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ONVO - Q4 2017 Organovo Holdings Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, and welcome to the Organovo Fiscal Fourth Quarter 2017 Earnings Conference Call. (Operator Instructions)

Please note this event is being recorded. I would now like to turn the conference over to Steve Kunszabo, 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 2017 earnings call. Joining me on the call this afternoon our CEO, Taylor Crouch; our CFO, Craig Kussman; and our General Manager, Paul Gallant. Today's call will begin with the discussion of the 2017 fiscal fourth 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 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 the 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 and Director*

Thanks, Steve, and good afternoon, everyone.



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Let me start by noting that it's an honor to be hosting my first earnings call here as the new CEO of this remarkable company. I'm grateful for the warm welcome I've received from our analysts and investors, our customers and partners and my many talented colleagues at Organovo.

We're developing innovative solutions and growing a dynamic business that has the potential to dramatically enhance how new drug are explored and profiled. At the same time, we've embarked on a therapeutics program built on our unique ability to create human tissue for critical unmet needs. I'm thrilled to have joined Organovo during such a transformational time in its history and look forward to our shared success in the years to come.

Before I turn to the customary business of our earnings call, I'd like to spend a bit of time on my professional background and highlight some of the important capabilities I see at Organovo based on my experience in drug development and R&D partnerships.

Most recently, I worked to build a group of 3 investigative clinical research site groups into leaders in their respective fields, spanning over 20 major therapeutic areas and tens of millions of dollars in annual revenues for a broad spectrum of major pharmaceutical and biotech clients.

Notably, these companies are on the cutting-edge of infectious and metabolic diseases impacting the liver, including hepatitis C, diabetes and NASH, otherwise known as fatty liver. Many of these same clients are also turning to Organovo to facilitate the understanding of their drugs in our disease models.

I've also led other high-growth companies, including my 9 years leading the sales effort at PAREXEL, a global CRO, which enjoyed nearly a fivefold increase in organic revenues during my tenure. Most importantly, I've been fortunate to work with talented scientists, drug developers and clinicians in several commercially-focused companies with the opportunity to create high-value collaborations throughout the research and development process.

Strategic and high-value deals making has been an important part of my track record in the pharma space.

With regard to Organovo, our foundation is strong. First, we target attractive markets with critical unmet needs. One example of the gap that exists in pharmaceutical discovery was recently highlighted in the Journal of American Medical Association (sic) [Journal of the American Medical Association]. In short, approximately 1/3 of drugs approved in the United States between 2001 and 2010 were later found to have a safety issue. Three of these drugs were subsequently removed from the market while many others required updated safety warnings. These types of studies highlight the need for advanced 3D human tissue models to assess drug safety and Organovo is leading the way.

Just as significant, the changing backdrop of first-world populations regarding deteriorating liver health makes it critical for all of us to understand how new and existing drugs perform in real-world patient populations where up to 1/3 of the U.S., and other major pharmaceutical markets are experiencing impaired liver functions. This dynamic is changing the way drugs are going to be discovered and developed, and Organovo's unique liver tissue modeling capabilities have the opportunity to play a critical role in this evolution. When taken all together, we offer high-value drug profiling solutions.

Second, we enjoy favorable competitive dynamics with a first-mover advantage. As I listened to our customers in my first few weeks, it's clear that what they want is differentiated, high-content solutions that are closely related to human tissue. Functional biomarkers, histologic evaluations and metabolism data all matter when our clients are optimizing their drug candidates or assessing next steps after receiving a challenging safety signal in the preclinical development process. Our liver and kidney tissues recreate the key aspects of in-vivo form and function where other models fall short.

Third, our innovative capabilities leverage our leading technologies and are protected by a growing and robust IP portfolio. Our NovoGen 3D bioprinting process delivers a superior solution and we continue to make significant engineering enhancements to advance that platform. Our IP portfolio now includes nearly 50 exclusive patents globally and more than 100 patent applications pending. These patent filings don't just relate to our bioprinting technology but also cover uses in drug discovery and tissue construct. We'll continue to build out our IP portfolio and believe it gives us a strong position.



