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PRESENTATION

Operator

Good afternoon, and welcome to the Organovo Fiscal Third Quarter 2018 Earnings Conference Call. (Operator Instructions) Please note, this conference 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 third 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 third 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 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 jumping right into the excellent progress we've made advancing our liver therapeutic tissue program. We believe our liver NovoTissues has the potential to become a revolutionary therapeutic application in treating many forms of liver dysfunction and impairment. In particular, we're starting a range of clinical indications involving inborn areas of metabolism that can become life-threatening and often result in the need for a liver transplant.

Patient need is great in treating these debilitating pediatric liver diseases, where annual cost of care are quite significant and current cell and gene therapy treatment regimen has had limited success. Our liver tissue aims to change all of this. In late December, we reached our first regulatory milestone with the FDA granting Orphan Status for our NovoTissues treatment of Alpha-1 antitrypsin deficiency, or A1AT. Patient populations suffering from this rare disease are in desperate need of new treatment options. The FDA's quick action recognizes the importance of novel tissue engineering-based approaches for these vulnerable patients. The FDA's Orphan Drug Designation program also provides important developmental and economic incentives to sponsors, so that we can expect to have more frequent interactions with the FDA, including protocol assistance as we design and execute our study.

We also qualify for tax credit for clinical research cost and a waiver of certain registration fees. Finally, Orphan Designation also comes with a 7-year term of market exclusivity upon FDA approval of the Orphan Drug. Taken together, these benefits can provide a more streamlined and cost-effective path to commercialization, while also being substantial drivers of our capital plan and partnering opportunity.

As for our ground-breaking science, we are creating a liver tissue patch that will be approximately the size of a dollar bill when implanted into humans. Simply put, our immediate target would be to supplement the function of a deteriorating organ with healthy tissue. Ultimately, we could delay the need for a transplant, reduce annual cost of care for patients and perhaps even potentially cure some of these diseases.

We've also begun new animal model studies in a second therapeutic indication within the area -- in one areas of the metabolism. The second disease known as FAH deficiency, frequently causes severe liver damage and commonly requires patient to receive a new liver at an early age. We look forward to reporting proof-of-principle data in the coming months on this second important indication.

I like to emphasize that unlike traditional drug development, where a different drug candidate is progressed for each indication, we are embarking on a strategy where the same healthy tissue patch could potentially be used across multiple disease areas. This approach could offer important synergies in terms of manufacturing, R&D and derisking the development process.

Overall, we're pleased with the progress we've made toward developing multiple IND track therapeutics programs. We continue to target the submission of our first investigational New Drug Application to the FDA by the end of calendar year 2020. Until then, we'll continue to conduct safety and dosing investigations in small animal disease models as we move to defining and scoping IND-enabling studies.

Let me move now to an update on our commercial operations. As we announced last quarter, we continue to shift our R&D and business development efforts to high-value disease modeling capabilities. In addition, we're seeing great commercial traction from our Samsara subsidiary, which more than doubled its contribution to our business versus the year ago quarter.

Samsara's procurement and delivery of high-quality human cells provides key building block for our own R&D mission, and these same cells are also increasingly in demand for our clients' research programs. We expect that our disease modeling and Samsara revenues combined will be the cornerstones of our revenue growth as we look ahead to fiscal 2019. These core sources of revenues should also be bolstered by a range of fee-for-service and collaborative agreement, NIH grant payment and proceeds from technology licensing agreement.

As a reminder, the objective of our platform technology is to produce living tissues that mimic key aspect of human biology and disease. Our ability to manipulate our bioprinted tissues to crossover from a healthy to a disease state in liver and kidney system can facilitate breakthrough translational research from target discovery through to high-content drug profiling.

Importantly, by anchoring our work in liver disease, we are addressing growing markets that align with major therapeutic research areas in the biopharmaceutical industry. The case for our focus on tackling the spectrum of nonalcoholic fatty liver disease is quite compelling. Let's briefly review the key factors.

As a starting point, 1/3 of birth world population suffer from deteriorating liver function. Liver disease is a growing public health crisis throughout the United States, Europe and Asia. As a leader in liver research, it's important for us to be a partner in treating liver disease as well as understanding how new and existing drugs perform in our dynamic tissue models, as a potential predictor of human reponse.

Furthermore, according to a recent JAMA publication, approximately 2/3 of patients over the age of 50 with either diabetes or obesity are thought to have NASH with advanced fibrosis. This truly is an epidemic. Not surprisingly, the global pharmaceutical industry has launched over 250 clinical therapeutic programs to pursue treatments across the liver disease spectrum, including NASH and fibrosis.

