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ONVO - Q1 2018 Organovo Holdings Inc Earnings Call

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## AUGUST 09, 2017 / 9:00PM, ONVO - Q1 2018 Organovo Holdings Inc Earnings Call

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**PRESENTATION****Operator**

Good afternoon, and welcome to the Organovo Fiscal First Quarter 2018 Earnings Conference Call. (Operator Instructions) Please note this event is being recorded.

I would now like to turn the conference over to Steve Kunszabo, Vice President, Investor Relations and Corporate Communications. Please go ahead.

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

Good afternoon, and thanks for joining us. I'd like to welcome you to our fiscal first quarter 2018 earnings call. Joining me on the call this afternoon are CEO, Taylor Crouch; our CFO, Craig Kussman; and our General Manager, Paul Gallant. Today's call will begin with the discussion of the 2018 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 the 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 non-GAAP financial measures. These non-GAAP financial measures are not prepared in accordance with generally accepted accounting principles. Please refer to today's earnings release for a definition of these non-GAAP financial measures.

With that, let me turn things over to Taylor.

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

Thanks, Steve, and good afternoon, everyone. Let me start by noting that our top line results of \$1 million for the first quarter came in where we expected based on the outlook we provided on our last earnings call. We were on course in the first few months of fiscal 2018, and we've reaffirmed



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our full year revenue and negative adjusted EBITDA guidance today. Craig will have more on our financials and the key elements of our outlook in his remarks.

Having given a comprehensive account of my professional background in Organovo's strategic position on our first call together in June, I'll spend my time today on how we're executing against the key objectives that I laid out for our 1-year plan.

As a quick review, our day-to-day effort is anchored in 2 key areas: first, achieving rapidly growing adoption of our liver and kidney tissue research services; and second, progressing preclinical development milestones for our liver therapeutic tissue. Given the growing opportunity to engage with our clients in the liver disease space, we continue to direct our commercial and research efforts to meeting our client demand for our healthy and diseased liver tissue model. Although we have a vibrant technology platform that can be leveraged in other ways, we've deprioritized other research and product development areas for now.

Our current focus is squarely on driving customer adoption and revenue growth in high-value drug profiling for our established liver and emerging kidney systems. Our midterm internal R&D goals for our therapeutic tissues business are to achieve a scientific and regulatory (inaudible) that facilitate a path to a successful IND for our liver patch in calendar year 2020.

In our commercial tissue business, our bioprinted liver remains the main engine of growth. We continued to see a healthy balance of new sales and repeat business during the quarter, with nearly 70% of our orders coming from existing customers as we more deeply penetrate client accounts. Half of these studies also represented compound screening in a disease model, while the others included toxicity testing and metabolism work. This diversity of client applications once again illustrates the relevance of our high-value drug profiling solutions across the drug discovery spectrum.

Customer demand for evaluating compounds in disease tissue systems is growing rapidly. And partnering with us represents an attractive return on investment for clients that are directing significant R&D dollars into critical areas of liver disease research, such as NASH and fibrosis. We're pioneering the capability to bioprint disease tissues as the starting point for research collaborations. We're now able to create a spectrum of dynamic conditions to evaluate how the liver transitions from a healthy to a disease state, allowing us to explore how new drugs potentially inhibit this process.

Our clients increasingly see our novel approaches as a way to prioritize drugs early in the discovery process as well as to explore ways to repurpose established drugs.

Given the rush to advance new drugs to market to address the serious public health concerns from a range of liver diseases, we believe our tissue systems can play a valuable role. I'm pleased to see so many major pharma and biotech clients partnering with us to address these challenges.

A real testament to our innovative technology is the recent 3-year \$1.7 million grant award we received from the National Institutes of Health to collaborate along with the University of California, San Diego, to study liver disease and specifically NASH in our 3D bioprinted liver model. Nonalcoholic fatty liver disease affects an estimated 100 million people in the U.S., with up to 20 million having NASH. It's critical for us to understand how new and existing drugs perform in real world populations and to work with leading partners to address the large unmet needs of patients with impaired liver function. We're thankful to the NIH for supporting this critical research field, and we look forward to partnering with UCSD to achieve innovative and clinically significant results.

A key area where development work is also ongoing, in large part to enhance product functionality, is our kidney tissue model. Customers are asking for uses beyond classic toxicology such as transporter function. This feature is particularly important as the regulatory pathway for their drug candidates often requires them to specifically submit data related to kidney transporter function. This explains how drugs are processed by the kidney as well as identifying potential sources of toxicity. Successfully completing this work could add nicely to of our menu of applications.

