

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

EVENT DATE/TIME: MAY 31, 2018 / 9:00PM GMT



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

CORPORATE PARTICIPANTS

Craig Kussman *Organovo Holdings, Inc. - CFO*

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

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

CONFERENCE CALL PARTICIPANTS

Brandon Couillard *Jefferies LLC, Research Division - Equity Analyst*

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

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

Yasmeen Rahimi *Roth Capital Partners, LLC, Research Division - MD & Senior Research Analyst*

PRESENTATION

Operator

Good day, everyone, and welcome to the Organovo Holdings, Inc. Fourth Quarter 2018 Earnings Conference Call. (Operator Instructions) Please note that this event is being recorded. And I would now like to turn the conference over to Steve Kunszabo of Investor Relations. Please go ahead.

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 Fourth Quarter 2018 Earnings Call. Joining me on the call this afternoon, our CEO, Taylor Crouch; our CFO, Craig Kussman; our General Manager, Paul Gallant; and our Chief Scientific Officer and President of Samsara, Sharon Presnell. Today's call will begin with a discussion of the 2018 fiscal fourth quarter full year results, followed by Q&A.

Before I turn things over to Taylor, I'd like to caution all participants that our call this afternoon may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts and include statements about our future expectations, plans and prospects. Such forward-looking statements are based upon our current beliefs and expectations and are subject to risks, which could cause actual results to differ from the forward-looking statements. Such risks are more fully discussed in our filings with the Securities and Exchange Commission.

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.

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

Thanks, Steve, and good afternoon, everyone. Let me start by reflecting on the fiscal year we just wrapped up, which was a busy and transformative period for us. We are a much different organization that we were 1 year ago. We've evolved in the way we define ourselves, how we bring the value of our platform technology to customers and future patients, and ultimately, how we aim to create sustainable and growing value for all of our stakeholders.



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

Organovo is a biotech company, pioneering the remarkable ability to 3D bioprint tissues with human functionality. We are harnessing our platform to potentially treat a range of pediatric and adult liver diseases in the medium term, and today, we are successfully funding a growing portion of this therapeutics mission by providing our clients access to our technology platform.

Our primary goal is to develop our own novel therapeutics and to treat a group of life-threatening rare diseases for which there are few current treatment options other than organ transplantation. Our healthy NovoTissues liver tissue product, can potentially address a broad range of target indications, offering important synergies in terms of manufacturing, R&D and derisking the development process.

Our objective is to simultaneously advance multiple IND-track research programs in critical unmet disease areas, commencing with Alpha-1 antitrypsin deficiency or A1AT. We believe this indication alone represents the opportunity to generate peak revenues approaching \$1 billion.

Adding in other liver diseases that typically end in the common need for liver transplant, such as single mutation inborn areas of metabolism, urea cycle deficiencies and acute-on-chronic liver failure, a total peak revenue target exceeding \$4 billion may be achievable for our NovoTissues platform. And this is just in liver disease.

Because each indication represents a serious unmet medical need, we have the opportunity to work closely with the FDA and other regulatory bodies to streamline our path through development into the market. And of note, we should be able to capture various attractive incentives along the way that the FDA provides to induce research in these areas.

Using our same liver platform today, we are working to create near-term value by allowing our customers to access our disease-modeling capabilities in order to facilitate their own discovery and development programs. Our foundational ability to characterize specialized human cells and build robust functional human tissues has led us to the opportunity to develop custom disease models that mimic conditions of nonalcoholic fatty liver disease, NAFLD, and nonalcoholic steatohepatitis, NASH.

Given the rapidly growing number of NASH development programs, we will continue to work with early adopter clients to explore a range of conditions for which our tissue platform might add value to their internal research programs. Now I'd like to outline our goals for fiscal 2019, beginning with our therapeutics program.

We've already taken several big steps in fiscal 2018 to build out our IND-track therapeutics programs. In our first indication, A1AT, we implanted our liver patches into diseased mice, showing a high degree of functionality and a significant reduction in disease features, all the way through 125 days.

This timeframe, if translatable to humans, would offer a significant and perhaps lifesaving benefit to patients awaiting full transplant where supply is severely limited.

