment. Repeat business and multi-faceted orders are coming in at faster pace, owing in part to the master service agreement we're more often signing with our customers. Master service agreements are streamlined way of doing business, and we're already seeing evidence of shorter cycle times, orders with multiple tissue types, liver and kidney, and studies from different R&D locations across a customer's footprints. We're increasingly connected at multiple touch-points within an organization, interacting with scientists and R&D executives at all levels. Ultimately, we aim to become a standard and customary part of the toolkit that biopharmas use in their drug discovery work flow.

In addition to addressing toxicology challenges, the power of our platform can be harnessed to model disease states and evaluate efficacy. Robust published data validating our liver fibrosis model has resulted in an uptick in customer orders. The primary alternative that exists today for studying disease states is the animal model, which often does not effectively reflect human biology, and has long cycle times with studies lasting six to nine months. Customers want better and faster, and we're filling that need.

Supporting these financial and operating achievements is continued scientific progress. As I've shared before, more scientific data will accelerate our financial results, and we're investing to do more in this area. Our recent publications in two respected journals, PLOS ONE, and Toxicological Sciences, are undoubtedly chief drivers of customer adoption. Scientific data and peer referencing are invaluable in accelerating the sales process, and you should expect to see more on liver and kidney at the numerous commercial events and scientific conferences we'll be attending before the end of 2016.

I will now discuss the commercialization of our kidney program. We met our target and began commercial contracting for our kidney tissue service in September. The kidney proximal tubule model is a natural expansion of our preclinical product and service portfolio, allowing customers to study the effects of drug exposure on a key portion of the human kidney relevant to drug discovery and development. With just several weeks under our belt since launch, we've already signed multiple commercial orders with several companies. Early adopters, such as Ardea Biosciences, a subsidiary of AstraZeneca, and the La Jolla Pharmaceutical, have provided strong feedback on the product and how they're integrating it into their drug programs.

Overall, we expect the commercial ramp for kidney to be faster than it was for liver for three important reasons. First, the lack of existing alternatives, particularly effective 2D cell models, is even more acute than in the liver business. Second, we expect customer engagement times to be shorter. When we launched the ExVive of human liver tissue in late 2014, we hadn't yet begun to build out commercial organization and we were bringing a first of its kind product to a market that has essentially been using traditional preclinical models for decades. We now have dedicated sales directors across the United States and Europe that have been with Organovo for about one year, backed by strong group of technical and marketing professionals supporting business development. Put simply, we know our customers better than we did 12 months ago and we can leverage the same commercial infrastructure to penetrate the kidney market faster.

And third, the decision makers for liver and kidney toxicology work are often the same people or groups at biopharmaceutical companies. We've already worked with these scientists on liver toxicology studies. They understand that we can deliver superior results for their drug development programs, and they should move ahead more quickly with us because of an existing relationship.

I'd like to update you now on one of our key partnerships, namely our collaborative agreement with Merck. We continued to successfully execute against the major phases of this large long term deal with a gain in collaborations revenue during the fiscal second quarter, reflecting our achievement of the milestone related to custom disease modeling. We continue to expect that this valued relationship will be an important contributor to total revenue in the quarters ahead.

Changing focus to discuss our therapeutic tissue business, as with our kidney program, we met a major objective here by moving bioprinted human liver tissue forward as the first candidate we advanced in our therapeutic tissue portfolio. I shared some of the highlights of this program earlier in my remarks, but I want to add a few additional thoughts. The early pre-clinical results have been promising and support our decision to move forward with a formal pre-clinical development program. Our animal studies have shown robust vascularization, the stable the detection of liver specific proteins and metabolic enzymes, and key evidence of functions detectable in blood serum. We also believe that our approach is designed to overcome many of the challenges that cell therapies and conventional tissue engineering have struggled to address, including limited engraftment and significant migration of cells away from the liver.

We still have lots of work to do in optimizing and selecting the final tissue design and getting through pre-GLP and GLP efficacy and safety studies before reaching an IND submission in the next three to five years. But we're very excited by our path forward. We'll also pursue break through therapy designation, clinical development outside the United States, and other opportunities to help accelerate our time to market.

I'll wrap up by noting that it's been a busy first-half of fiscal 2017. Our liver businesses on track to grow more than 200% year-over-year in fiscal 2017. Our kidney program is off to a good start and will be a top line contributor soon. And liver therapeutics tissue is positioned to move ahead as our first potential tissue replacement product. We've increased our total revenue guidance along the way, and strengthened our balance sheet so that we can continue to make the targeted investments to grow our business and maximize the value of our platform technology. We look forward to strong execution from our team during the second half of fiscal 2017.