Before I turn to our therapeutic tissues business, I wanted to emphasize the key steps in our customer adoption curve. This is relevant to both how we execute our sales plan and to how we achieve inflection points in our revenue profile. First, the time between our initial meeting with the customer and a booked order has become significantly shorter, it's now about 90 days for many clients. This is a really quick window, especially when considering the complex nature of selling a breakthrough and potentially disruptive technology to a very sophisticated group of clients.



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Second, there are 3 phases to the customer adoption cycle. In phase 1, customers want to kick the tires and test our tissue systems in specific pilot studies. Ultimately, they're answering the question, could Organovo's platform meet a company-specific set of objectives in their drug discovery, market validation, need optimization or any number of applications. Next, they move on to a series of validation studies that serve to customize the parameters of their work in a breadth of applications. We also begin to see a steady stream of repeat orders in the second phase for many clients.

Finally, we expect clients to fully integrate us into their drug discovery workflow for deployment across their pipeline. In this final phase, customers seek to lock down custom applications with our platform for steady-state screening that will be implemented as a new standardized component of their ongoing drug discovery process. All of our customers are in the first 2 phases of this adoption curve today. Importantly, we expect this to be an evolutionary process with a number of our earliest and key customers moving to discuss routine use by the end of this fiscal year. It's heartening to know that as we have these conversations, our customers are already building us into their budgets for next year. Our goal is to end our fiscal year with one or more clients implementing the third stage of adoption on a routine multiyear basis.

Let me move now to a quick progress update on our therapeutic tissues business. We're making excellent progress against our scientific and regulatory milestones, and we remain on track to submit an Investigational New Drug application to the FDA for our liver therapeutic tissue during calendar year 2020. We continue to conduct pre-GLP studies [in] small animal disease models for our target indications and are seeing promising results in terms of functionality, vascularization and the production of key human metabolic enzymes.

As I shared last quarter, we've also observed that diseased animals that received our transplanted bioprinted liver tissues are beginning to show functional improvement in liver health versus nontreated animals. Specifically, we continue to see very encouraging results in a well-established mouse model for one of the inborn areas of metabolism, alpha-one-antitrypsin deficiency. We view this as potentially revolutionary -- we view this as potentially revolutionary biology and see it as pointing towards some fundamental advances into how we treat debilitating liver diseases in the future.

I'm also excited to share that our liver patches continued to thrive 90 days post-implementation, more than triple the duration of our first preclinical studies. Stay tuned for scientific conferences later this year where we expect to present data on even longer durations, where we will demonstrate how well our bioprinted livers are performing in small animal disease models.

As I look ahead to next steps for this program, we have important targets in front of us. We expect to submit our application seeking orphan designation in the next several months. And we plan to start animal disease model studies in an additional indication within the category of inborn areas of metabolism by the end of this calendar year.

In closing, it's been a busy and exciting time during my first few months leading Organovo. I've met with many of our current and prospective customers, and I continue to hear great feedback. I've also enjoyed meeting many of our analysts and investors and look forward to building strong relationships within this community.

Once again, my emphasis is on growing our revenue from liver and kidney tissue research services and achieving the scientific milestones for our liver therapeutic tissue that move us rapidly down the path towards human clinical trials. And while marshaling our significant capabilities and resources in 3D tissue printing applications, I continue to be very mindful of our cash burn rate as we gain revenue traction and client validation of our remarkable platform. Fiscal 2018 will be a truly exciting year.

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

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

Thanks, Taylor, and good afternoon, everyone. I'll begin by recapping our key financial metrics for the fiscal first quarter and then summarize the fiscal 2018 guidance we've reaffirmed today. I'll wrap up my thoughts by briefly reviewing our balance sheet and liquidity profile, including the draw against our at-the-market or ATM facility during the period.



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Organovo generated fiscal first quarter total revenue of \$1 million, which was up 11% from the prior year period and up 22% sequentially. Total revenue growth benefited from an increase in customer activity for our liver tissue research services. During the quarter, we continued to take the necessary steps to optimize our tissues for certain client-specific needs and recently had productive meetings with a couple of key customers. We expect to reach a successful conclusion that allows us to record the balance of our deferred revenue in fiscal 2018. This will give us the foundation for larger routine use client relationships.

