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ONVO - Q4 2016 Organovo Holdings Inc Earnings Call

EVENT DATE/TIME: JUNE 09, 2016 / 9:00PM GMT



## CORPORATE PARTICIPANTS

**Steve Kunszabo** *Organovo Holdings, Inc. - VP of Investor Relations & Corporate Communications*

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

**Paul Gallant** *Organovo Holdings, Inc. - General Manager, Commercial Operations*

## CONFERENCE CALL PARTICIPANTS

**Ted Tenthoff** *Piper Jaffray - Analyst*

**Michael Kay** *Kay Associates - Analyst*

**Brandon Couillard** *Jefferies LLC - Analyst*

## PRESENTATION

### Operator

Good afternoon, and welcome to the Organovo Holdings Earnings Conference Call for the Fiscal Fourth Quarter of 2016. (Operator Instructions) Please note, this event is being recorded.

I would now like to turn the conference over to Steve Kunszabo, Vice President of Investor Relations of Organovo Holdings. Please go ahead.

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**Steve Kunszabo** - *Organovo Holdings, Inc. - VP of Investor Relations & Corporate Communications*

Good afternoon, and thanks for joining us. I'd like to welcome you to our fiscal fourth quarter 2016 earnings call. Joining me on the call this afternoon are CEO, Keith Murphy; and our General Manager, Commercial Operations, Paul Gallant.

Today's call will begin with a discussion of the 2016 fiscal fourth 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 Organovo's 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 risk. 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.

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

Thanks, Steve, and good afternoon, everyone. As Steve mentioned during his introduction, Paul Gallant is joining me on the call today to provide his perspective as our senior customer-facing sales and operations executive.



You may remember that we welcomed Paul to the Organovo team last August as our General Manager of Commercial Operations. He's done a great job building our sales, marketing and operations infrastructure during the last several months, while also moving forward key business development initiatives. His day-to-day interaction with our customers and partners can provide an important perspective for all of our stakeholders and we plan to have him periodically join us for our earnings announcements and other investor events.

Before I dive in on the recent developments in our primary business lines, our financial highlights for the fiscal fourth quarter and our outlook for fiscal 2017 and beyond, I'd like to update you on our CFO search. Barry Michaels, our former CFO, spent his last day with the company in early April. Because of his departure, we have been engaged in a robust search process to identify Barry's successor. Of course, our aim is to attract a high-quality finance executive with strong industry acumen and leadership skills. No news yet, but as soon as someone is in the seat, we'll make an announcement.

I'll now turn to our financial and operating progress, starting with our top-level results, after which I'll discuss the significant developments and revenue drivers in each of our market segments. I'll wrap up my comments by briefly reviewing the full year fiscal 2017 financial targets we issued today and walking you through our balance sheet and liquidity profile.

Organovo recorded fiscal fourth quarter total revenue of \$0.5 million, which was a gain of 105% from the year-ago period and 67% on a sequential basis. Total revenue benefited from the recognition of milestone achievements through our collaborative work with L'Oreal and Merck.

It's important to remember that the pace of customer decision making and their R&D calendars are important drivers of revenue. For example, a customer involved in a multistage contract can be very pleased with the results of one phase of toxicology work we've done for them, but may need to reorient their work plan to incorporate learnings from that phase as they move forward with additional testing.

This kind of delay, along with other drivers of decision-making, unrelated to Organovo's technology or scientific results, can lead to choppy quarterly results as revenue recognition moves around a few months forward or back, but it does not typically change our longer-term revenue outlook.

In the preclinical safety segment, we're establishing a solid foundation around our exVive3D Human Liver Tissue. In short, we've continue to build out our sales footprint both geographically and to address new potential vertical markets. We've grown customer adoption among global top 25 pharmaceutical customers, reaching five, with an additional customer from this segment added recently, and we've maintained a solid cadence of repeat agreements.

We've also made robust scientific progress as evidenced by our customers' peer-reviewed posters as recent events such as the Society of Toxicology's annual meeting, and by our own internal validation studies. Paul will have more detail on all these fronts, as well as our kidney tissue development during his remarks.

I'd like to update you now on our partnerships and then on our tissue therapeutics research. As we noted last quarter, we completed Phase I of our agreement with L'Oreal ahead of schedule, with a gain in collaborations revenue during the fiscal fourth quarter primarily coming from our achievement of this milestone. We are pleased with our progress and look forward to working with this partner in developing 3D skin tissue.

