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ONVO - Q1 2017 Organovo Holdings Inc Earnings Call

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Edward Tenthoff *Piper Jaffray - Analyst*

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PRESENTATION

Operator

Good afternoon. Welcome to the 2017 fiscal year first quarter Organovo earnings conference call.

(Operator Instructions)

After today's presentation, there will be an opportunity to ask questions. Please note this event is being recorded.

I would now like to turn the conference over to Steve Kunszabo, please go ahead.

Steve Kunszabo - *Organovo Holdings, Inc. - IR*

Good afternoon and thanks for joining us. I'd like to welcome you to our fiscal first quarter 2017 earnings call. Joining me on the call this afternoon is CEO, Keith Murphy.

Today's call will begin with a discussion of our 2017 fiscal first quarter results, followed by Q&A. I trust you've had an opportunity to review this afternoon's earnings release, which is available on the Investor Relations section of our website.

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 our 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. - CEO*

Thanks, Steve, and good afternoon, everyone. I'll get started by highlighting that we nearly tripled total revenue year-over-year in our fiscal first-quarter and affirmed our guidance across the board today. We're pleased with our strong top-line progress to begin the year, which puts us on track to hit our financial and operating targets in fiscal 2017.

Before I begin on our usual business, I'd like to welcome Craig Crossman, our new CFO to the executive team. As you saw in our announcement Tuesday, Craig brings significant financial, operational and strategic expertise in the life science and healthcare space to our organization. We look forward to his contributions, as we enter our next phase of commercial development and growth. You'll have an opportunity to hear from him on our next earnings call if not sooner.

I'll now move on to a summary of our numbers, starting with our high-level results after which I'll discuss the significant developments and revenue drivers in each of our markets. I'll conclude my remarks by briefly taking you through the fiscal 2017 financial targets we affirmed today and updating you on our balance sheet and liquidity profile.

Organovo generated fiscal first-quarter total revenue of $0.9 million, which was up 191% from the prior-year period and 63% 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. In the preclinical safety segment, the adoption of our liver research services has really picked up pace, with an increase in new customers signing orders during the last few months.

We're 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, we continue to make headway having added two new customers recently to reach seven within this segment. Importantly, we continue to see a high percentage of repeat business from our established customer base.

The breadth of applications that we can offer is diverse and superior to what can be achieved with traditional preclinical models. It includes traditional toxicity testing of compounds in the late preclinical stage of drug discovery, drugs in development that are on clinical hold due to toxicity issues, as well as other use cases. The true power and versatility of our platform is showcased by working across multiple disciplines with multiple tissue types in multiple markets.

Let's take the evolution of our customer relationships as an example to drive this point home. Many of our new customers now work with us under what are called master service agreements. Rather than signing up for just a single order or transaction, it's generally a more extensive process that provides a comprehensive framework for how we're going to work together and can include detailed supplier due diligence on their part.

While these agreements may take longer to iron out, they lay the foundation for a deeper and long-term relationship that can simplify repeat business, shorten cycle times for orders and lead to higher volumes. A good example of this is an agreement we signed with one of our newest global top-25 pharma customers. This is not just a one-off transaction, but rather a number of orders that includes work with our liver and kidney tissues, looking at both toxicity and efficacy in a series of studies will complete for them. 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 bio-pharma use in their drug discovery workflow.

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 publication with Roche Researchers in the respected journal +1 delivers on that promise and there's more to come. These types of papers along with the customer posters that were presented at the Society of toxicology's annual meeting earlier in the year are undoubtedly chief drivers of customer adoption. In short, there is nothing more valuable than pure referencing and scientific data to build credibility with our customers and accelerate the sales process.

I'll now discuss the progress on our kidney program. As we announced a couple weeks ago, we remain on track to commercialize our second tissue, the kidney proximal tubule. Our pre-commercialization activities have allowed us to build early demand resulting in our first customer orders to study key aspects of kidney pharmacology, including compound transport, metabolism and toxicity. The early access program has actively engaged

with the number of additional customers and we're taking the final steps in the manufacturing, marketing and quality areas in the coming weeks to assure a successful introduction to the broader market.

We plan to debut the kidney tissue in early September at Euro Talks 2016, Europe's marquee event in the field toxicology. Kidney is a natural expansion of our preclinical product and service portfolio, and we look forward to providing news on post-launch developments.

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

We also continue to see great promise for our tissue replacement products and revolutionizing transplant medicine and substantially improving patient outcomes. No change to our plans and our timeline here, we're achieving solid results in animal models for the multiple tissue types that we're evaluating and we're on pace for being able to share some high level data in our next steps inside of 12 months.

Our goal remains an investigational new drug or IND submission with the FDA in the next three to five years depending on the tissue type. Stay tuned for news in the second half of calendar 2016.