I'll focus next on operating expenses. We recorded \$0.3 million in cost of revenues for the fiscal first quarter, a 79% gain from the prior year period. The increase in cost of revenues was largely due to the increase in product and service revenues. The related quarterly product and services gross margin was 68%. We'll continue to closely monitor this metric as we keep an eye on profitability on our tissue services business.

Research and development expenses were \$5 million, a 13% year-over-year increase, largely due to higher costs related to materials and outside services for our ongoing validation studies as well as increased facilities cost.

We reported \$5.9 million in selling, general and administrative expenses during the fiscal first quarter, a 16% year-over-year increase primarily resulting from noncash stock-based compensation expense and other employee costs. SG&A also included approximately \$0.3 million of onetime CEO transition cost. When broadly considering the trend lines for our R&D and SG&A expenses, the full year effect of fiscal 2017 headcount adds and expenses supporting the preclinical development of therapeutic tissues will be the principal cost drivers in fiscal 2018.

And finally, a brief review of the full year fiscal 2018 outlook we reaffirm today and a few quick notes on our balance sheet and liquidity profile. We continue to forecast total revenue between \$6 million and \$8.5 million for fiscal year 2018, with the primary contributions coming from our liver tissue commercial services. This compares to \$4.2 million of total revenue in fiscal 2017. Our total revenue guidance includes minimal contribution from collaborations and licensing revenue, because we completed the work and recognized the associated revenue for key agreements in fiscal 2017. As a result of our recently announced NIH grant, we also expect to record between \$0.2 million and \$0.4 million of grant revenue in fiscal 2018.

Our fiscal 2018 total revenue guidance continues to be weighted towards a significant ramp in our revenue during the second half of the year. We expect these sequential increases to be guided by a greater penetration of our key accounts, increased customer adoption of our core capabilities and high-value drug profiling and successful completion of our ongoing validation studies. As we shared in June, we still expect to exit the fourth quarter of fiscal 2018 at a double-digit annualized revenue run rate.

On the same basis for the full year fiscal 2018, we expect negative adjusted EBITDA between \$29 million and \$31 million. This compares to \$29.8 million of negative adjusted EBITDA for fiscal 2017.

At the end of the fiscal first quarter, we had a cash and cash equivalents balance of \$55 million and now have approximately \$18 million of funds available under our ATM facility. In combination, this gives us approximately \$73 million in available liquidity to carry out our business plan and invest in our key growth initiatives. We'll continue to use our ATM facility opportunistically to extend the cash runway for the business, allowing us to scale our liver and kidney tissue research services and moving our promising liver therapeutic tissue closer to our established goal of an IND in calendar year 2020.

The ATM facility is a flexible tool that lets us strengthen our balance sheet in a disciplined way while moving us forward to key value inflection points as we consider our long-term capital plan.

I'll wrap up by noting that we're seeing great results advancing our liver therapeutic tissue through preclinical studies and are focused on the day-to-day steps we need to take to accelerate customer adoption and improved revenue growth. We've hit -- we've got the right resources in place to execute against our plan, and we'll continue to carefully guard our cash position and only deploy capital against the highest return opportunities. We look forward to updating you on our progress in November.

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) Our first question comes from Brandon Couillard with Jefferies.

### Samuel Brandon Couillard - Jefferies LLC, Research Division - Equity Analyst

This might be a better question for Paul. But with regard to Taylor's comments about the accelerated cycle time improvement, should we expect that to translate into faster revenue ramp? And is there an opportunity for that cycle time, which I believe you said is now 90 days between meeting and booking an order, is there room for that to perhaps even go lower over time?

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

Brandon, I'll start and this is Taylor. First with the cycle time, in all of my career in selling high-tech revolutionary services, typically, I would plan at something like more 9 months between first contact and first contract. And the fact that we're regularly seeing 90 days and indeed sometimes even faster is pretty remarkable. I don't know that it can be compressed much more than that, because there is a design element that follows every engaged client discussion and then a contract process. What's nice is that as we're designing, we're actually able to start teeing up experiments according to the design. And so often, we're able to start client projects within days of executing a contract. And many of our projects are only 2 to 3 months in duration. So the faster we engage, the faster we see those revenues accumulating. I think to the -- to your first question about the adoption curve, indeed, as we get clients move from project-by-project contracting to this third steady-state phase, where they're committing to multiple years, a more steady workflow and a more repetitive workflow: a, this should layer in, we hope, at an accelerating basis and is certainly one of the reasons we've indicated that we expect to end this year on a very nice ramp and we would expect to be going into the following year with much more, what you would traditionally call, backlog visibility as we engage in those contracts.

