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PRESENTATION

Operator

Good afternoon and welcome to the Organovo Holdings fiscal second 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, Head 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 second quarter 2018 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 a discussion of the 2018 fiscal second 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 these forward-looking statements. Such risks are more fully disclosed 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. I'll get us started by highlighting that our top line results of $1.4 million for the quarter represented our second-highest quarterly revenue to date and our third consecutive quarter of sequential revenue growth. This is good progress as we streamlined the business around maximizing the uptake of our liver and kidney tissue systems. But we still have more work to do.

We updated our full-year revenue and negative adjusted EBITDA guidance today, which reflects the latest assessment of our growth trajectory. We are prioritizing disease modeling capabilities as we head into the second half of our fiscal year and de-emphasizing our work in the routine

toxicology research area. Our guidance also shows the benefit of cash burn from our organizational restructuring. Craig will provide more detail on our financials and the revised elements of our outlook in his remarks.

As I consider the steps we've taken in the last few months to recalibrate our direction and evaluate the best path forward, our strategic identity has come into clearer focus. Our highly customizable 3D tissue platform affords us the ability to monetize our capabilities in many ways. We provision and curate primary human cells for use in research applications through our Samsara business. We've created dynamic disease models that can facilitate drug discovery and profiling in ways never thought possible. We've struck licensing agreements that capitalize on our proprietary technology and intellectual property, and we continue to develop our own novel therapeutic tissue products to address critical unmet disease areas. We are working across a broad value chain that spans the drug discovery and development ecosystem with what we believe are the industry's leading liver and kidney tissue systems.

Moving now to our commercial tissue business where our bioprinted liver remains the primary engine of growth, I'd like to share a few leading indicators underscoring the strength of new business, the health of our revenue mix, the growing value of our services and our significantly reduced cycle times.

First, we added 8 customer accounts in the first half of fiscal 2018 including 3 clients projects with products already in clinical trials and we continue to see momentum in bring new business aboard.

Second, we continued to see a healthy revenue mix during the first 6 months of our fiscal year, with a 60% to 40% split between repeat business and new orders. This is consistent with our breakdown in fiscal 2017 and supports the ongoing move by our clients up the adoption curve.

Third, we've driven our average revenue per order higher over the last 2 quarters, largely as the result of shifting our work to compound screening and disease models. In the first half of fiscal 2018, approximately 65% of our orders represented disease modeling projects. This is good news because our competitive differentiation is particularly strong in these applications including target identification, marker validation and lead optimization.

Lastly, our cycle time from sending out a customer proposal to closing an order has declined sharply. In late 2016 we were averaging over 7 months for this important business development metric. In the first half of fiscal 2018, we've brought the span down to under 2 months, in part owing to the master services agreements and repeat business we have with our existing customers as well as to better understanding our client needs relating to projects outlined and study design. In addition, as a result of our business development, marketing and scientific outreach, many new and existing clients are seeking out our services with a sense of urgency to interrogate their drugs on our platform.

Our progress in studying liver disease has also been bolstered by the $1.7 million grant award we received from the NIH to collaborate with UC San Diego to evaluate NASH in our 3D bioprinted liver model. I also note our collaboration with Viscient Biosciences to develop a custom research platform that targets early discovery work for liver disease. We're also pleased with the distinction and reception our posters received at the recent American Association for the Study of Liver Disease annual meeting, which is one of the most influential conferences in the liver disease space.

Overall, our shift to disease modeling services recognizes the important role that liver disease plays in pharmaceutical R&D while also representing the highest-value opportunity for our commercial business. We're seeing deeper engagement from our clients in this space as we discuss annual budget allocations and framework agreements for our services. Ultimately, these are important steps as our customers move from single-project commitments to dedicated research plans and meaningful annual revenue commitments.

Let's turn now to a quick progress update on our therapeutic tissues business. As many of you saw in our recent announcement, we achieved major scientific milestones for the extended survival and functionality of our liver therapeutic tissue and we remain on track to submit our first investigational new drug application to the FDA during calendar year 2020. Our bioprinted liver tissues showed significant engraftment, retention and functionality through 125 days post-implementation in well-established animal models for one of the inborn areas of metabolism, namely alpha-one-antitrypsin deficiency. Importantly, thorough evaluation of the treated animals suggests an approximately 75% reduction in the pathologic hallmarks of disease in treated areas. In short, our liver patch meaningfully cleared the disease in the immediate area of the implant.