As for our Merck relationship, we continue to work on both the toxicology and custom tissue disease modeling parts of that agreement. We've now recorded revenue from the early phases of this long-term multipart agreement, and with the majority of the total contract value still in front of us, we expect this deal to be an important contributor to total revenue in the quarters and years ahead.

We also continue to see great promise for our tissue replacement products. In late April, the Vatican hosted a regenerative medicine conference in which I was invited to present. As I noted to the audience there, the potential exists for Organovo's technology to revolutionize therapeutic applications and materially improve patient outcomes.

We're achieving solid results in animal models for the multiple tissue types that we're evaluating, and now believe that we're inside of 12 months for being able to share some high-level data and our next steps. Our goal is to reach an investigational new drug, or IND submission, with the FDA in the next three to five years, depending on the tissue type, which would allow us to enter clinical trials. Stay tuned for news as we move through calendar 2016.



And now, a quick summary of our expense trends before I wrap up with our fiscal 2017 and long-range guidance. We reported \$4.4 million in selling, general and administrative expenses during the fiscal fourth quarter, a 3% year-over-year decrease, primarily resulting from lower and full year related costs, including non-cash share-based compensation expense.

I'd also add that while the bulk of our costs here come from employee-related expenses such as salaries and benefits, we expect the growth rate for SG&A expense in fiscal 2017 to be materially lower than the 23% expansion we posted in fiscal 2016. We expect the pace of our hiring to decrease now that we've reach approximately 115 total employees. We'll add targeted headcount in fiscal 2017 to support the functional areas, but additional hiring will be driven primarily by the need to grow the in-vitro tissue business to support demand.

Research and development expenses were \$4.5 million, a 25% increase from the prior-year period, largely due to higher employee-related costs such as salaries and benefits and lab supplies. Our research staff supports product development and sales activities that align with the ongoing commercialization of our products and services, as well as in meeting our obligations under existing collaborate and research agreements.

Finally, a brief review of the full year fiscal 2017 outlook we issued today, and a few quick notes on our balance sheet and liquidity position. We forecast total revenue to be 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 highlighting 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 fiscal year 2017, we expect net cash utilization to be between \$32.5 million and \$36.5 million. This rate of annual net cash spend is consistent with the level we reported in fiscal 2016, and with our consolidated operating expenses reflects that the business is reaching the right size to execute against our business and growth plans.

With the 2016 fiscal year end cash balance of \$62.1 million, and using this range for net cash utilization, we have nearly two years 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. Lastly, we continue to anticipate that we'll initiate commercial contracting for our kidney tissue product in the calendar third quarter of 2016.

In closing, we continue to lay the groundwork to support our excellent long-term growth prospects. We're reaching attractive markets with critical unmet needs, extending our first-mover advantage in a rapidly evolving space, and fortifying our position for the world-class IP portfolio that is constantly expanding.

The power of our technology platform is that it allows us to expand our products and services portfolio in many ways, leading to a great breadth and diversity in our revenue profile. We expect our liver business to more than triple this year, our kidney product is on schedule, and our skin model is hitting its important milestones. There's much to be excited about as we look ahead to fiscal 2017, and we look forward to updating you on our progress again in about two months.

With that, I'll turn it over to Paul for a deeper dive into our sales and operations progress.

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**Paul Gallant** - *Organovo Holdings, Inc. - General Manager, Commercial Operations*

Thanks, Keith, and good afternoon, everyone. I'm excited to be on today's call to share my perspective on our commercial progress and all the critical work we've done in the 10 months since I joined Organovo, including building our sales footprint, aligning ourselves with our customers, generating our scientific data set and expanding our manufacturing capacity to support future growth.

I'll spend my time with you today in four key areas, our sales organization footprint and how we maximize our reach with customers; the evolution of our liver toxicology business, including customer use cases and our expanded scientific data set; the development of our kidney product as we look ahead to commercialization in a few months; and the steps we're taking to target revenue opportunities in disease modeling.

But before I jump in, if there's only one thing I'll leave with you today, it should be providing an understanding of the power and the versatility of our technology platform. We're working across multiple disciplines to bring our innovations to market in a host of areas. It's multiple tissue types in multiple markets that really drives home the breadth of our long-term revenue profile. In short, we can do many things with this platform to address a number of revenue opportunities.