With that, I'll turn it over to Craig for a more detailed financial review.

Craig Kussman - *Organovo Holdings Inc - CFO*

Thanks, Keith, and good afternoon everyone. I'll begin by summarizing our key financial metrics for the fiscal second quarter, and then walk you through the full-year financial targets we affirmed today. I'll wrap up my thoughts by briefly reviewing our balance sheet and liquidity profile.

Organovo generated fiscal second quarter total revenue to $1.4 million, which was up 358% from the prior year period, and up 54% on a sequential basis. Total revenue benefited from an increase in customer activity for our tissue research services and milestone achievements through our collaborative work with Merck.

As Keith noted, we're seeing traction in our commercial business with three recent global top 25 pharma wins, a healthy pace of orders for our fee based liver toxicology services and a solid early response to our kidney program. It's worth reinforcing that the breadth of applications we can offer is diverse and superior to what can be achieved with traditional pre-clinical models. It includes toxicity testing of compounds in the late pre-clinical stage of drug discovery, drugs in development that are on clinical hold due to toxicity issues, as well as other use cases, such as disease modeling.

I'll focus next on operating expenses, and would continue to underscore that the core driver in the forecast growth of our cash operating expenses for the foreseeable future is the people we bring onboard to grow our commercial operations to support the manufacturing and sales functions. We now have approximately 115 employees on the Organovo team.

We reported $0.4 million in cost of revenues for the fiscal second quarter. This is only our second period reporting this expense line item and as the description suggests, it captures our cost related to manufacturing and delivering our product and service revenues. It's an important factor of how effectively we're commercializing the business, and provides insight to our financial health when considering the associated profit margins.

Research and development expenses were $4.5 million, a 4% year-over-year decline, largely due to a decrease in the use of outsourced professional services. While this non-core item caused a blip in how our R&D expenses trended in the fiscal second quarter, higher employee related costs due to increased staffing will continue to be the principle driver going forward.

We recorded $5.9 million in selling, general and administrative expenses during the fiscal second quarter, a 14% year-over-year decrease, primarily resulting from lower compensation expense related to non-recurring separation and payroll costs for two former executives. Given that these are not run-rate items, we expect that higher employee related costs will get us back to moderate year-over-year increases in future quarters.

And finally, a brief review of the full-year fiscal 2017 outlook we affirmed today, which was updated just two weeks ago, and a few quick notes on our balance sheet and liquidity profile. We forecast total revenues between $4.5 million and $6.2 million for fiscal year 2017 with the main contributions coming from our liver tissue services and research collaboration agreements. This range is higher than where we started the year. And when compared to fiscal 2016's total revenue of $1.5 million, represents approximately 250% growth at the midpoint of the range.

On the same basis, for the full-year of fiscal 2017, we expect net cash utilization between $31 million and $34 million. Our net cash utilization of $15.4 million in the first half of fiscal 2017 is consistent with this guidance. This range is lower than where we started the year and reflects a measured approach in how and when we add headcount in key areas. We expect our net cash utilization will continue to trend down on an annual basis as we grow revenue and achieve operating efficiencies.

At the end of the fiscal second quarter, we had a cash and cash equivalents balance of $51.7 million, which includes net proceeds of $4.5 million from the issuance of nearly 1 million shares of common stock in at the market or ATM offerings. In addition, as we've covered in detail, we raised $25.6 million from the equity offering we conducted in late October. When considering all of these factors, we have approximately $75 million of cash on hand today to carry out our business plan and invest in our key growth pillars.

To build on what Keith outlined during his remarks, we'll deploy our capital with an eye toward maximizing the value of our platform technology. We'll continue to scale the commercial toxicology business, but more importantly, increase the revenue we capture by expanding our service offerings. We'll invest in product development to bring new tissues to new markets with new applications. And, we'll spend a portion of the proceeds

to move our promising liver therapeutic tissue into a formal pre-clinical development program. All-in-all, we're executing against the same long-term plan.

In closing, I'm very excited to have joined Organovo in late August, during what is transformational time in the Company's history. My first two months on the job have been busy with meeting investors, fortifying our balance sheet and spending time with the team as we formulate our strategic thinking for the years ahead. I believe that that's still ahead of us.

With that, I'll turn things back to the operator for the Q&A portion of the call.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Brandon Couillard, from Jefferies.

Sachin Kulkarni - *Jefferies - Analyst*

Will you quantify the expenses associated with the metabolic service offering for the liver and kidney, as well as that for tissue product?