We also reached our first regulatory milestone for the A1AT program with the FDA granting orphan status for our NovoTissues treatment of that disease. As I look out over the next 12 months, we will complete the necessary steps to begin IND-enabling studies for this program in fiscal 2019. In addition, we hope to work closely with the FDA and key advisers to finalize the confirmatory animal studies and scientific validation path will need to follow for a successful pre-IND meeting for this first indication.

We also began new animal model studies in the second therapeutic indication within the category's inborn areas of metabolism. The second disease known as Type 1 Tyrosinemia caused by the deficiency of the FAH enzyme, frequently causes severe liver damage and commonly requires the patient to receive a new liver at an early age.

As you may have read in our recent press release, we presented preliminary proof of principle data at an industry conference a few weeks ago, showing improved survival rates as well as good retention and evidence of human functionality of our tissues in established animal models for this condition.



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

As we look ahead to the rest of fiscal 2019, we'll work to validate this disease area using the same or similar tissue constructs as are being studied in A1AT. Much like our first program, we'll pursue orphan designation for this indication with the FDA with the goal of ending our current fiscal year with 2 liver therapeutic tissue programs on track for IND submissions in 2020.

You can expect us to present important updates of these revolutionary therapeutics programs at major industry and scientific conferences throughout the year. As I've mentioned, while we are advancing our tissue platform in a broad range of in-vivo animal studies, we're also making great strides to create immediate value by providing access to our technology platform for partners, collaborators and clients.

The stream of revenues generated through this access provides scientific validation and financial support for our therapeutics pathway, and also has the potential to generate new pipeline ideas and capabilities.

A key building block of our platform is primary human cells, provided by our wholly-owned subsidiary Samsara, which has quickly become a cornerstone of our revenue growth. Samsara capitalizes on our ability to procure and characterize high-quality human cells that are in demand for our clients' research programs, while also supporting the development of our liver disease models in our therapeutic tissues program.

This business more than tripled its contribution to our total revenue during fiscal 2018, and we continue to expect robust uptake of our cell-based products this year.

Our recently announced multi-year agreement with Lonza Bioscience Solutions, one of the world's leading suppliers to biopharma and specialty ingredients markets, represents Samsara's largest contract to date and further supports a healthy growth trajectory. Importantly, Samsara's work with customers often serves as a key indicator of market trends and the close relations between Samsara and its clients can lead to larger partnering relationships spanning our full platform capabilities.

Because of our ability to create a disease testing capability, which we believe will be translatable, namely predictive of real human outcomes, we have the potential to provide patient-on-a-plate results in a fraction of the time and cost of conducting human clinical trials. As a result, we believe our clients will turn to us to provide solutions across the R&D spectrum from novel drug targeting research to comprehensive lead candidate profiling, to teasing out competitive advantage aspects of drugs already in the clinic.

Similar to our commitment to communicate progress on our therapeutics program, we will continue to participate in venues such as AASLD The Liver Meeting, EASL The International Liver Congress and the NASH Summit, where our platform advances in NASH have been generating considerable recognition.

Finally, as we advance the functionality of our tissue platform with eyes on the clinic, we will continue to build out our global IP portfolio, which today includes over 100 patents and pending applications.

In closing, fiscal 2019 is shaping up to be an exciting year with a number of important milestones in sight for both our therapeutics program and our tissue platform operations. We have an outstanding team at Organovo, bolstered by a group of collaborators and partners with the ability to transform liver health.

As such, we'll continue to generate new horizons and pipeline opportunities based on our growing body of knowledge around 3D bioprinting functional tissues. As always, I look forward to updating you regularly on our progress in the months ahead.

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

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

Thanks, Taylor. Good afternoon, everyone. I'll start by summarizing our key financial metrics for the fiscal fourth quarter, and then we'll recap our balance sheet and liquidity profile. I'll conclude my discussion with the quick review of our at-the-market or ATM financing strategy, including our thoughts on future capital requirements for the business.

MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

Organovo generated fiscal fourth quarter total revenue of \$1.1 million, which was up 36% from the prior year period and down 4% sequentially. On a year-over-year basis, total revenue results were driven by a bigger contribution from our Samsara subsidiary and higher grant payments. I'll focus next on operating expenses.

We recorded a \$0.3 million in cost of revenues for the fiscal fourth quarter, a 55% increase from the prior year period, reflecting higher cost from liver disease modeling studies. Research and development expenses were \$4 million, a 28% year-over-year decline, primarily resulting from lower employee and lab supply costs related to our organizational restructuring and the prioritization of our R&D projects.