The data show that the approach of delivering a 3D bioprinted tissue patch directly to the liver offers great promise in solving the retention and integration issues that have held back many cell and gene therapy attempts at treating these debilitating pediatric liver diseases. These are also major achievements because we believe they align with the historical expectations of regulators for these types of preclinical studies and allow us to confidently move on to the next phases of our development work now that these elements have been completed.

Regarding next steps, we'll continue to move forward with our application to seek orphan drug designation in the next several months, and we've now begun new animal model studies in a second therapeutic indication within the category of inborn areas of metabolism.

In closing, we've taken concrete steps in the first half of the fiscal year to sharpen our focus on liver and kidney tissue systems, we've shifted our commercial priorities to be centered on higher-demand and higher-value disease modeling projects and we've restructured the organization to support these objectives. In doing so, we've improved our future revenue growth trajectory while also reducing our operating costs and materially lowering our cash burn rate. My emphasis will continue to be on meeting with customers, driving adoption of our platform commercialization, finalizing key proof-of-concept work for our liver therapeutic tissue program and translating all of this progress into value inflection points. And we will continue to be good stewards of our balance sheet. I look forward to communicating with you again soon as we execute against these important commercial and research milestones.

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

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

Thanks, Taylor, and good afternoon, everyone. I'll begin by recapping our key financial metrics for the fiscal second quarter and then summarize the fiscal 2018 guidance we updated today. I'll wrap up my thoughts by briefly reviewing our balance sheet and liquidity profile.

Organovo generated fiscal second quarter total revenue of $1.4 million, which was down 2% from the prior-year period and up 37% sequentially. Total revenue results were driven by lower collaborations revenue, as key collaboration agreements were completed in the prior fiscal year, partially offset by grant payments related to our recently awarded NIH grant. Product and service revenue was $0.9 million, down 8% from the prior-year period. As Taylor noted, we're recalibrating our business development effort to focus on higher-demand and higher-value disease modeling services. Although we saw a significant increase in disease modeling orders, which were approximately 65% of total orders in the second quarter, these gains were not enough to offset the toxicology research services revenue we recorded in the year-ago quarter. Despite the short-term impact as we now deploy our resources against this new market opportunity, we see robust uptake of compound screening and disease models and expect it to be a major revenue growth component going forward.

I'll focus next on operating expenses. We reported $0.3 million in cost of revenues for the fiscal second quarter, a 35% decline from the prior-year period. The drop in cost of revenues was largely due to a greater contribution from higher-margin primary human cell and tissue products. Research and development expenses were $4.9 million, a 9% year-over-year increase, primarily resulting from higher facilities and employee-related costs. We recorded $5.7 million in selling, general and administrative expenses during the fiscal second quarter, a 3% year-over-year decrease, largely due to lower external professional services fees and facilities costs. SG&A also included approximately $0.4 million of one-time CEO transition and employee severance costs. As we look ahead to the fiscal third quarter, it's worth emphasizing that we'll record an approximately $0.9 nonrecurring charge related to our recently announced organizational restructuring.

And finally, a brief review of the full year fiscal 2018 outlook we updated today and a few quick notes on our balance sheet and liquidity profile. We now forecast total revenue between $4.5 million and $6.5 million for fiscal year 2018, with the primary contributions coming from a few key components: continued strong growth of our disease modeling services, recording the balance of our deferred revenues from the previous year, accelerating growth from our primary human cell and tissue products and accelerating progress on our NIH grant, of which $200,000 to $600,000 is reflected in our fiscal 2018 guidance range.

While we've revised our fiscal 2018 outlook and now expect a delay in ramping to a double-digit annual revenue rate, we remain confident that one or more of our customers will move from single-project commitments to annual revenue commitments over the course of the next few quarters. Achieving this goal with our customers should position us to meet this important revenue metric in 2019.