Many global pharmas have major research programs aimed at liver disease and several of these companies are among our early adopters.

Lastly, liver disease is complex and requires a multipronged approach to treatment. Our leading clients are already working with us to validate multiple platforms that evaluate different conditions of disease induction, progression of the various liver disease states and multiple classes of drugs. In short, our biopharma clients want more human relevant data in their drug discovery workflow to support decision-making around which programs to move forward. And we believe this demand will lead to growing and sustainable engagement with our platform.

I'd also like to share a few leading indicators demonstrating our momentum as we shift to disease modeling collaboration, where our goal continues to be moving our clients from single project studies to larger longer-term relationship.

I'm pleased to note that we've added 11 customer accounts and completed over 40 orders in the first three quarters of fiscal 2018, which puts us ahead of the pace we were on in fiscal 2017. In the fiscal third quarter, substantially all of our service revenue related to developing custom disease models, with some of our repeat clients now moving forward to begin testing their proprietary compounds on our platform.

This is good news because our competitive differentiation lies in our ability to emulate human disease on our tissue platform that predicts how drugs will perform in human. We regularly hear from clients that existing animal model and simpler screening platforms do not answer key questions of functionality required to improve drug development success rate. 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 and look ahead with excitement to forging lasting relationships.

In closing, if you break our business down into its 2 key components, we're developing our own therapeutic solutions to treat disease, while also providing access to our dynamic tissue platform that allows our clients to do the same. This foundation supports multiple paths to monetizing value for our stakeholders, including the curation and delivery of high-quality cells, the partnering of our platform to develop custom models for high-content drug profiling and being successful in our own research mission to deliver revolutionary therapeutic solutions for treating disease.

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 towards our cash burn rate. We look forward to an exciting fiscal 2019 and to updating you again 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, and good afternoon, everyone. I'll start by reviewing of our key financial metrics for the fiscal third quarter and then recap the narrowed fiscal 2018 guidance range we updated today. I'll conclude my remarks by briefly summarizing our balance sheet and liquidity profile.

Organovo generated fiscal third quarter total revenue of $1.2 million, which was unchanged from the prior year period and down 15% sequentially. On a year-over-year basis, total revenue results were driven by higher grant payments and a growing contribution from our Samsara subsidiary, which offset lower collaborations revenue, as key collaboration agreements were completed in the prior fiscal year.

Product and service revenue was $0.8 million, up 19% from the prior year period. We continue to see growing demand from customers for our ability to provision primary human cells for scientific applications, which also supports our commercial and research missions to build dynamic custom tissue models.

As we've assessed the best path forward to monetize the value of our platform technology, penetration at the biopharma space with liver disease modeling services along with Samsara's procurement and delivery of cell-based products to commercial customers will be the key drivers of revenue growth over the next 12 months.

As Taylor noted, the case for moving into high-content drug profiling is quite attractive. Our success in this area will hinge on engaging with our clients to validate multiple disease interrogation platforms, and from there to forward sustain relationships that allow us to become integrated components of their R&D workflow.

I'll focus next on operating expenses. We reported $0.2 million in cost of revenues for the fiscal third quarter, a 9% 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 million, a 20% 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 recorded $4.9 million in selling, general and administrative expenses during the fiscal third quarter, a 12% 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 costs and a $0.8 million nonrecurring charge related to our organizational restructuring.

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 $5.2 million for fiscal year 2018, with the primary contributions, as we wrap up the year, coming from a few key components: Continued uptake of our liver disease modeling services; accelerating growth from our primary human cell and tissue products; as Samsara is becoming increasingly bigger piece of our revenue mix, it has had great commercial success in the last 9 months owing to the high quality and differentiated self-provisioning products it offers to biopharma companies; and ongoing progress on our NIH grant for which we've already reported $0.4 million year-to-date and expect to book approximately $0.2 million in the fiscal fourth quarter.

On the same basis for the full year fiscal 2018, we now expect negative adjusted EBITDA between $25 million and $26 million. We've continued to improve our cash burn throughout fiscal 2018, which is primarily driven by the reduced operating costs we're benefiting from as a 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.

It's worth highlighting that at the midpoint of our new guidance range, our operating burn rate, as measured by this metric, has improved by $4.3 million versus our last fiscal year.

Now for our balance sheet. At the end of the fiscal third quarter, we had a cash and cash equivalents balance of $47.3 million, which includes net proceeds of $3.1 million from the issuance of nearly 2.3 million shares of common stock in at-the-market or ATM offerings. With approximately $14.6 million of funds still remaining under our ATM facility, we have access to nearly $62 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, as we've continued to do in early 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 plan. The S-3 filing we made today, which replaces the remaining amount of our expiring shelf registration supports our ongoing ATM activity. If we're able to continue -- successfully executing against our planned ATM strategy, our cash position and overall liquidity will be sufficient to last us through the remainder of calendar 2018.