### Paul Gallant - Organovo Holdings, Inc. - General Manager

Brandon, this is Paul. Just to add a couple of comments to that. I think part of the drivers of shrinking that period of time: one has been, as we've talked about in previous calls, many of our customers we establish master service agreements with. And that allows us to quickly contract and do subsequent orders, because terms and conditions have already been agreed upon. So that can help us accelerate that time period. In addition, with the repeat orders that we're seeing, customers are familiar with us. And typically, it's going straight into another study design. So that's reducing the cycle -- the whole sales cycle, because we're going directly into a study design, which we are getting much more efficient in, in reducing the number of iterations between us and our customers as we understand their needs and we better understand our model.

### Samuel Brandon Couillard - Jefferies LLC, Research Division - Equity Analyst

That's very helpful. And then also curious what you can share with us in terms of gauging the relative uptake of kidney versus liver and any improvements or anecdotes that you can speak to as far as the cross-selling effort, how that might be resonating?

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

So Taylor here. First, the uptick that's really kind of got us moving to a gallop is on the liver disease modeling side. I think I may have mentioned in a prior call that clients are kind of following us down our R&D mission real time, engaging with us on not only routine work, but also on very customized R&D like collaborations. And this is taking up a significant part of our resources, fortunately the same resources we wanted to devote to these same profiling activities on the liver side. There is certainly a pent-up demand on the kidney side as well, including kidney fibrosis and



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toxicity. But this transporter area that I referred to in the call has us going back into the labs and optimizing our models to see how we can tease out these capabilities and if we're indeed able to unlock those, I think we'll see a very exciting uptick on that side of the business as well.

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**Operator**

Our next question comes from Ren Benjamin with Raymond James.

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**Reni John Benjamin** - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Maybe just a couple of questions. One, Taylor, can you just review for us how many customers do you have now and how many did you gain in fiscal first quarter and how many do you expect to end by the -- how many do you expect to have by the end of this fiscal year? And I guess, there might be 2 ways to kind of look at drug and revenues. One is to, of course, penetrate deeper with the existing clients that you have and get to that phase 3 of customer adoption, as you've mentioned, with your existing customers. And then the other is just, obviously, get more and more newer customers starting off at phase 1. And I just kind of wanted to get a sense of the -- what trajectory you are now pursuing?

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

Thanks, Ren. The -- with regard to number of customers, we're certainly in the dozens now. And I'm not sure if I've given enough information that one could actually do the math. But given the number of new clients and existing clients that we reported on in our last quarter, and that about 70% of our work is coming from repeat business this year -- this quarter. That again suggests a continuing nice uptake on clients. And I should note that this uptick is across the board. We've had meetings with virtual startups, all the way through to, let's say, the remaining intransigent top 10 pharma companies that have listened to our story over the past year or 2, but have wanted to see how we progress. And I can say, even in the last couple of weeks, I visited several of the largest pharmaceutical companies who've shown not only enthusiasm, but a sense of urgency to engage. And by that, I mean talking about utilizing budgets that they have for the second half of this year, talking about their budgets for the coming year. And one thing I wanted to also mention and not exactly from your question is that we're also seeing dedicated functions springing up among large pharmaceutical companies. People and sometimes groups who have as their primary job description to evaluate and bring in complex new in-vitro modeling systems, particularly in this 3D space. So their mission is completely aligned with us. They've got budgets, and they're now showing up as ambassadors with us to other departments within the pharmaceutical companies. And that kind of brings us to your second point, which is that the penetration is coming -- inside accounts is coming not only from this adoption curve of, okay, we see how your model works in a standard condition. Now let's see how it works in 5 other conditions, some of which are very germane to how we might want to progress to steady-state screening. And these groups -- initial pilot groups are talking it up amongst therapeutic teams, toxicity teams and even their drug development colleagues. And we're seeing additional meetings and additional interests leading to penetration in that direction.

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**Reni John Benjamin** - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Got it. And when we think about the repeat orders and the 70% coming from existing customers, are there -- those customers -- are the kind of the remaining customers, is it just that their order is typically a longer-lived order, one that necessarily won't fall into this fiscal year? Or are there customers that are potentially dropping out as well?