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With that overview, let's jump to how we'll grow revenue and realize the promise of our technology platform. Craig will follow me with a detailed financial view; and Paul Gallant, the GM of our commercial business, will also join us for Q&A.

As I consider our 1-year plan, we're focused on 2 clear objectives. First, rapidly growing adoption of our liver and kidney tissue research services, which includes ongoing pioneering investments in dynamic disease modeling; and second, hitting key preclinical development milestones for our liver therapeutic tissue program. While we have a vibrant technology platform that will leverage in other areas, these 2 goals have our immediate focus.

In our in-vitro business, liver research services will continue to be our major engine of growth this year. The leading indicators of broader customer acceptance are taking shape as illustrated by our penetration with top 25 pharma customers as well as leading biotech and focused therapeutic companies who are all increasingly turning to us for potential solutions. Many of our clients have a deep bench of therapeutic expertise in the liver and kidney space and it's highly encouraging that these customers are often the first adopters of Organovo's liver and kidney systems.

Perhaps the best example of market penetration is that we completed over 50 revenue-generating customer orders in fiscal 2017 versus 10 in fiscal 2016. We continue to pick up new clients at a rapid pace while also seeing important follow-up project demand from repeat customers.

Ongoing customer adoption rests squarely on the breadth of our scientific validation work. We published a number of peer-reviewed publications in the last year, including 8 presentations at the Society of Toxicology meeting in March, which is our biggest and most important commercial conference of the year.

I'm pleased to share we've now studied a group of 46 compounds and accurately characterized the safety profile in a high percentage of the cases based on clinical correlation. These studies have included a combination of classic misses, known safety drugs -- known safe drugs and customer's proprietary drug candidates, and the investigative work was often done on a blinded basis. Demonstrating the refinement offered by our tissue models, we were not only able to accurately identify toxicity in problematic drugs, but just as important, did not errantly flag safe drugs. In many of these cases, traditional toxicology models did not provide an adequate safety signal.

Lastly, it's worth recognizing that our remarkably high success rate comes from a single model, our exVive human tissue, demonstrating the comprehensiveness of our solution versus using a mix of traditional preclinical models.

Compound screening in disease tissue systems will also be a major revenue driver in our in-vitro business. Customer pull-through beyond classic toxicology is very logical in this space, particularly when considering the significant emphasis placed by our customers on the critical research fields of liver fibrosis and NASH, fatty liver. Here, again, you can't model disease effectively using cell cultures nor can you replicate the predictive power of human tissue response in animal models. Our solution can start with healthy cells to build a tissue and then induce a disease or can use diseased cells as the raw material for building the bioprinted tissue. And in both cases, our system showed strong comparability to the clinical pathology of that disease.

We are effectively offering a human preclinical model and enabling drug discovery to get early insights into potential clinical outcomes, especially in the lead -- in the stage of lead optimization. Customer demand in this area is robust, and you'll hear much more from us on this opportunity going forward.

Turning now to our second objective. Let me give a quick progress update on our therapeutic tissues business. We recently presented new preclinical data, demonstrating promising early results of our bioprinted liver tissue in diseased animal models. Our liver patches are now lasting 60 days post-implementation, more than double the duration of our first preclinical studies.

When evaluating our results, we've also observed that diseased animals that received our transplanted bioprinted liver tissues had a meaningful improvement in liver health versus nontreated control animals. All in all, these are notable achievements as we move forward in developing a novel therapeutic solution for our first-indication pediatric inborn areas of metabolism or IEM. The life expectancy of a child born with one of these liver coding errors is typically early adolescence at best unless a liver transplant is received, and we believe our therapeutic tissue approach may offer revolutionary new way to improve the quality of life for these patients.



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Given our progress to date, we continue to aim for an IND submission during calendar year 2020. To achieve that significant milestone, we'll spend the next 18 months doing the following: optimizing our final tissue design; continuing to conduct pre-GLP studies in small animal disease models for our target indications; seeking orphan designation in the U.S.; and partnering with contract research organizations to define and scope IND-enabling studies.

We'll also continue to have discussions with the FDA and other regulators relating to our existing and future products to help facilitate the timely review and approval of new therapeutic tissues through the Regenerative Medicine Advanced Therapy process. Our recent testimony before Congress is just one example of how we're working to connect with and educate key decision-makers about the patient and economic benefits of 3D human tissue model and therapies.