Now, before I wrap up with our fiscal 2017 guidance and balance sheet profile, I'd like to provide a quick summary of our expense trends. We reported $0.2 million cost of revenues for the fiscal first-quarter. This is our first period reporting this expense line item and as the description suggests, it captures our costs related to manufacturing and delivering our product and service revenues. It's an important indicator of how effectively we're commercializing the business and provide insight to our financial health when considering the associated profit margins.

Research and development expenses were $4.4 million, a 7% increase from the prior-year period, largely due to higher employee-related costs, such as salaries and benefits and lab supplies. We recorded $5.1 million in selling general and administrative expenses during the fiscal first-quarter, a 9% year-over-year increase, primarily resulting from higher employee related costs, including non-cash share-based compensation expense.

Finally, a brief review of the full year fiscal 2017 outlook we affirm today and a few quick notes on our balance sheet and liquidity position. We continue to forecast total revenue between $4 million and $6 million for fiscal year 2017, with the principal contributions coming from our liver tissue services and research collaboration agreements. This compares to fiscal 2016 total revenue of $1.5 million and represents approximately 230% growth at the midpoint of the range. It's also worth recapping that we expect minimal revenue impact from our kidney tissue, given that initiation of commercial contracting will occur about halfway through our 2017 fiscal year and keeping in mind the long revenue recognition cycle.

On the same basis, for the full year fiscal 2017, we continue to expect net cash utilization between $32.5 million and $36.5 million. Our net cash utilization of $8.6 million during the fiscal first-quarter was consistent with this range. With a quarter and cash balance of $53.5 million and using this range for net cash utilization, we have approximately 19 months of cash on hand to carry out our current business plan. We'll continue to be thoughtful in deploying our resources to balance growth and operating efficiency.

And wrapping up my thoughts, I believe that it's increasingly clear that the right building blocks are in place to support our long-term plan. We're reaching attractive and growing markets with critical unmet needs, extending our position as a first mover in the 3-D Bio printing space and capitalizing on our technology leadership to grow our product and service offerings. Our liver business is hitting its growth targets, kidney is on track to be a top-line contributor in the near future, and we're hitting key milestones in our collaborative research partnerships.

Overall, we've started the year with solid sales and revenue momentum. We look forward to a strong execution from our team during the remainder of fiscal 2017. 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) Edward Tenthoff from Piper Jaffray.

Edward Tenthoff - *Piper Jaffray - Analyst*

Keith and everybody, congrats on a really good quarter and just continued moment. I am excited to see the initial disorders for the kidney product, I just wanted to see (inaudible) in the launch, but can tell us any qualitative response that you're getting from new customers?

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

Thanks for the question, Ted. So, it's hard to quantify it, but as you say qualitatively, I think what we can say is that, we're getting a very strong response. As I think, we've tried to describe the kidney is an area where there aren't very good solutions available at all and people have an urgent need for some new solutions in the kidney area. We're seeing that play out in the discussions where people are very excited about the opportunity to start work with the kidney, and we think that will lead to a faster pace of initial orders, especially when you combine that with the fact that we've got an existing sales force at this point and they've built customer relationships.

So we're very bullish and we think that the customer response has been strong, we get a lot of incoming questions about kidney tissue availability, and people have been waiting for the moment when they can start to work with it. So, we think people are excited about it.

Edward Tenthoff - *Piper Jaffray - Analyst*

And is it really the same selling point as with the liver product?

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

Well, I think there are multiple selling points for both, and I would just add a little color where talking - multiple things people can be doing, the top two might be toxicity and metabolism, right. So, people can not only look at the impact of a drug in the terms of the safety effect on the tissue, but kidney and liver are responsible for breaking down drugs into new chemical compounds and then clearing them from the body as well. This is a really important area and we've seen that as being something that people have strong interest in studying in the kidney environment.

Metabolism is very important overall, because when we qualify or when we quantify the markets as we've talked about them, for example, saying there are 6,500 programs out there that are addressable customer opportunities, and that we can do a contract at the 150K size, with each of those a little over once a year, that's our opportunity.

When you add metabolism to that, it could easily double the entire market size, meaning that in addition to a toxicity program and 150K contract in that space, we can do an equal size contract with each of those programs in a given year. So, metabolism is a very strong multiplier for our overall market and that's something that's been focused on by some of the early kidney customers.

Edward Tenthoff - *Piper Jaffray - Analyst*

Excellent, that's really helpful Keith. Looking forward to more detail on the launch.

Operator

Brandon Couillard from Jefferies.

Unidentified Participant

Hi, it's Sachin in for Brendon. Keith, will you provide an update on the next steps associated with the skin collaboration with L'Oreal?

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

So, we've guided last time that we had hit some initial milestones in that, I can't give you more color than that because we're in the midst of that contract, but we definitely plan to continue to give updates as that moves forward. Just to give you the big picture on that and about where we stand, the steps in that initial contract as we laid it out are to develop skin tissue models, and then what was contemplated was the validation of those and moving them towards commercialization. So, the initial model met that first phase where we had built it and we're in the validation and moving towards commercialization stages now for the initial model and then moving along next models as well.