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

I think it's more of the former. Given that we've really only been in the revenue-generating business for a year to 2 years, some clients who finished their first projects might be on a cycle of every 6 months in terms of evaluating and thinking about next steps. There are a few clients that have accepted our capabilities and view these as more appropriate for very specific or sporadic uses where we've answered a specific question, particularly for a smaller biotech company, and they don't have a discovery screening program to apply this to. But the vast majority of our clients are moving at a pretty steady pace, I don't want to say quarter-by-quarter, but approaching that in terms of sequencing projects. And as we go into this final stage of adoption, clearly, we like to go from -- we have a pretty good sense who's going to be back next quarter and the next quarter, et cetera,



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with projects. But we would love to have even more visibility where we can tell you exactly what we'll be doing for a client 9 months to 12 months from now.

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**Reni John Benjamin** - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Got it. And then just switching gears real quick to the therapeutic side. It seems that besides evaluating the potential of these tissues in the various indications, it seems that another approach could also be to increase the size of the printed tissue. Is that something that's being explored? Or do you feel that -- if I remember right, you're up to about \$1 bill size of printed tissue. Do you think that, that's enough?

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

It's actually a great question. I was in a meeting just yesterday with some of our external advisers who were so excited about what we were seeing in the animal models that they were asking us, what about multiple patches, expanded tissue sizes, et cetera. By the way, in the animal model, we're dealing with much smaller patch sizes than what we anticipate in the human therapeutic space. But I was introduced to the concept of the real estate of the liver yesterday. And apparently, we have plenty of real estate still to cover with patches proportionally in animal models and certainly in humans. And we really don't know what the end amount of patching, if you will, would be. There are a lot of scientific indications that the size that we've targeted should provide roughly the right amount of impact to balance an impaired liver. But in theory, more could be better or supplemental patches. And then finally, of course, the geometry of our patches, I don't know that we've reached limitations in our size, but we certainly have done a lot of work optimizing the 3 dimensions such that we can characterize well and predict how those particular tissue geometries will work.

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**Operator**

(Operator Instructions) Our next question comes from George Zavoico with JonesTrading.

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**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

Following up a little bit on Reni's question regarding your customers. It's nice to hear that you have -- you're in the dozens now. I'm wondering a couple of things about that, though. Are there any customers that are -- that provide 10% or 20% of your total revenue? In other words, are you dependent on a smaller number of customers for a large portion of your revenue?

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

I'm going to let Craig to see if he can quantify that further. Right now, I'd say we've got a nice range of customers. There are no big gorillas that completely dominate our revenues. And because of the sequencing of projects in a given quarter, the top 3 clients shift around a little bit, which is actually quite good.

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

Yes, on a -- in a given quarter, a single or 2 or 3 clients can represent a significant proportion of the revenue. But if you expand that throughout the course of a fiscal year, they are typically not at that meaningful size. So -- but it is fairly lumpy. And historically, if you go back to the beginning, we did have a couple of customers who did represent the lion's share of our revenue. But we're moving away from that.



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**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

Okay, that's -- so yes. That's typically, how (inaudible) you're dependent on 1 or 2 customers, at first. It's nice to see that you're moving away from that. And in that regard, are you seeing any customers doing or submitting abstracts for presentations that are based on work that they've done that's independent of your input? Are you seeing that? I mean, that's sort of like independent validation of your technology.

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

The answer is, we have a couple of different configurations that our clients have approached us with regard to publishing. Generally, it's a collaborative approach, whether it's abstract or paper or joint presentations, which we, of course, like. We -- I just came out of a large meeting last week where -- and the client specifically said, we'd love to write a paper together with you and present it at a major conference. I'm talking about what we've been able to show with your model, and we want to help you all get as much traction as possible, because we just think it's critical what you guys are doing.

**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

That's great. And in that regard, in parallel with that, you mentioned that you have R&D like collaborations as well with some customers. The R (inaudible) obviously, the D part is discovery. And discovery can be proprietary. So are you seeing -- do you have rights to everything that these R&D collaborations provide for you, any new discoveries? Or could that be shared -- or is that shared with the sponsor that -- or the collaborator that you're working with?

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

It's a great question and one that we're very thoughtful about as a biotech company, especially given that we have a research mission and an end target to create proprietary therapeutics. Our proprietary platforms, which we're working to enable alongside with our clients, do involve some discussions about how we sort out ownership territories and the like. But what's very encouraging is that we haven't found that process to tie us up. And the vast majority of our clients started out by saying, we want you all to succeed. We understand that you want to develop this platform and offer it to some companies, and we don't want to stand in the way of that. And we, in turn, signaled to our clients, we understand that their drugs are proprietary and we want to help them understand profile and enable those drugs to get to the market, but we certainly don't expect to take any proprietary position in that process.