Let's start with our sales footprint. When I joined Organovo last August, we essentially had one dedicated sales executive supporting the commercial launch of our first product, the liver tissue. Today, we have a VP of Sales and four dedicated sales directors across the U.S., Europe and Asia, working on deals with pharmaceutical customers. We now effectively cover the globe to cultivate pharma customer relationships and can begin to explore non-pharma markets, including cosmetics, chemical, consumer health and CROs. Supporting the sales force is a staff of four commercial and technical marketing professionals, bringing the total size of our commercial organization to 10 employees. We believe that the size, structure and expertise of this group allows us to effectively target our near-term revenue opportunities.

In our liver business, sales momentum has been ramping since our participation in the Society of Toxicology's annual meeting in mid-March. As a reminder, we had a joint presentation with Bristol-Myers Squibb that was standing-room only and five peer-reviewed posters, including two of which were presented by our global top 25 pharmaceutical customers, namely Astellas and Bristol-Myers Squibb.

We've had one additional global top 25 pharmaceutical customer win in recent weeks, bringing our total to five with this important group, and there are additional near-term opportunities in our pipeline. Repeat orders have also continued at a good pace as evidenced by the fact that we're now on a third contract with one of our earliest global top 25 pharma customers.

As the adoption of our solutions grows and we take a hard look at customer needs, three primary use cases are emerging, first, traditional toxicity testing of compounds in the late preclinical stages of drug discovery. We believe we've built a strongly differentiated model that enables better drug candidate selection.

Second, drugs in developments that are on clinical hold, due to toxicity issues, the value proposition for customer in this instance is huge, as they've already invested many millions of dollars in development, and are incentivized to turn that compound into a revenue producing asset.

And third, in-depth mechanistic analysis of toxicology issues. What this means in practical sense is that drug-induced liver injury can involve complex series of interactions with multiple cell types, which can be missed by standard 2D cells in animal models given their limitations. Our 3D printed tissue really stands out here, with 100% multi-cellular composition that effectively models native tissue architecture.

A great example of this type of use case was presented at the Society of Toxicology's annual meeting by Bristol-Myers Squibb. In short, they are able to identify multiple mechanisms of a known toxic compound using our 3D liver model, which were not have captured in traditional 2D models. We continue to build the scientific proof set that validates our liver tissue model, as this is vital in building credibility and increasing customer adoptions in all of our business lines.

Turning now to our kidney program. Kidney tissue development remains on track with the initiation of commercial contracting in the third quarter -- third calendar quarter of 2016. As many of you know, we hit the functional validation milestone for our kidney tissue last October. Since then, our focus has been on taking the necessary steps in the development, manufacturing and quality areas to ready this product for commercial use.

More recently, we've commenced an early-access program with preferred partners, allowing us to prime the market while also providing an evaluation period for potential customers. We're seeing strong interests from about a dozen companies, and we anticipate that these actions will drive early success.

Finally, a quick outline of our progress in the disease modeling space. In addition to addressing toxicology challenges, the power of our platform can be harnessed to model disease states and evaluate efficacy during the drug discovery and development workflow. Robust data validating our liver fibrosis model has resulted in a significant uptick in customer interests. This data, along with our internal validation work, is leading to a higher pace of customer wins. As we have emphasized before, we expect to have increased market penetration with the liver tissue as the data set grows.



In wrapping up my thoughts, I'm encouraged by our commercial and scientific momentum. The power and the versatility of our technology is clear, and we'll leverage it to address critical unmet need for our customers. The right building blocks are in place to support our success, and I share Keith's view that 2017 will be a year of solid revenue growth for Organovo. I look forward to participating in future calls and investor events.

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

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) The first question comes from Ted Tenthoff with Piper Jaffray.

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### Ted Tenthoff - Piper Jaffray - Analyst

Thanks so much for the update and a very constructive guidance rolling forward here. I'm looking at -- a couple of questions, if I may. Firstly, just with respect to the skin collaboration with L'Oreal, can you kind of layout what next steps are there?

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### Keith Murphy - Organovo Holdings, Inc. - Chairman and CEO

Well, there's many phases in that contract, and the initial phases were development of a model. The next phases beyond that are validation, and then commercialization in some sense of those. And so, we need to work on the next phase agreements to move that forward, and then continue to execute scientifically, but we're very encouraged by the early results. We're very happy with the scientific results on that side, and I believe it's safe to say our partners as well. So we're encouraged by everything that's happened, it's just about moving that forward through the next steps.