On the same basis for the full year fiscal 2018, we now expect negative adjusted EBITDA between $26 million and $28 million. This is an improvement in our cash burn from our previous estimate and is largely driven by the reduced operating costs we'll benefit from as the result of our organizational restructuring and a streamlined focus on our existing commercial opportunities and therapeutic tissue program. By comparison, we recorded $29.8 million of negative adjusted EBITDA for fiscal 2017.

Before I move on to our balance sheet, a few quick words on the evolution of our Samsara subsidiary and its growing contribution to our business. First, it provides us with great expertise in the sophisticated isolation and curation of our target liver cells. Second, we're able to further explore how disease origin cells perform in our tissue models across various disease states. Finally, it benefits us from a business development perspective, as many clients who worked with Samsara first moved to also engage in more complex liver and kidney disease services. All in all, great synergies between the 2 operations as Samsara becomes a more meaningful portion of our total revenue.

Now for our balance sheet. At the end of the fiscal second quarter, we had a cash and cash equivalents balance of $50.7 million and we have approximately $17 million of funds available under our ATM facility. In combination, this gives us approximately $68 million in available liquidity to carry out our business plan and invest in our key growth initiatives. As circumstances and market dynamics permit, 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 human clinical trials. 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. If we're able to successfully execute against our planned ATM strategy, we do not currently envision a traditional equity raise such as a follow-on equity offering for the remainder of fiscal 2018.

I'll wrap up by noting that we believe there's a growing value for Organovo as we continue to advance our liver therapeutic issue and achieve major scientific milestones. As for our commercial business, we continue to streamline our operations and redeploy our effort against the best opportunities to grow our revenue in the liver and kidney space. Disease modeling represents a big part of this future path. We look forward to updating you on our progress in February.

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

QUESTIONS AND ANSWERS

Operator

[Operator Instructions.] And our first question comes from Brandon Couillard with Jefferies. Please go ahead.

Christian Peter Trigani

This is Christian on for Brandon. First off, I understand you're taking a broader shift into disease modeling, but it would be helpful if you could provide additional commentary in terms of the key variables that drove the materially lower full year revenue outlook. I'm just trying to understand, given the magnitude of the downward revision, why you didn't ultimately decide to prerelease the development or update the full year view concurrent with the restructuring plan announced in early October.

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

This is Taylor. And one of the challenges that we face, and that's why we've given a broad revenue guidance, even for this remaining several months of our fiscal year, is that we have a number of binary events that we hope and plan and are working toward breaking our way, which could result in significantly more revenues. But as each month closes, we have to recognize the risk that some of these binary events don't go our way in this fiscal year but move into the final -- into the next fiscal year.

As an example, we've mentioned that our deferred revenues for clients that we have hoped, and certainly still plan to try and achieve this year, may or may not fall into this fiscal year. And similarly, you see with our NIH grant revenue a significant range tied to certain operational risk variables and NIH grant approval processes that affect this range. So it's more an issue of being more cautious about the outcomes as we see -- as we evaluate these binary events, as well as reflecting that we truly had hoped to see some more traditional routine tox business from our earliest clients. But now we realize that the investments we would have to make to convince them to move over their thresholds to incorporating us into what ultimately is a lower-margin but higher-volume business, those thresholds don't provide us the same return on investment as we're seeing by investing now heavily in our disease modeling platforms, which are being driven by significant and enthusiastic demand from those clients. So it's a number of forces that are coming together, and our visibility on these forces clarifies as we approach the end of the year. And we just thought it was more prudent to wait until this call to clarify that situation.

Christian Peter Trigani

Okay, understood. That's very helpful. And then I guess, also probably for Taylor, maybe a 2-part question. I would be very interested to hear an update on how the conversations are progressing in terms of moving the target one or more clients for a larger multiyear routine use engagement. To be clear, do you still expect that to occur within the fiscal year '18? And maybe help us quantify how many customers might be in that Phase 2 bucket currently that could over time move to steady-state use over maybe the next 12 to 18 months.

And then secondly, do you think you have enough current capacity to perhaps inboard those customers over time? And if so, maybe give us a rough percentage of what capacity you think you would need to commit to such customers to fulfill a larger engagement.