We reported \$4.4 million in selling, general and administrative expenses during the fiscal fourth quarter, a 23% year-over-year decrease, largely due to lower employee and noncash stock-based compensation expenses.

SG&A also included approximately \$0.3 million of onetime CEO transition cost. And finally, a brief review of the full year fiscal 2019 goals we announced today and a few quick comments on our balance sheet and liquidity profile. We forecast a net cash utilization rate between \$22 million and \$24 million for fiscal year 2019, and we believe we have the sufficient funds to meet our operating and capital requirements well into fiscal 2020.

The significant and ongoing improvement in our net cash utilization will continue to be driven by thoughtful management of our R&D programs and supported by revenue from our commercial opportunities.

As for our total revenue outlook for fiscal 2019, while we're not providing a specific target, we do expect overall growth, with contributions coming from all parts of our business. Now for our balance sheet. At the end of the fiscal fourth quarter, we had a cash and cash equivalents balance of \$43.7 million, which included net proceeds of \$2.1 million from the issuance of 1.5 million shares of common stock in ATM offerings. With \$50 million of funds available under our new ATM facility, we have access to approximately \$94 million in capital to carry out our IND development plans.

As circumstances and market dynamics permit, we'll continue to use our ATM facility opportunistically to extend the cash runway for the business as we've successfully done during 2018. 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 plans. Related to our financing strategy, we'll be seeking an increase in our total authorized common stock at our annual meeting in July.

In order for this proposal to pass, a majority of our outstanding common stock must be voted in favor of this proposal. We encourage our shareholders to vote in favor of this critical measure as it's important to have an ongoing access to capital as we move through the IND process and into the clinic with our lead programs.

In wrapping up, I'll reflect on the 2 key components of our business. We're developing our own therapeutic solutions to treat disease, while also providing access to our cell-based products and dynamic tissue platform that allows clients to do the same.

These are harmonious and complementary paths for creating value with meaningful commercial, operational and R&D synergies. Importantly, we plan to execute against these opportunities, while also being mindful stewards of our cash burn rate.

We look forward to a productive and successful fiscal 2019. 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) And our first questioner today will be Ren Benjamin with Raymond James.

MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

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

I guess, just to start off with, Craig, can you talk a little bit, you provided total revenue kind of outlook and that it will be positive, but at least from where -- kind of thinking about the 2 revenue-generating kind of programs, it seems like it's easy enough to sort of model for this year. But what seems to be happening is, is there a pretty dynamic shift that's occurring to the disease type models that are making it tougher to think about a steady revenue stream? Or what's kind of leading to this kind of lack of clarity in terms of revenue outlook?

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

Ren, this is Taylor. Why don't I start, and clearly appreciate your concern and thoughtful question. The -- as we've looked back over the last 1.5 years, and evaluated our approach to giving revenue guidance, one thing we concluded is that we are providing a disservice to shareholders to try and predict our immediate revenue inflection points. And the reason for this is that, while we have nice growing revenue streams on the Samsara business side, on the disease modeling side we see a recurring theme, which is very rapid uptake of early adopters to commit to a first project. Typically those same adopters want to pursue a stream of projects. But all of the projects are aimed at customizing our research to their specific needs. In other words, requiring significant design elements and customization and unpredictable results. And the out shot of that is, we're rarely able to predict which project will lead to the next project with what timing, and typically there is a break for quite a lengthy scientific discussion of, okay, we found some cool things, we've developed some cool functionality, what's the best next step? And so we've really begun to think of our revenues in a completely different way. First and foremost, they're a validation that the building blocks we're using, that the functionality and the 3D bioprinted tissues that we're building ultimately destined for therapeutics have value and tremendous value to be unlocked to partners. And we do believe that we have the opportunity to build a valuable downstream business from those kinds of collaborations. But first and foremost, we now view these as funding mechanisms for our main mission, validation and exploration of key functionality of our tissues. And finally, actually as a way to generate new pipeline and new pipeline ideas. So we're just fundamentally moving away from a tools or P&L orientation to that side of the business and focusing much more heavily on our midterm goals to bring therapeutic products to the marketplace.