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### Ted Tenthoff - Piper Jaffray - Analyst

Now when it comes to revenue breakdown between kind of collaboration in product and services, it looked like kind of in the fiscal fourth quarter, in the March quarter we saw a shift more to the collaborative side, away from the product and services. And I know that you highlighted that some of the products and services will kind of come from a large partner early in fiscal '17. So in the June, September, let's call it this summer, whatever. Is this a trend that we should continue to expect, or how should we be thinking about those revenues going forward?

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### Keith Murphy - Organovo Holdings, Inc. - Chairman and CEO

Yes, it's not really a trend. One of the things I noted is that the products and service revenue can be choppy, just because of when the timing hits for different contract execution and then completion. The same thing is true, probably even more so, for collaborations, because there can be major phases of work in the last multiple quarters that happened to be completed in a specific quarter.

And so I would not say that's a trend. I would say that both are going to be growing as we get into the next year here, and that the -- of course, that the predominant thing we're expecting is significant growth on the order of 200% growth plus in the liver tissues business. So that's going to be the biggest driver as you see us grow the revenues in 2017.

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### Operator

The next question comes from Brandon Couillard with Jefferies.



**Brandon Couillard** - *Jefferies LLC - Analyst*

Keith, as far as the revenue guidance for the year, what does that contemplate in terms of number of new liver contracts?

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

Well we're not breaking it down. We're still seeing contracts in the same rough range of averaging about \$150,000 per contract, so you can do some of that math yourself. We haven't given specific guidance around numbers of contracts.

And also I would just note that, that number is comprised not only of Paul's business, the in-vitro tissues business, but the collaboration revenues as well. And so we have to be cognizant of that. So it's hard to break it down exactly by number of contracts. I think we focus on the total revenue side, as the key thing to be guiding on.

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**Brandon Couillard** - *Jefferies LLC - Analyst*

Now that we're at the end of the year, any chance you'd be willing to share an update on the backlog or total order value for liver to date?

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

So we just -- we've tended, as you see, to focus on the -- going forward, focus on the total revenue for the year. I think that some of the reasons that revenue guidance is the best indicator is just that not all contract bookings are going to be ultimately recognized, and as we've talked about before, they vary quarter-to-quarter in terms of when exactly they're going to get recognized.

We're just preferring to use the GAAP metric. What we're going to try to do for you, Brandon, is to shrink the total turnaround time from initiation of engagement with the customer to execution of an order. If we can do that successfully, we really think this is going to be the most useful metric on a going-forward basis, and we're trying to get that number down, at least within the things that we control on our side.

As you can expect, as we have, we've got -- as we guided, as we just -- as Paul just mentioned, some of our customers are on their third order from us now, their third contract with us. So as we build the relationships across the industry, we're going to have the ability to turn the next contract faster with people, and those delays, that you have when you start up a customer relationship, aren't going to be as important. So I think you're not going to be as worried about that on a going forward basis if we're executing the right way.

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**Brandon Couillard** - *Jefferies LLC - Analyst*

Qualitatively, Keith, what would be the factors that would push you towards the low end or the high end of the revenue range for the year?

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

Well, it's a great question. So it's a very fair question. It's a broad guidance, so we take note of that. It's a 50% difference from the low end to the high-end. And I think that reflects just the status of where we are in the growth phase of this product and service right now. It's early days, but we wanted to make sure we were guiding because we didn't want to leave it just completely silent. But I think we're confident in that range, but there's play within that range for the reason that it's hard to be predictive when you're still starting and in the early days.

So it's really about total uptake, right? And what's going to drive that are, new data that we generate. Paul mentioned the importance of the data from customers that came out at Society of Toxicology. I think another big driver is going to be publications that come out. And that -- we're obviously working on publications in the liver space. And then, peer referencing, word of mouth, customer to customer is also very important.

So Paul, you want to comment, maybe, too about -- we've obviously, built now a way to manage key accounts and then getting the key accounts to there -- [that will exist] to their next contract as a part of driving that to the upside too. You want to speak to that?