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

Okay, thanks. Both great questions. With regard to our clients moving along the adoption curve, and so the Phase 2 that you referred to, for the others on the call, represents the final validation of our custom research platforms, a process that we're undergoing for each of our clients. And in some cases, by the way, we're validating more than one platform. And the final step of that phase is to begin running standard reference compounds through our platforms to show how they modulate the very diseases that we've created in our tissues in these unique platforms. And I am pleased to say that we now have a handful of clients that are in this final step of the -- of testing the modulation strategies with either reference or, in some cases, with proprietary compounds. As son as that's completed, we believe the very next step is to move to more routine use for proprietary screening and profiling larger numbers of compounds. And we do indeed have conversations underway at more than one client along those lines, and that continues to give us confidence that we will exit this fiscal year tracking toward that routine use, more annual perspective kind of collaboration agreement.

Your second question as regards to capacity, we actually have significant capacity here to expand, certainly to meet the needs both for our commercial tissue business as well as our therapeutic tissue research program to handle various growth scenarios over the next couple of years. So we don't worry about capacity, and we have scalable, modular capacity built around our printing platforms that can easily be scaled up when and if necessary.

Christian Peter Trigani

Great. And then maybe if I can sneak one more in. Recently we noticed another 3D tissue player in the landscape signed a deal with the CRO, Charles River. Now I understand this player has a somewhat different focus and value proposition, but would be curious to know at a high level if you see an opportunity over time to potentially work more closely with other CROs out there, and if so, possibly over what time frame that could occur. Thank you.

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

Actually, I'll grab that question as well. As you may know, my background, a big part of my career has been spent in the CRO industry and the biotech positions I've held in those positions, I've also been instrumental in putting strategic CRO collaborations in place with all of the leading CROs. And certainly, we see an opportunity as we scale and as we establish more repetitive use applications on our platform to work with CROs, certainly if we approach a capacity constraint. And so I think it would be very reasonable to expect us to be working, collaborating and announcing appropriate agreements in the fiscal year to come along those lines.

Operator

Our next question is from George Zavoico with B. Riley-FBR. Please go ahead.

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

I have a question about your therapeutic tissues, your liver tissues. Your shit in focus -- part of it is perhaps a disappointing potential revenue stream from the toxicology research services, but it must be balanced by some sort of marketing surveys that you may have done with the therapeutic tissues despite the fact that you're waiting for an IND until 2020. So the question is what kind of supportive marketing information do you have that really speaks to the potential demand and the potential revenue stream from this, and are you looking for partnering opportunities as well in this regard, in this sector?

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

So first, in terms of demand, we mentioned some of our cycle time statistics. And a year ago, the process of getting a meeting with a classic toxicology decision maker to discuss how our experimental but promising platform might be useful, there was interest, but I wouldn't call it overly enthusiastic, and often it took months and months to close a first revenue opportunity with those decision-makers.

On the disease modeling side, our partners are therapeutic teams, clinicians that actually have real problems they need to solve with a high degree of urgency, and/or people in discovery who so far have had no other in vitro solutions to explore how their drugs will perform in human-like settings in these disease models. So we actually have a significant amount of people -- clients -- reaching out to us. We have clients that we've talked to in the past about toxicology coming much more enthusiastically to discuss our disease models, and I'd say we have a veritable Who's Who of people working in the NAFLD, NSH and fibrosis space across U.S., Europe and Japan beginning to move forward with us along this adoption phase. So it's really a demand-driven opportunity. We see the market opportunity is quite significant because the later you get in discovery, as you know, with research services, the more the value of the drugs you're touching has. And so as you move forward to lead optimization, preclinical candidates and certainly drugs that are always in the clinic, we are creating and enabling a much higher-value outcome for our clients in their decision-making. And we're seeing an uptick in the revenues and the sense of urgency that they have to work with us. And all of these things have built toward the decision to move in this space, as well as recognizing that we, as liver experts, already are developing our own therapeutic solutions with our tissues in and around the liver space. And this gives us tremendous credibility with sophisticated clients focusing liver disease or better understanding their drug in the liver and kidney environment.