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

That makes a lot more sense. And I guess, just in relation to this kind of transformation of the company. It seems to me and I'm probably thinking about this incorrectly, so I'd love to learn a little bit more of how you guys are thinking about it. That transformation typically involves a different type of expertise. Something that moves beyond sort of the P&L and the diagnostic side, more into therapeutics development. Do you guys feel that you have the right team for, is this something -- is the R&D team going to be expanding in the near future? And you're looking at 2 kind of disease indications right now, where could we be at the end of 2019? Would we be closer to 3 or 4 indications? Or do we want to kind of stick with A1AT and NASH, and really let that be the kind of the platform to spring off from?

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

Well, first, I think that is a very important point that you raise, as companies typically move from discovery into development phase clearly with IND targeting ultimately a first in human studies.

I will point to the fact that some of my loss of hair results from big chunks of my career spent in drug development exactly in the phase -- phases that the company will be moving toward. But clearly, we will look to add clinical and other classic expertise areas over the coming years as we move toward the clinic. We also have surrounded ourselves by outstanding consultants and experts in what is a very rapidly involving field of regenerative medicine solutions going into regulatory conversations and clinical conversations. But I also want to add a unique aspect of what we're doing in building 3D bioprinted tissues is that, this is going to be a point-of-care solution for patients in all aspects. And as a result, the unique platform capabilities, a deep expertise that Organovo has developed, is going to be here and to grow and continue to give us a sort of a cutting-edge leadership advantage as we bring these tissues solutions to point-of-care opportunities in the future. So what I see is building on this platform continuing to identify the functionality that the FDA and other authorities are going to want to see demonstrated, which will happen by our deep platform expertise, while supplementing with the classical functions as we move toward the clinic. And to your second question, the strategy we



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

hope to be able to elucidate more as we get through the year and interact more with regulatory authorities is to build a core IND-track program around our lead indication Alpha-1 antitrypsin deficiency, and then piggyback on the safety and efficacy models that we developed there for other functions built off of the same healthy tissue constructs going into multiple disease areas with the same product solution, if you will. And that's the synergy that I referred to upfront in my comments. One program potentially has the opportunity to expand to any number of diseases, all of which have the common end outcome of needing a liver transplant and the end potential benefit of postponing the timeframe to transplant by inserting the healthy functioning patch of the kind that we're producing. So we hope to piggyback on INDs as quickly and cost-effectively as possible following this synergistic approach.

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

Got it. Maybe just one final one if you will entertain me. The -- you named the couple of conferences, EASL, AASLD and the NASH Summit. I don't know off hand -- off the top of my head when some of the conference -- if any of those conferences are coming up or if they've all passed. But can you give us a sense for the next 6 months or so for the rest of calendar year when we might see some additional data.

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

Sure. Well, so conveniently the U.S. Liver Meeting is always in November. And the European sister meeting is typically in the spring about 6 months apart. So that gives us a nice pacing for the outputs of our research program. As we develop breaking news or scientific news that might not best be [wait] or batched into those meetings, we'll certainly look for interim opportunities to present that data and get that out to the public. And in parallel, as I said, we hope to be interacting with the FDA and other regulatory authorities. And that can create other news flow, for instance, as we pursue second orphan drug disease designation, we would expect to have news around the FDA's ruling on that.

Operator

And our next questioner today will be Brandon Couillard with Jefferies.

Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

Taylor, could you break out how much you expect to spend on the therapeutic tissue programs in fiscal '19? And with respect to the \$1 billion [TAM] you spiked up for A1AT. How does that break down between ASP size of addressable patient population, U.S. versus rest of world? And then lastly, how you would perceive those sort of commercial time line of when, I guess, this might theoretically, you know, have an approval from a regulatory standpoint?

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

Brandon, this is Craig. I'll take the first part of the question on the R&D spend related to therapeutics. For fiscal '19, we're expecting to spend almost \$5 million on that program. And that would be up from about \$2.5 million this year that we spent in fiscal '18.