In closing, I'm excited to be leading Organovo through its next phase of commercial growth. In my first year, I'll emphasize listening to our customers and putting compelling validation data in front of them, 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 toward human clinical trials.

I also look forward to meeting with our analysts and investors over the coming months, starting with the Jefferies Healthcare Conference tomorrow in New York.

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

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

Thanks, Taylor, and good afternoon, everyone. I'll begin by summarizing our key financial metrics for the fiscal fourth quarter and then take you through the new fiscal 2018 guidance we issued today. I'll wrap up my thoughts by briefly reviewing our balance sheet and liquidity profile.

Organovo generated fiscal fourth quarter total revenue of \$0.8 million, which was up 48% from the prior year period but down 29% sequentially. On a year-over-year basis, total revenue benefited from a significant increase in customer activity for our liver tissue research services. On a sequential basis, our total revenue declined, as expected, due to the delayed customer orders we described on our last earnings call.

You'll recall that we received customer request to qualify an additional cell source as well as for additional validation data to support specific use cases. Taken together, these items delayed several hundred thousand dollars of our forecasted revenue into fiscal 2018. I can now share that we've successfully qualified the additional cell source that our customers required to move forward with their orders, and we anticipate recognizing the associated revenue in the first half of fiscal 2018. As for the validation studies to support specific use cases, this work is ongoing with strong engagement from our customers.

We're taking the necessary steps to optimize our tissues for certain client-specific needs and expect that we'll reach a successful conclusion that similarly allows us to record the deferred revenue this fiscal year.

I'll focus next on operating expenses. We recorded \$0.2 million in cost of revenues for the fiscal fourth quarter. It captures our costs related to manufacturing and delivering our product and service revenues. It's an important indicator of how effectively we're commercializing the business and provides insight to our financial health when considering the associated profit margins.

Fiscal 2017 was our first year of breaking out this metric and we reported a related annual gross margin of 70%. This is a good start as we keep an eye on profitability on our tissue services businesses.

Research and development expenses were \$5.5 million, a 22% year-over-year increase, largely due to higher costs related to increased staffing, scientific validation work and lab supplies.



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We reported \$5.8 million in selling, general and administrative expenses during the fiscal fourth quarter, a 30% year-over-year increase, primarily resulting from higher employee and outside professional services costs. SG&A also included approximately \$0.3 million of onetime CEO transition costs.

When broadly considering the trend lines for our R&D and SG&A expenses, it's worth noting that our headcount leveled off in the second half of fiscal 2017.

Our core business infrastructure is at a sufficient level to support anticipated fiscal 2018 customer demand and revenue-producing opportunities. Modestly higher employee-related costs from the full-year effect of fiscal '17 headcount adds and expenses supporting the preclinical development of therapeutic tissues will be the principal cost drivers going forward.

And finally, a brief review of the full-year fiscal 2018 outlook we issued today and a few quick notes on our balance sheet and liquidity profile. We are forecasting total revenue between \$6.0 million and \$8.5 million for fiscal year 2018, with the main contributions coming from our liver tissue commercial services. We expect minimal contribution from collaborations revenue right now given the state of our commercial research partnerships.

As I shared last quarter, these agreements are often long term and typically have multiple phases with interim milestones. We have completed all of the work we and our partners have agreed will be performed under these collaborative agreements and have recognized the associated revenue.

More specifically, for the first quarter of fiscal 2018, we expect total revenue in a range between \$0.9 million and \$1 million. Our fiscal 2018 total revenue guidance is weighted such that the second half of the year will be significantly higher than the first half of the year. We expect this sequential ramp to be guided by greater penetration of our key accounts, increased customer adoption of our core capabilities in high-value drug profiling and successful completion of our ongoing validation studies. We expect to exit the fourth quarter of fiscal 2018 at a double-digit annualized revenue run rate.

It's also worth emphasizing that in fiscal 2017, our product and service revenue was generated 40% by new customers and 60% by existing customers, demonstrating a healthy mix of new sales and repeat orders. We anticipate this encouraging trend will continue in fiscal 2018.