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

Is that for that the tissue products we talked about has potential add ons? Is that what you're asking?

Sachin Kulkarni - *Jefferies - Analyst*

Correct.

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

Yes, so we haven't undertaken to quantify that yet. Sorry, we can't you be that level of details just yet. First of all, to be clear, we're evaluating product opportunities. So there is nothing specific that we're talking about when we say that we've got opportunities. I mean there's specific things that we are clearly evaluating that you would understand that come from the existing partnerships. So obviously, evaluating next steps in skin for L'Oreal, and then some undisclosed tissues with Merck. But I can't give you exact number there, because obviously we're still working on that.

In terms of the metabolism offering, we haven't undertaken to qualify that. I think it's safe to say, it's still little bit early. But I think the opportunity that we feel there is very strong. It's the same customer base. Again, we can leverage the customer relationships that we're building. We can leverage the sales team that we've already established. And I think that there's a strong demand for that, both in the liver side and on the kidney side as well. So, we're very excited about being able to add that. And we've demonstrated internally that we've got the capability to do metabolism with some early data, which is looking very strong too.

Sachin Kulkarni - *Jefferies - Analyst*

And then would you also provide an update among the traction with the pharma customers? And percentage of them are repeat and how many of them actually indicated interest for the kidney assay?

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

So we haven't talked about the specific repeat numbers, what we've said is very strong. We see strong repeat business. And we've also - I can also say that the trend that we've seen is that the second contracts are higher value than the first contracts that are done. Which is - all of these trends are in our favor. We've had a very strong response.

I think that's driven by a few things. I think it's driven by the fact that we're hitting a key need for the customers, that they grow to understand the value of the offering after they've used it a little bit. And then it also speaks to the increasing level of validation. So as we work with these customers, some of what they're doing is, for example, testing internal compounds that had failures for them. So we've talked to you about compounds known to the space that were late stage failures that we were able to detect that couldn't have been detected, were not detected with, for example, rat and traditional 2D cell culture tox models. But internal to each customer, each company, especially large pharma companies, they have misses that aren't known to the world that they want to test with us. And a number of them have undertaken to test those. And we feel we're doing very strongly with them in terms of that kind of testing which leads them to greater confidence in our platforms. So that's all been very positive.

And I think, if anything, the anticipation and excitement about the kidney platform, is even higher than it was at liver launch. In part, because as we've said before, there's a stronger unmet need there. They don't have an in vitro model that they can use. And the data that we're showing, it's still early, but the data is very powerful. And I think there's a strong response to that; so, a lot of interest. And so, yes, some of the existing customers are obviously interested in using that, but we're getting new customers as well, who have a first use for that. So it's exciting across the board in the kidney space.

Operator

John Meckler, from 3D Advisors.

John Meckler - *3D Advisors - Analyst*

Just a quick question about Samsara Sciences, are you guys able to give us a little update on what's going on there and any sort of idea of its contribution to the, I guess, top line?

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

So we don't provide specific guidance on Samsara's top line revenue. It's been going for on the order of a year now. We launched commercial operations in January 2016. I think one key thing to remember is that it's not only about the top line with Samsara. They've got an early contribution that will be growing overtime. As it's relevant to do so, of course, we would give more clarity on that. But for now, it's a smaller portion of our overall revenue.

But I think something that's good to remember is that Samsara yields a lot more value than just top line revenue contribution and marginal profit. It's delivering cells to our core businesses, our core business and our core R&D efforts. And there's a cost savings involved with that that's quite substantial. And when we undertook to build Samsara, remember that that was actually our primary motive.

The cost of cells is quite high, especially on the liver side. Availability of cells in some cases can be difficult, that's very true on the kidney side. And so to have a source for cells that assures both lower cost and ongoing supply or secondary supply for risk mitigation has been really critical and we've seen that pay-off in spades already. So we're very happy overall with Samsara. And the other opportunity that we are taking advantage of is taking additional revenue and marginal profit. As we can do so, we'll update you in the future on that.

Operator

This concludes your question and answer session. I would like to turn the conference back over to Keith Murphy, CEO, for any closing remarks.

Keith Murphy - *Organovo Holdings Inc - Chairman, CEO*

Well, thank you everyone for your time today. I'd just like to say we're grateful that Craig has joined us. He's been here for since August now, and everything is flowing quite nicely under his tutelage. I think the reporting speaks to that. And we're very happy with where things are and very excited about the future.

So thanks everyone for continuing to follow, and for your time on the call today. Thank you.

Operator

Ladies and gentlemen, the conference is now concluded. Thank you for attending today's presentation. You may now disconnect.