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

Thanks. And with regard to our projections, we've worked with an external market research consulting group that's done a pretty meticulous analysis of many of the orphan disease areas that we're going to be targeting, building up from incidents in the U.S., major European markets and rest of world a penetration approach, which in areas such as A1AT, where there is no viable alternative once you reach the transplant stage, there we assume a very high penetration rate in terms of creating market opportunity. In some of the other diseases, we're looking at where there may be palliative care that can stretch out the time line to transplant we've taken more of a medium penetration assumption. And in terms of our pricing, we've basically benchmarked off the cost of palliative care for these disease areas. For instance, in the A1AT area, somewhere in the order of \$250,000



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

per patient. And we've decided to leave as an upside the pricing one might expect to garner based on the pharmacoeconomics of delaying transplant, avoiding hospitalization, possibly skipping transplant and certainly quality of life and life expectancy changes. So as you may know, in particularly in the pediatric orphan disease area, but also generally in the orphan disease area, while pricing is important and highly scrutinized, there is a fair amount of leeway for breakthrough drugs in lifesaving areas where there are strong patient advocacy groups, low incidence and huge unmet need. So I think we've taken a conservative approach for the first indication A1AT to come up with this market -- peak market revenue estimate approaching \$1 billion. And certainly, as we get close to the clinic, we'll help work with the analyst community to model this out in more detail. In terms of time to market, if you start with the 2020 as the target IND filing date, one could envision commencing clinical trials as early as that year or shortly thereafter. And typically in this space, one might expect a fast-track program measured in handfuls of patients to get through a combined Phase I/II study and move to perhaps a final Phase II proof-of-concept study. Depending on the path that we're able to reach a handshake with on the FDA, a 2-study program of the kind I've mentioned could compress a typical drug development time line that may span 7 to 10 years into a much shorter period that could be half that or better. So again, as we get more information from the FDA, we'll be as transparent as possible on demonstrating time lines and assumptions for the market. And by the way, I think, just one number to throw out there is our market penetration assessment for A1AT is based on about 65,000 patients each in the U.S. and Europe.

Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

And on the Samsara business, any chance you'd give us a sense of the size of that revenue stream today? And could you talk a little bit more about the terms of the Lonza contract and the potential size there?

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

I think in -- sorry, we often have this conversation. We try to be -- remain qualitative on the components of our revenue. What we did mention is that our revenues have tripled year-over-year in Samsara. And we clearly see the advent of Lonza opening up global markets for us as a nice additional boost to revenues going forward. So with that, I think, Craig wanted to say something as well.

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

Yes, for the last year, Samsara revenues were over \$1 million to our fiscal 2018 results.

Brandon Couillard - *Jefferies LLC, Research Division - Equity Analyst*

It was helpful. Last one, Craig, in terms of the cash burn outlook for the year, what have you assumed for proceeds generated from the ATM facility?

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

That gross -- that burn that I gave was -- did not include any ATM proceeds. And the comment regarding our \$43.7 million starting point combined with our burn expectation over the next year and then the following, like 18 or 24 months means -- is really without any ATM financing. So any ATM financing we do would be additive to our cash balances.

Operator

(Operator Instructions) And our next questioner today will be Matthew Cross with Jones Trading.

MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

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

First off, I was hoping you might be able to provide some additional detail around your recent Type 1 Tyrosinemia data presentation. I know in the press release, you mentioned that the animal model for the indication showed good retention, sustained functionality and survival benefit. And I was wondering if you could explain a bit more about what actual biomarkers you're looking for there to support those conclusions? I assume the engraftment measures are somewhat similar to what you looked at for A1AT, but I was curious what else you're watching for that is specific of this indication in the animal model?

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

Right. Matt, this is Taylor, and thanks for the question. The -- we start, as you say, by looking for strong evidence of engraftment, which we can see with histology. And looking at the interface between our patch and the native tissue. And as we've seen in all of our animal models and certainly with A1AT, there is very rapid acceptance and engraftment and vascularization, which would suggest communication and acceptance between our patch and the host liver. That's obviously very important. The next thing we look for is circulating proteins and enzymes in the blood, in particular, human enzymes indicative of the patch and its functionality. And as in the A1AT animal model, we see, for instance, the evidence of functioning enzymes as one would expect in the FAH animal model. What's nice about the FAH animal model for Type 1 Tyrosinemia is it's a model where the mice, if not treated, have a pretty predictable mortality rate. And so the goal in that model is to see if we can differentiate the survival curve of our test animals versus that of the control. And we see a nice differentiation between our animals and the control. I forget the number exactly, but I want to say it's close to a 50% difference between the 2 groups. And we've seen this in 2 different animal studies. And that's the data that we presented at the Advanced Medicine World Regenerative Conference a few weeks ago.