On the same basis, for the full year of fiscal 2018, we expect negative adjusted EBITDA between \$29 million and \$31 million. This operating metric is defined as GAAP net loss adjusted for net interest, income taxes, depreciation and amortization, share-based compensation expense and onetime cost, such as the approximately \$1.1 million in CEO transition costs we expect to incur in fiscal 2018. This compares to \$29.8 million of negative adjusted EBITDA for fiscal 2017.

We've moved from net cash utilization to adjusted EBITDA because this metric eliminates working capital and capital expenditure timing considerations from our guidance and provides a clearer metric of our profitability.

We've included a non-GAAP definition and reconciliation table in today's press release for your review.

At the end of the fiscal fourth quarter, we had a cash and cash equivalents balance of \$62.8 million and approximately \$22 million of funds available under our at-the-market or ATM facility. In combination, this gives us nearly \$84 million in available liquidity to carry out our business plan and invest in our key growth initiatives.

I'll wrap up by noting that we've made meaningful progress in fiscal 2017. We achieved our key objectives in continuing to advance our liver therapeutic tissue through preclinical development. And while revenue growth ultimately came in at the low end of our initial annual guidance due to additional scientific work our customers asked us to complete, we, nonetheless, reported a near tripling of our total revenue from the previous fiscal year.

As Taylor laid out in his remarks, we're zeroed in on 2 primary goals: growing revenue from our liver and kidney tissue research services; and hitting the next set of milestones as we move toward human clinical trials with our 3D bioprinted liver.



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The right formula is in place for success in fiscal 2018, and we look forward to updating you on our progress in August.

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) The first question is from Ross Muken at Evercore.

Luke England Sergott - Evercore ISI, Research Division - Associate

It's Luke in for Ross today. I guess, just kind of looking at the commercial -- the tissue side. Can you just talk about the cross-selling opportunities that you guys have seen? And how many of your customers are actually becoming kidney and liver versus just liver as before?

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

Luke, this is Taylor. Let me start by saying that, actually -- Luke, cross-selling is a good question, but actually, our more immediate focus is cross-selling within accounts, penetrating our liver capabilities, testing across multiple users in large pharmaceutical companies and engaging them in both the therapeutic and healthy liver tissue model capabilities of the company. So what we're seeing is an important uptick in repeat business with clients that started working with us last year while, of course, we're also enjoying a steady flow of brand-new customers to the fold. We certainly have also had a number of engaging discussions around the kidney. And our learning curve on the liver platform, which was to continue rapidly with our research to explore disease models in those tissues, seems to be a recurring demand also on the kidney side. So you'll hear us talking just as much about our kidney research as about early adoption from clients on the kidney side.

Luke England Sergott - Evercore ISI, Research Division - Associate

Great, that's helpful. And then I guess, when you talk about penetrating deeper into the accounts and accelerating the revenue growth, how much of the -- is it where you have established a name for yourself with the commercial capabilities, and how better your model is than what's currently available? How much is it -- swinging for the fences on large projects versus still trying to prove out the capabilities to clients?

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

Great question. Again, Taylor here. The process that we're seeing starts with companies typically saying, "We really like your models. Can you tweak it for this particular purpose," either to fit the class of drugs they're interested in or a set of markers or other capabilities they'd like to see, particularly given the dynamic capability of our models, which really is unique out in the marketplace. Then we see clients progressing to multiple tests of our capabilities and/or validation, let's say, across donors or across classes of drugs. And finally, and this is exciting for us, we're beginning to see the first -- or hold the first conversations with some of our larger clients about how would we translate these capabilities into routine screening programs across a large number of discovery candidates and across a long period of time. So I think that's going to be the -- sort of the 3-stage adoption curve that we see. And occasionally, we'll see clients jump in at a much larger level, but the predominant scenario is that 3-stage adoption curve I just mentioned.



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Luke England Sergott - *Evercore ISI, Research Division - Associate*

I guess, last on guidance. As you look at the revenue ramp, it's still pretty steep and -- as expected, which is how we look at the business in general. What kind of puts and takes do you see within that, within the quarter as you talked about the second-half ramp? But what are your assumptions within that with -- for the different tissues and -- et cetera?