I'll wrap up by noting that like Taylor, I envisioned two cohesive and fundamental elements of our business. In the long-term, we're developing our own novel therapeutics to treat liver disease. In the short-term, we're helping our customers advance their own programs by providing vital data to support their decision-making. We look forward to updating you on our progress again very soon.

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 comes from Reni Benjamin of Raymond James.

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

I guess, maybe starting off, can you talk a little bit more about the current collaboration that -- I think Craig mentioned that some of the revenues were lower this quarter primarily because the collaborations weren't completed. Is there a transfer rate -- I don't want to say renewal rate, but is there -- do those collaborations then potentially morph into more of the disease-specific type of collaborations? Or do they end? And can you give us some color on that?

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

Yes. These collaborations were basically around the development of specific tissues. And they are pretty much -- you can think of them that at least the historical ones that we've done have really been kind of one-off, and are not necessarily intended to lead to, what I would call, routine type of screening or disease modeling.

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

Okay. So then as we try to envision how the disease modeling collaborations will grow, can you maybe provide some additional color in terms of the engagement that you are expecting from not only your current clients, but moving forward how you plan on obtaining additional clients?

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

Sure. Reni, this is Taylor. We continue to enjoy a steady stream of new clients entering what I've described in the past as our adoption curve queue with starter projects. And we also continue to enjoy a steady stream of those clients converting to repeat clients, as they work with us in a series of supportive projects towards developing custom disease models specific to their research classes of drugs. And this sort of predictable bill has happened for the area of NASH, for liver fibrosis, and we're starting to see that in other therapeutic areas as well, including our important progress in the kidney fibrosis space. So our business model has kind of a layer-cake approach, where we see each of these custom models layering in, sometimes 2, 3 or more at a given client, and each of them being interrogated by multiple classes of drugs by our clients. So it's kind of a predictable and growing adoption rate. And that's really how we see our business going across liver, moving on to other organs as opportunities arise.

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

Okay. And just maybe to dig in a little bit here. Can you give us a sense as to right now of all the clients that you have, how many are starter clients versus repeat clients in the -- of those that are evaluating specific disease tissue types?

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

So in general and this is held pretty constant for the last quarter, too, it's about 60% returning clients, 40% new clients, which kind of makes sense because I think we've got a broad and aggressive business development outreach out there. So you, obviously, always want new clients entering the fold. And I think I mentioned, there is quite a large number of major pharma and biotech companies just targeting the NASH base alone. And

we're doing, I think, a great job of canvassing that broad opportunity. But clearly, what we want is clients moving forward to complete custom models and then ultimately moving forward to more steady state for recurring and long-term predictable use of our platform.

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

And when you talk about the canvas sort of opportunity that you have, right, those that are focused on NASH, how many -- I guess, you must have a certain percentage that you've already tapped and then probably goals for, call it, this calendar year. How -- I assume, it should be going, but can you give us a sense as to how many of those you could penetrate? And if there is any pushback at this point in your search?

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

Sure. Let's say, our target, and you could look at major liver meeting exhibitors or attendee list to see that a target universe is certainly over 100 potential clients. We feel we're doing a pretty good job of getting our message out to clients either through direct business development outreach or through our regular presence at meeting conferences as presenters. We've mentioned in the past that we have dozens of clients. We've not quantified it further than that. I mentioned, I think in this call, 40 total discrete projects just in this -- the first three quarters of this year. So that gives you a sense that we're well on our way to penetrating that market. But certainly, there's plenty of account work to go. And I think the other part of your question was, does it always work? I have to say, I am pretty surprised at our conversion rate, positively surprised, and how high our success rate is from, let's call it, a cold call to the opportunity to submit a bid to our ability to close those first bids. And it's certainly well over 50%. Clients that don't move forward with us initially, typically it's for 2 reasons. One, they would prefer for us to finish all of our custom work and move more towards highly validated reproducible conditions for our platforms. And by the way, those tend to be talks clients versus those that are comfortable working with us side-by-side on the cutting edge as we tease out all the capabilities that our living tissues can produce in this dynamic disease modeling environment. So I'd say late to doctors is one reason. And then there are clients that are trying other complex modeling approaches or just generally sitting on the sidelines and either vary of new technologies in general or they are more specialty pharma companies that have -- don't have much of a discovery effort primarily focused in the clinic. But I should say even in the -- we have a number of clients, even that just have products in the clinic that are working with us to profile drugs that are already in human testing. So generally, to say, a very nice adoption rate.