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**Paul Gallant** - *Organovo Holdings, Inc. - General Manager, Commercial Operations*

Yes, sure, Keith. So we recently hired in a new sales director, whose main focus will be, one, on developing sales in Asia, most specifically in Japan. But also another key responsibility for this individual will be -- is to stock and manage some of our key accounts and develop those key accounts going forward, because we know, in some of our top 25 pharma customers, we have multiple activities going on in each of those accounts and we need someone to manage the relationship, develop and help the sales reps, develop the relationships with individuals across the organization, both on a transactional basis, but also on a strategic basis.

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

Yes, so broadly speaking, Brandon, we got to push existing customers to grow what they're using and then, new customers, we got to get them through the doors faster as well. And so all of that contributes to being at the higher end.

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**Brandon Couillard** - *Jefferies LLC - Analyst*

That's helpful. And one for Paul, since you're here, I mean, how many of the five -- top 25 pharma accounts have placed repeat orders? And then, when we look at the kidney product, you talked about a lot of dozen indicated interest, let's say, in the early-access program. First, how many orders are existing liver customers? And then secondly, how does that compare to the prelaunch period or experience that you went through with liver in terms of just the number of customers interested?

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**Paul Gallant** - *Organovo Holdings, Inc. - General Manager, Commercial Operations*

Sure, great questions. So I can't comment specifically on the rate of repeat of those top five, but I can tell you it's a high percentage of repeat business from those pharma, expect for the one that we just recently signed up, it's a little too soon for that. So those key accounts are -- we're building great relationships with. They're happy with their data, and ordering repeat business and follow-up studies based on the initial findings, which is great.

And then, with regards to kidney, I would say about half of the customers -- the companies, the accounts are the same as the liver accounts, but the end customer is different. It's not always the same group that is ordering liver that have interest in kidney tox tissues as well.

And I can't speak, Keith, directly to early access. If we did that with the liver that was before me.

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

We did do it to some degree. And I would say, it's going to be about the same number of folks that we would have doing this. Paul obviously has folks, he's already engaged with to potentially become the first early access on the kidney side. And so I would expect that to be the same, with a limited impact on revenue in the fiscal year, of course.

One added color or comment, is just that, Paul spoke to the repeat business. I would say that customer feedback across the board, top 25 global pharma all the way through down to the smallest customers we have, universally, very good feedback on the data that they're getting, the correlation they see with their expectations and the in-vivo expectations they have. So we know that people are appreciating the work that we're doing and that's been very strong.

It's more of a commercial challenge. Of course, you always have to introduce any new product, and product adoption takes time. But the results that people are getting are very highly valued, and then, I would say the level of wow factor with the kidney might even be higher in the sense that they have nothing to work with today, and they're definitely seeing the value of what we're bringing to the table on the kidney side. So it's very exciting.

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**Operator**

(Operator Instructions) The next question comes from Michael Kay with Kay Associates.

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**Michael Kay** - *Kay Associates - Analyst*

Would you say that the majority, if not all, of the majors and some of the minor pharmaceutical companies are aware of what Organovo has? And number two, what kind of feedback are you getting in terms of their concerns or why they maybe hesitant to sign up for what you have? And number three, the last one is, could you talk about the competition, in other words, if I was President at Merck or one of the big pharmaceutical companies, why would I choose your company? Are there competitors that have price advantage, or is Organovo's technologies such that it's very superior to other technology that attempt to do the same thing?

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

All right. Thanks, Michael. Yes, I get the nature of the question, and I'll kind of cover it in two phases. First, talking about how widespread understanding there is of what we offer in the market. I think that's the first question, and then, speaking to competition a little bit and what alternatives might be in front of the customer right now.

So on the first side, I would say it's not -- this effort is not just selling into a market, it's a market development, and that means you start from scratch in terms of customer awareness of what we're doing, which is, of course, why it takes time. You have to educate the market, a growing number, and probably at this point a majority of the potential customers out there have at least heard about what we're doing.

I know there is a distinct difference between Society of Toxicology in 2015 -- in March or February of 2015, and Society of Toxicology this past March, clear difference in the number of people who had heard about us. Clear difference, as Paul reported at the time, in the number of people coming to find us because they knew about what was going on and appearing at our presentation. And the presentation you mentioned was standing room only, and really we have a lot of follow-up from people who couldn't get in. And so there's a growing awareness.