Unidentified Participant

And have you thought about like what the ASPs will be for those kinds of products?

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

Well, we certainly thought about it, I don't have any color I can give you. I can say that the cosmetic space has a different cost profiled in the pharma space and we have to make sure that we can get good margins in that space, but we're addressing that and we're making sure that we think we can have an attractive profile for our product in that space for sure.

Unidentified Participant

Got it. And then, following the kidney launch, will you discuss your R&D priorities?

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

So, obviously, you mentioned the skin tissue, that's a huge R&D priority for us, and I think you've been aware that we have an on-going program in cancer and as you've seen our trend happened before as we developed liver tissue, we had significant R&D resources expending on that as those wound down a little bit post liver launch those resources a lot of them went on to kidney, and that'll line down a little bit now. The primary things that those folks are going on to are next-generation kidney and liver tissues because we do want to keep developing those tissues and oncology work as well. The skin team obviously has been in place and will remain working on that.

Unidentified Participant

And investments planned for like sales force or commercial organizational expansion over the next 12 months? How should we think about SG&A guidance forward?

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

Well, what you're seeing is a growth in the sales and the acceleration in the sales growth, and that's going to drive what you're asking about, that's going to drive a need to grow the sales team so as were successful in penetrating the market, we're going to need to grow the sales team. We're also going to need to - in concurrence with that, grow that the manufacturing resources that we have on board to meet the demand.

So, right now, we think we're sitting pretty from a facility standpoint - facility capacity, but we've only hired the manufacturing labor force necessary to deliver to the demand, and so, as demand is growing, that will need to grow overtime and then the sales team would grow as well. I would say that with the current footprint, you have to start from a certain baseline to get regional coverage, and so the need to expand isn't immediate but as the sales continue to grow we will have to do that.

And if I could just go back to your question about the R&D resources, another key thing to point out, Sachin, would be that R&D resources are critical on what I talked about in my comments, showing new data for the existing tissues to drive continued sales growth in those areas, and we have a constant presence doing that, you saw the recent publication, but we've got a lot of work that goes into making sure that we're having a continuous flow of data. So, I mentioned metabolism in my answer to an earlier question and to get uptick in metabolism, we need to show course baseline data that validates the use of our tissues in metabolism.

So that kind of thing is also an investment, I would call that - it's more like development work that's a lot closer to the commercial organization to drive sales directly, and so, when we look at investments on that side, you're looking at projects that cost in the hundreds of thousands and you look at an ROI that can be quite quick in terms of getting a return on those investments.

Operator

James Jeffrey from Deloitte.

James Jeffrey - *Deloitte - Analyst*

So, this is more up to current competition and 3D Bioscience is a competitor company, the medical Bio printing and they have a higher throughput rate due to magnetizing cells rather than organelle those layer-by-layer method, and understanding the competitors right now have a smaller percentage of the market and the future market of Bio printing may very well work several major players, I was wondering if you can speak to current competition on your radar and any potential concerns you have to sustaining a longer-term competitive advantage?

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

So, here's how I would speak to that. I think that as we look at what we're trying to do, it's very important to point out that we are targeting to be a high content and necessarily then we are lower throughput, so I think there's quite a few great technologies out there that are seeking to address the highest throughput possible, that's not what we're trying to do, I mean we'd like to do the highest throughput we can, but naturally by seeking the best possible content, meaning the best biological results for a given drug or a sample that's being tested. We naturally limit ourselves.

And so, right now, we're in 24 well plates, and I don't foresee us getting to more than 96 well plates in the types of throughput we can do. That's sort of a - that's a nice threshold to reach eventually and our work with the NIH, the MCATs Institute that does high throughput screening, they see that as - hitting that threshold as really sufficient given the content of data that we're giving.

But, think when you talk about how the market might be developing overtime, not necessarily in terms of current competition, because like you say it's hard to compare with when really everyone's comparing with the gold standard in the markets right now which is still the use of traditional rat models and cells in the dish, but what I would say is we tend to compete more the way we're seeing things happen with rat model use than with cells and tissues, and people seeking high throughput solutions I think are going to be more competing with the earlier stage screening that's

being done with cells and the dish if that make sense. And that's where you might see things grow where people are - some people are growing into that early higher throughput screening area, while we're going to be sticking on the high content lower throughput area.

Operator

This concludes our question-and-answer session. I would now like to turn the conference back over to Keith Murphy for any closing remarks.

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

Thank you everyone for your time today. I'd like to thank you for joining the call and listening in. I just want to reiterate I think we're in a really strong position, we're delivering on what we've been trying to do, and we're validating the promise of 3-D Bio printing. The entire team is focused on the next steps, which is continuing our commercial uptake of this - of the technology growing into the kidney uptake that we expect to see as we launch this kidney tissue as well.

So, we really appreciate all your time and attention spent in following the company and we look forward to continued interactions in the future, thank very much.

Operator

The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.