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

So the disease modeling aspect, which is the services part of your therapeutic tissue sector, that's the part you see, say, perhaps revenue per unit or revenue per client is substantially greater than the toxicology services, and that could drive your own research into developing your own therapeutic tissue for which you expect an INDD in 202? So that's sort of the balance? Is that -- am I understanding that correctly?

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

I think that's a good way to look at it. And clearly, we're still in an early revenue-generation mode. I see a logical and attractive opportunity to build our revenues along the lines that you just described. We also have mentioned in our comments many of the other ways that complement our platform in terms of how we can monetize our capabilities, starting with our very sophisticated ability to isolate and curate cells, which we do for ourselves, but is also a growing demand out in the marketplace, all the way through to licensing of our technologies for people who would like to bring some of these capabilities in-house. But certainly in the field of NASH, fibrosis and other liver disease areas that we're being asked to begin looking at, we see an overlapping layer by layer of model -- of platform development clients, revenues associated with that, and then the product screening and profiling revenues that come with each of those overlapping platforms that we develop. So it's a nice, healthy business model.

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

And you also mentioned the kidney disease modeling. When do you see your kidney products getting to the same level of interest where you can provide these services like you are now with the liver disease modeling?

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

We already have some early traction in the area of kidney fibrosis with a handful of clients. And clearly, we've prioritized most of our internal platform development to fleshing out our NASH and NAFLD disease model capabilities, often with our clients side by side, funding these developments because they're so enthusiastic. But we see a similar kind of demand from folks in the kidney space. And so we would expect on a staggered basis to be layering in more and more kidney disease model revenues, certainly as we go into the next fiscal year.

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

And so that would be in that 2019 fiscal year, okay.

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

Correct.

Operator

And our next question comes from Reni Benjamin with Raymond James. Please go ahead.

Bin Lu

This is Bin Lu on behalf of Reni. I apologize if my questions have already been answered, as I had some technical issues here. I know your (inaudible) is as the toxicology business represented 35% of the orders in the second quarter, so how should we be thinking this line of business going forward? Is it fair to assume that it's going to end close to 0 in the next couple of quarters?

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

No, I think as a percent of total revenues, it might decline. As an absolute value, I suspect it will fluctuate. But we will continue to provide services in toxicology. A number of our clients have specific issue space, tox problems they need to solve. Others are trying to understand their targets with respect to classes of drugs that they want to explore, mechanism of action. And we also have products in the clinic that are hitting tox issues where those clients are coming to us. And so it's the combination of those more custom solutions, approaches, that generate our -- the tox line of our business. But we -- and we would expect to continue to see some revenues from there.

But really, a key part of our guidance change was recognizing that those revenues may not grow significantly while our disease modeling revenues are really just now taking off.

Bin Lu

Got it. That's very helpful. My second question is your future outlook on the disease modeling business. So maybe can you sort of quantify like the size of this opportunity for (inaudible)? For example, how many, the number of preclinical studies right now by those pharma companies that could be potentially replaced by your disease modeling tissues?

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

The short answer is that this is an emerging market. And so we are basically a path-breaker in this field. What I believe and what we're seeing indications of is that our clients are engaging us at multiple high-value points in the discovery and development process. So we have clients that want to use our platform as a brand-new way, novel way to establish new drug target classes and/or markers that go with them. And that's a pretty high-value platform generation opportunity that you can model looking at other platform collaboration approaches. Take antibodies, for example.

The second area that we're quite active in is in profiling drugs as you approach your handful of optimized leads. Which of these leads should be in what rank order progressed into animal studies? And again, our ability to give answers to that question with hints, if not strong indications of how a drug may fare in actual human setting, has significant value. And so we're seeing engagement on each of those market segments. And you can go to those classic markets to look at how those are sized.

We also have a number of -- the entire regenerative medicine space. So clients who are looking to re-engineer cells and deliver therapies through re-engineered cells or through DNA-RNA therapeutic vectors, et cetera, are all paying close attention to our platform technology as a delivery capability for getting their therapeutic strategies into the body and accepted and to the target organs. That gives us opportunities in the future for significant collaborations.