But like with anything, that takes time to grow it and we do -- that's why Paul's built a team, that he described, to make sure we're pitching as well. So one thing to think about is, at the toxicologist level, there's certain level of adherence, but we've got to continue to increase awareness at the Executive Vice President of R&D level, at the early development team leader level. You know make sure that everyone who could ask someone further down the chain to be looking and then using this technology is aware, and that's one thing we're focused on for sure to grow the penetration.

And then, to your question about competition, the predominant thing that is used -- I'm going to speak to the liver space, and then broadly kidney as well. The predominant thing that is used today is animal models and 2D cell cultures. And animal model and 2D cell cultures we know don't fully meet the bill and aren't fully predictive, but that's the main thing that people are thinking of as an alternative when they're looking at the options in this space.

There is some use of other technologies that have been around since around 2007, 2008, that people do turn to sometimes, but those are low single-digit percentages of the market and not a major -- a major driver for us in terms of competing with them. It's more about competing with what people do historically, and the gold standards in 2D cell culture and in animal models.

And I think we present a very compelling picture in terms of how we compare to that because of the level of prediction and matching of the performance of our tissue with native liver. So remember, the unmet need out there is that they know there are gaps in prediction for animal

models. They know there are gaps in prediction for 2D cell cultures, and we've got to grow the data set that demonstrates that our tissues really does match.

One of the best examples to point to is the liver fibrosis data that Paul highlighted, which you get from no animal model and you can't get from any cell culture. You can't show that, and that is seen in humans. And so our ability to match that really speaks volumes to these customers about why we are one of the best options out there, and we think we're a very powerful option for them. So, hopefully, that gives you a good picture, a lay of the land in a short timeframe there.

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**Operator**

The next question is a follow-up from Ted Tenthoff with Piper Jaffray.

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**Ted Tenthoff** - *Piper Jaffray - Analyst*

I had a quick question about R&D. Obviously, we saw some R&D growth from fiscal '16 over '15. But for the most part, quarterly '16 results were pretty stable. Is this sort of the quarterly spend we should be looking for, for R&D? Will that be growing? How should we be thinking about that?

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

Very good question, and the one thing I'll point out that while it was stable, what we were spending on has changed over time. If you think about it, leading up to the liver launch, we were obviously spending more on liver. We continue to spend on liver. You've heard me refer to additional data and we drive that with R&D spending. But the predominant R&D spend today inside the company is kidney development, as you would expect. And so those two sort of switch positions a little bit and evens out to be the same, which is what you're noting at in the consistency year-on-year.

On a forward-looking basis, I think it remains to be seen a little bit what exactly will dominate. Those R&D numbers could potentially go down after the bolus of our kidney spend, if we're successful especially in having outside partners like L'Oreal fund the next tissues like kidney. But we have the option to continue to invest in new tissues as well and keep that R&D spend up, and these are the kind of things that we'll think about a little bit as we move forward.

But we have options. We have options to think about trying to drive to profitability with the existing in-vitro platform exclusively, or we could invest in new things in an R&D spend setting and think about how fast we can grow the overall value proposition, and we'll be communicating about the options and our decisions around that over time.

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**Ted Tenthoff** - *Piper Jaffray - Analyst*

I appreciate it. I guess, maybe one question, you talked about the tissues, what about sort of human therapeutic as an investment potential?

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**Paul Gallant** - *Organovo Holdings, Inc. - General Manager, Commercial Operations*

Yes, and that's obviously a huge opportunity. And you heard me say that in the next 12 months or so, we're going to be talking exactly about what tissues we're choosing to move forward. And so a portion of that R&D spend is on early studies, animal studies for these therapeutic tissues, and that would grow, as we're looking out in the next several years, into larger animal studies and GLP toxicology studies that would grow the R&D on that side as well. And so those become huge opportunities. We do see \$1 billion plus market opportunities available in that space. But you do have to spend to get there, and that would include longer-term clinical spend.

So if you think about our options from a financing perspective, we could be financing -- either finding strategic finance for those kind of opportunities or financing around driving one or more of those programs, which should add to overall enterprise value. Or we may have options to think about



if we're developing the revenue the way we expect to, if we continue to grow that a couple of hundred percent a year, then you open up [debt] option for financing as well.

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**Operator**

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

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

Thank you all for your time today. We appreciated the good questions. We hope you enjoyed the call. Thank you for joining us, and we'll see you next time.

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**Operator**

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

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