**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

Okay. Okay, that's fair. And finally, regarding -- you mentioned, Taylor, you have -- you've built a spectrum of dynamic conditions, I think is what your words were for your liver product. So how many products, I guess, do you actually offer to your clients? You have liver tissue that you make a certain way. And then, I guess, once the tissue is made, you can modify it to present different dynamic conditions. What's your product mix now in that regard?

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

Well, this is one of the things quite exciting about the adoption curve is because -- by the very word, dynamic, really -- and I mentioned customized validation. Most of our clients are saying, "Okay, in these 28 days that you've created a living dynamic model, what kinds of exploration do we want to do." And that can range from putting out healthy tissue, taking it to a disease state and then co-administering an inhibitor through to starting with a disease tissue and seeing if we can reverse the process. And there are, I don't want to say infinite strategies, but there is a wide range of explorations that our clients want to subject this model to. And in many ways, that gets to the heart of part -- step two of our adoption curve, which is where they're saying, okay, let's try a bunch of different things, see if we can fine-tune the model specific to either our class of compounds or the



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targets or receptors or the disease space that we're interested in. So I think my answer is, our product is a set of highly defined capabilities. And each project, and ultimately, steady-state streaming solution may be a different combination of conditions or dynamic features to that platform.

**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

And then, I guess, that speaks to the grant you got as well to try and recapitulate the progression of NASH. So I presume -- I don't know maybe you -- maybe it's too early to say, but have you taken your liver tissues through the typical steps of NASH progression? Have you shown fatty deposits and fibrosis developing in your tissues as you stress them like a human liver would be stressed under disease conditions?

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

Yes. And our -- both in NASH and in fibrosis, and we've published some data on this, we've been able to demonstrate taking healthy tissue to confirmed and familiar sets of conditions in both of those disease states. But each disease state is actually a broad range of conditions, including steatosis and fibrosis and inflammation among other conditions. And we, of course, have the ability to add or change cell types in these liver models. So ultimately, I think we're going to have a whole nuanced spectrum of disease conditions across a broad dynamic range of inputs and outputs. And it's exactly that, that makes us, I'd say, largely unique in the drug discovery space and why we have such a queue of clients asking to join our R&D missions as well as tapping into this on a more commercial like basis.

**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

Yes, what you just said is really intriguing, your ability to add more cells. So in an inflammation model, for example, you're going to need to add neutrophils, maybe lymphocytes, maybe monocytes macrophages, is that what you mean by saying adding cells?

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

I probably shouldn't go any further into the detail on this call. But suffice it to say, we're -- the composition of our tissues and the optimization of them is taking into account these disease processes and what accents one would like to see in those models.

**George B. Zavoico** - *JonesTrading Institutional Services, LLC, Research Division - Senior Equity Analyst*

Okay. Yes, okay. I understand your limitations in being able to say what you (inaudible) ability to answer the question. I understood completely. But it's a very interesting direction to pursue, for sure, I think. Okay. And look forward to continuing progress with all your products and your therapeutic approach as well.

**Operator**

We have a follow-up question from Ren Benjamin from Raymond James.

**Reni John Benjamin** - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Craig mentioned key valuation inflection points. And as you think about the rest of fiscal year 2018, what in your mind are the key valuation inflection points for this year?



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

Craig just pointed to me, and I'm delighted to answer the question as well. The -- a bunch of things. First of all, as I mentioned, I really hope and feel pretty confident that we're going to be able to talk about multiyear collaborations by the end of our fiscal year. And from a financial point of view, that's fantastic. From a validation point of view, it's also fantastic. And it also allows us to align our resources a little better over the long term, especially given that many of these collaborations are parallel our own internal R&D mission. We also expect to have and present additional key milestones on the therapeutic side at some notable conferences coming up in that I think we'll continue to generate significant enthusiasm. And in fact, each time we present our data, there's generally a queue of clients standing at the podium and follow-on meetings to discuss how to either engage around that research or parallel it with other applications relevant to those clients' own cell engineering and DNA development strategies. So I think lots of validation from that perspective. We do hope to submit for orphan drug designation from the FDA. And that process should give us and our investors a lot more clarity as to how this path moves forward. And certainly, we would hope that as we engage in more and more strategic discussions with our clients that some may express an interest not only in collaborating, but in investing in some kind of strategic way. So there are various ways I see our value inflection points being impacted over the coming 6 to 9 months.

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**Operator**

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

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