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

Well, I think we've tried to be pretty thoughtful about describing how we think the year is shaped in the comments that Craig went through with tight guidance on Q1, a sense of the fact that the second half will represent yet another revenue ramp versus the first half and how we expect to exit the year. With regard to run rate, we see the largest volume of those revenues coming from our liver tissue services, both in healthy and diseased model studies. And we see that building up along that acceptance curve or that adoption curve that I mentioned before.

Operator

The next question comes from Brandon Couillard at Jeffries.

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

Taylor, I appreciate some of your comments on what attracted you to the company. It sounds like much of the strategy will remain intact in terms of the strategic focus, but do you see any opportunities commercially to perhaps push harder in certain areas or in certain aspects of how you go-to-market that you think you could do a better job on?

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

Thanks, Brandon. Also, looking forward to meeting you tomorrow. By the way, I just reached over and pushed Paul Gallant, our General Manager, so that was good advice that you just gave me. We -- we're actually pretty excited about the uptake. We mentioned the 15 new client projects in 2016 versus 10 the prior year. And if you take any model and apply it to an increasing number of new clients and repeat business adoption curve, like I described, I think our challenge will be just as much to process and manage this increasing volume of clients as it is to reach these this revenue growth goals that we've described. That being said, there is an experimental component to everything that we do, and we really are working on cutting-edge, dynamic modeling systems. And our clients, surprisingly and quite pleasingly, are engaging with us real-time versus saying, "Sounds good. Figure it out. Get it published, and come talk to us in 2 years." Many of our clients want to be with us side by side on this mission, so lots of very positive dynamics. We'll certainly evaluate the number of folks we have out selling and position our business. I, myself, love rolling up my sleeves and joining in the process. I've already participated in 10 client meetings just in the last 6 weeks and expect to continue at least at that pace for as long as I'm CEO of the company. So I think we will have all hands on deck going out to capture opportunities as well as focusing on how to process and deliver along this steep ramp.

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

That's helpful. And then I guess, a 2-part question for Craig. Number one, could you speak to the materiality of the -- let's call it, the ancillary metabolomics services that, I think, you began to offer last year? And then secondarily, if I take the 50-plus orders and just divide that by the fiscal '17 tissue revenue, that comes up to something like \$63,000 per order. Help me understand the delta between that and what you described as your typical contract size for liver being \$150,000 to maybe \$250,000.



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

Yes. So the -- with respect to the first part of the question on metabolism, we -- thus far, we've had a couple of orders. So it's not what I would call material in terms of either the 5% or 10% thresholds from that standpoint, but we do expect that to grow in the future. And then with respect to the second part of the question, which was...

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

Average selling price.

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

The average selling price, yes. So when we quote a figure of \$150,000 or \$200,000 per year per customer, that's an annual amount that we would expect to receive from a given customer that would basically include multiple orders of the types that were -- that we have in our figures. So you could think of the 60 times the 3 on average per year is what would reconcile you with that number. So it's not -- when we gave the \$150,000 to \$200,000, that would be for what we would expect a given client to spend across the set of compounds that they're screening in a given year.

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

Maybe one for Paul. Any feedback that you'd like the share coming out of the SoT meeting? And it doesn't sound like kidney is really going to be a material contributor to the revenues next year. Any, I guess, numbers or in terms of number of clients or data points that you could share with us about how that update or how that launch is going?

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

I think the SoT conference was fantastic for us. We had a great presence there, including a number of poster presentations and podium presentations. And we had a significant booth presence as well, with a lot of traffic from existing customers as well as potentially future customers as well. And so that is sort of translating, post that conference, into deeper adoption into these accounts. So we found certain accounts where we've already been working in, but other groups were not aware of us at all. And our presence at SoT has allowed us to open up into -- and deeper penetrate these individual accounts. With regards to the kidney, there is a significant interest in the kidney space. And as we're out talking to customers and the voice of the customer, they have a need for kidney for sure in the tox space, so one of the high areas of interest and demand. And what we're working to address is the area of transporters to look at either drug-drug interaction or drug elimination and processing in the kidney. And that's an area of functionality and validation of what we're currently doing in-house.