And then as I mentioned, for each of the therapeutic -- sorry, for each of the disease models that we develop, and just to take NASH. NASH is comprised of several components: steatosis or fatty liver, inflammation and fibrosis. We can model various combinations of those or all of them at various stages of disease. So it's not like we're sitting on one NASH model. We're sitting on a factorial combination of models, and clients may be interested in having us develop 3, 4, 5 custom models to address various target classes of drugs. And so all of these layer on, and the same will be the case for the liver. We hope the same will be the case for others -- sorry, for the kidney. We hope the same will be the case for other liver areas such as hepatitis B. And these are ways that we see our revenues per client building up nicely over time.

Bin Lu

Great, that's very helpful. If I can, can I have one final question here? If I remember correctly, (technical difficulty) $200 million in the toxicology market. So given the change in focus, so how do you think about this long-term guidance and with the business model in business, do you think you can achieve a similar level of pixels from your (inaudible) tissues? Thank you.

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

I think the opportunity to generate significant revenues and growth is clearly there. We're dealing with experimental, disruptive technologies. The good news is disruptive technologies can replace screening platforms, discovery platforms, entire R&D approaches. And so you can take as a potential market the size of drug discovery and what percent of that we might participate in as creating very significant market opportunities for us. But disruptive technologies are also experimental, and I don't want to over-promise the ability of any one of our solutions to be expanded up to massive market sizes.

What I do know is that the closer you get to touching and adding value around drugs in the clinic, the more value you can capture. And the fact that we have clients with drugs in the clinic and classes of drugs coming to us to help them sort out real term decisions, we're now affecting orders of magnitude of value larger than the platform that's working to provide high-throughput screening of tens of thousands of compounds early in discovery.

So our challenge and our opportunity is to capture value all along this chain while also creating some of these drug delivery solutions in the midterm and ultimately to fund and continue the quite exciting progress we're seeing on our own therapeutics program, which clearly we believe has a very attractive NPV for one or more indications, almost custom fit to our therapeutic approach.

Operator

[Operator Instructions.] Our next question comes from Matthew Cross with Jones Trading. Please go ahead.

Matthew Cross

I was looking at your poster from AASLD, and it appears as though for both albumin and AAT levels, there's this kind of rapid uptick, peaking at Week 3 and then tapering off closer to sham. And I was wondering what you thought might explain that physiologically. Is that simply a post-surgical response, or could it have any positive or negative implications during engraftment?

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

I think we're, first of all, highly encouraged that we're seeing albumen and other enzyme production in -- over a significant time. These are still early proof-of-concept studies and so the quantification of those levels over time at the moment has to be viewed as just individual animal effects. And we're still testing out the effects. I'm certainly heartened by the fact that our advisers, such as David Brenner at UCSD, are -- and I don't want to over-speak, but using terms like "blown away" by the unexpected acceptance engraftment and clinical impact that these tissues are having in this first disease model. And as a result, we've been very encouraged to move to initiating our second disease model this year, as we mentioned in our comments. So generally, we're very enthusiastic about what we're seeing in the models.

Matthew Cross

Okay, great, that's good to hear. And then I just have one more quick one. In your release, you mentioned that you had begun to evaluate drug candidates already in the clinic. I was curious what feedback you might have received from customers regarding regulatory perception of this approach at the clinical stage and then the inclusion of those results in subsequent filings?

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

I think at the moment our clients in the clinic are viewing this as a confirmatory but nonregulatory indication that a drug they have prioritized either may be facing an issue or, if they have 2 or 3 candidates, perhaps they can rank them and decide which backup compounds might be accelerated.

The FDA has told us that they -- when we've asked them, "Well, how will you view dossiers showing up with our data?" And they said, "First of all, we'll be quite excited to see the uptake of these complex tissue modeling systems because we do believe that they're very important. But until we start to see submissions, it's really too early to say whether we'll start to set standards, start to demand that all clients begin profiling their drugs using these capabilities or continue to use it as a case-by-case approach."

The other thing I should mention is that many of our clients who have drug in the clinic or even on the market are looking not just for a tox question to be answered, but they're actually looking for mechanistic evidence that they drug could perform in our model, which would be a great repurposing strategy in a human-like setting before they start to gamble on teeing up additional clinical development programs on those drugs.

Operator

This concludes our question-and-answer session as well as today's conference. We thank you for attending today's presentation and you may now disconnect your lines.