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

Great. I appreciate that extra detail and looking forward to seeing future results as well. And then just a quick second one. I know in your release today, you highlighted that you'd pursuing an orphan designation for a second therapeutic liver tissue indication and was wondering if you could share with us kind of what key factors you're looking for right now in determining which of the collection of IMs that you may take forward as a second lead, if you will, to seek that designation?

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

Well, the place that we most logically will pursue for that filing would be the Type 1 Tyrosinemia, which we believe clearly qualifies as an orphan disease and as a pediatric orphan disease. That certainly would be something we would want to evaluate. We also are looking at other of the diseases in this class of single mutation inborn areas of metabolism. And frankly, we could start exploring multiple diseases in parallel. What we want to do is develop a thoughtful plan along the lines I mentioned earlier, of piggybacking off of a lead program, looking for studies and projects that are confirmatory versus require completely separate standalone areas of research. And that piggybacking strategy will be what determines which indications we prioritize for moving forward to the IND process.

Operator

And our next question will be Yasmeen Rahimi with Roth Capital Partners.

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD & Senior Research Analyst*

Can you elaborate a little bit more on your plans for expansion for the NASH profiling platform? And along the same lines, given the high interest in the space, has it changed your view on time lines on expanding the platform further and its utility?



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

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

Yasmeen, it's Taylor again, and thanks for your question. We are very excited about the potential of building out what we're calling a NASH map and looking at a range of the contours of that map that we think are critical for a drug discovery and development. First, we're working to develop different gradients of the disease. Perhaps one day even having this translate to NASH scores and graded independently by pathologists. But certainly, as a starting point, representing -- getting to NASH and the contributing conditions by different degrees and different amounts, which is very important to the drug discovery classes that are exploring an individual component of the disease, such as inflammation or a fibrosis and exacerbating those conditions in our model to help tease out nuances in drug response. The second thing we will be doing is exploring multiple classes of drugs, reference compounds to sort of feed the discussion among clients. And finally, and very importantly, looking at the critical role that the donor, the donor cells and the donor phenotype play in all of this. And that, we believe, is kind of cutting edge. It's increasingly a topic in major meetings that static research models and even cherry-picked human clinical trials, they are looking for a very pristine patient miss the fundamental role of human heterogeneity in predicting how drugs respond. And in a multifactorial disease, such as NASH, that's just a critical backdrop to understand and something that we believe our platform, our understanding of cells, donors and our wonderful Samsara subsidiary are able to tease out in quite a remarkable way. So we are investing resources of our own. We're working hand-in-hand with a number of early adopter clients and we continue to utilize NIH funds through our NASH grant. All to help us build out these features, answer these questions and build what we hope is a valuable tool for discovery and development.

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD & Senior Research Analyst*

And then maybe 2 follow-up questions along the same lines. As you're thinking to build out the platform, how are you thinking about capturing and bringing awareness to the biotech companies as well as large pharma partners to being attracted to the platform and wanting to be utilized by it? What sort of outreach programs do you have implemented to allow visibility among them to understand and wanting to be incorporating it into their R&D pipeline?

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

Well, first of all, we regularly present progress on our NASH map at major meetings. We were at AASLD last November with our initial findings of how we are able to induce this disease in our tissues, which was already pretty revolutionary. And then at The Liver Meeting and NASH meetings this spring, able to start talking about the role of heterogeneity and initial modulation observations with drugs. We -- the universe of NASH clients, even though there is probably about 240, 250 programs now launched in NASH, is accessible and very interested in engaging with us either as early adopters, as I mentioned, and we have -- we've mentioned in the past certainly a dozen or more clients that have engaged with us right out the chute and others who have said, "come to us when you can show us the feature for this validation with the reference compound." So there's clients in the wings. And ultimately, I think the fact that we've had clients, such as [Verus] for instance, recently, presenting our data in their posters. Other clients beginning to present how they're incorporating our Samsara cells into their research programs. That kind of awareness, the sense of Organovo inside is a very compelling way to spread the word.

Operator

And this will conclude our question-and-answer session and today's conference call. Thank you for attending today's presentation. You may now disconnect.



MAY 31, 2018 / 9:00PM, ONVO - Q4 2018 Organovo Holdings Inc Earnings Call

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2018, Thomson Reuters. All Rights Reserved.