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

And maybe -- Taylor here, to add one other comment. It's interesting, as we started talking to our clients about fibrosis and highlighting the capabilities of our liver fibrosis model, pharmaceutical companies across the spectrum of fibrosis research, and as you know, this occurs in the lungs, skin, kidney, liver and other areas, are coming to tease out how our model may help them even in distant-related fields because many of the mechanisms of fibrosis are similar. So while we're still developing these capabilities in the kidney, we're seeing clients engage with us to utilize the liver cell to understand fibrotic mechanisms of their drugs.

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

And maybe one more. Did you give us a metric on how many of the top 25 pharma you count as customers? I think, last quarter, it was 11.



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

I think we've decided not to continue keeping track, or I should say it differently, not to keep a running scorecard for you. We continue to penetrate the top 25 pharmaceutical companies. We also are heartened by the fact that many of our clients, including Astellas and Merck and ADVI have presented in public forums our data and credited us and, in many cases, disclosed collaboration set that we can't talk about. So we've just decided maybe to talk more about general adoption. And I also kind of want to highlight the fact that some of the most sophisticated companies focused in liver research are mid-sized as well as biotech companies, and these also are increasingly among the first adopters of our capabilities. So I think the validation is not just from large, sophisticated pharma companies but from leaders in liver research across a spectrum of companies.

Operator

The next question is from Reni Benjamin at Raymond James.

Bin Lu

This is Bin in -- on for Reni. The first question that I have is can you talk about sort of the data presentation that we might be expecting in the next 12 months? And then I will have some follow-ups.

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

So yes, we actually -- just as we had publications at the SoT meeting in March, we continue to submit abstracts and articles to a number of journals as well as some of the key upcoming meetings, so I think you'll see us regularly referring to new presentations. We're participating in 12 conferences coming up over the next year with either posters or presentations as well as publications, so we plan to stay quite active in that area.

Bin Lu

Great. Looking forward to seeing that. And then maybe can you provide some additional color regarding the profile of the 46 compounds you have studied so far? So would the safety of all of these compounds [now] successfully predicted by other models in the preclinical setting? And then I remember you mentioned the hit rate was quite high there, so what was the number? Was that in the 80% range or 90% range?

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

Sure. So as Taylor -- or I think I spoke a little about the validation set. Anyway, so we've completed a study of 46 compounds, and this is a collection of compounds which have clinical data on them, that have demonstrated liver tox. And some of the compounds are perfectly safe and did not demonstrate liver tox. So those are some controls that we ran alongside with these experiments because what our customers are looking for, in terms of a validated tool, is to understand how predictive that tool is and looking at the predictive power of calling something a positive or a negative. And so we chose a set of compounds with our feedback from our customers that were either -- would be termed easy to detect, which are some compounds that are -- were detected by other preclinical systems; and the other ones which are hard to detect, which were essentially missed by existing preclinical systems. And the compilation of that data is what we were describing today, where we're looking at around 80% where we scored extremely well. And this is just the initial set of data. We'll be generating more in the near future.

Bin Lu

Great. That's very encouraging data. So just one final question from me is, so given the data that you have so far and your conversations with your existing clients as well as potential customers, so what else do we think they may want to see from the data perspective so that they would increase their usage of these 3D tissue models?



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

Well, it's a question we review regularly in our commercial and R&D team. The wish list from our clients is extensive only because, not only is there a spectrum of non-alcoholic fatty disease that progresses all the way to cirrhosis and, ultimately, cancer and transplant, and ideally, we would have models and data along that entire spectrum, but also infectious disease impacting liver. The various viral diseases, hepatitis A, B, C, D, et cetera, are other areas that our clients would love us to tee-up in our research programs. And then there are specific conditions of the liver, one of which we're using is our proof of principle in our tissue therapeutics program, the inborn errors of metabolism area. What we're finding, and I mentioned it before, is that clients aren't waiting for us to complete our research mission. They're really engaging with us, giving us good ideas. In some cases, challenging us and bringing their own strategies to the table and working with us side by side on some of the challenges that I just mentioned and -- still in a commercially attractive way for the company. So it truly is an ideal partnership. And we would expect a similar rollout of that kind of uptake on the kidney side as we start to advance those programs.

Operator

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

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