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

Got it. And just one final one from me and I'll jump back in the queue. In the liver therapeutic franchise, you mentioned that we'd be seeing some principal data in the coming months. Can you kind of talk to us a little bit about what that proof-of-principle data looks like? And are we still on track for first IND in the calendar year of 2020?

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

Yes. So starting at the end, our target for our first IND submission is the end of 2020. And we're really heartened by Scott Gottlieb and others at the FDA, putting up as encouraging a set of announcements as possible for companies in our space, working with advanced regenerative medicine solutions, particularly in disease -- serious diseases with unmet needs, and even more particularly in pediatric and orphan diseases. And at Organovo, we check everything of one of those boxes quite demonstrably. With regard to how we choose to present and appraise investors of progress in our preclinical proof-of-concept work, I think you'll see us continue to present abstract and papers at leading conferences throughout the year, and we certainly have a scheduled queue of those. And that's where we'll typically demonstrate how our tissues respond in animals, how we may be affecting the disease condition. And ultimately, what we like to see in -- as clearly as possible is a changed survival rate in animals treated with our patch versus control. So these are the kinds of things we'll be talking about over the coming year.

Operator

The next question is from Brandon Couillard of Jefferies.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

This is Matt on for Brandon. I know it's a little early, but anything you're willing to share in terms of how you expect the revenue trajectory develop into fiscal '19, as I look at implied 4Q product revenues, it appears to point towards around $4 million to $5 million annualized rate?

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

Well, I like the way that you used the word trajectory. We certainly see momentum in our business. We see uptick, repeat business and engagement, all the key indicators of growth. So I would hope that we would be providing guidance along those lines going forward. The thing I'll continue to point out is that because we're working on custom disease platforms in collaborations, the projects and month-to-month revenues certainly that we see here internally can be bumpy. But overall, we see a nice uptake in growth. And underlying that is also a pretty strong and straightforward trajectory in our Samsara cell business, which we mentioned is already doubled in a year-over-year comparison. And we see that business continuing to takeoff. So really our decision to supply the raw materials that we're using to other sophisticated clients has turned into quite a successful business. And it also is a great door-opener synergistic with our clients. And we actually are beginning to sort of think of what turns like Samsara inside to demonstrate higher-quality platforms, obviously, including our own. So certainly nice drivers of growth going forward.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

And now that you filed orphan status with FDA, what are the next milestones for the therapeutic tissue? Are there going to be more data releases planned near term? And what are the next milestones you expect to demonstrate with the tissue?

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

Well, the classic regulatory milestones probably the next one we would announce would be results for acceptance of the pre-IND meeting. But that certainly would be outside of the coming fiscal year, but sometime between now and as we get closer to 2020. Outside of that, we -- as I mentioned earlier, we plan to be regular presenters of our data because we believe it's important, not only to demonstrate how the tissues could work in the clinic but also it so nicely underscores our fundamental message that we've created a living dynamic model, highly relevant, of human condition against which one can test drugs. And so all of our short-term commercial clients are fascinated and closely following our successes on the therapeutics side. And many of those clients who have regenerative medicine strategies or have an interest for therapeutic programs in some of these orphan disease areas, clearly are watching us carefully as we work with them on their more traditional drug approaches.

Operator

The next question is from Ed Arce of H.C. Wainwright & Co.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

I have a few questions. First on your liver therapeutic tissue program. You've got now two identified indications that you are proceeding forward with. And I guess the first is, are both of these using the same NovoTissues? And then around that, these 2 indications, A1AT and FAH, if you could just give us a little more detail around why you selected these 2 particular as your first couple therapeutic approaches? And is there any thought or consideration around being clear competitively of your own customers' targets? And then I have a few follow-ups.

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

Sure. So the -- let me start at the end of your questions. I think our clients are really rooting for us to succeed in creating systems that support profiling their drugs. And that's indicated by the fact that they're collaborating with us often real-time long before we've completely validated or

teased out the final capabilities of our platform. Typically, that's a sign of partnering versus sort of a hands-off transaction. I think with regards to our therapeutic strategy, our approach is to put patches comprised of primary human cells providing normal function into humans with impaired organs. Most regenerative medicine strategies, so those of large pharma and perfect biotech companies, are aimed at reengineering cells, using stem cell therapies, using a DNA, transcription strategies, et cetera, and so basically putting something very different into humans that what we're doing, which is healthy function -- functioning tissue. So if anything, our strategy is compatible with those strategies. And it's not unreasonable to imagine we may also partner some days to help clients with those more engineered solutions, embed those technologies into our tissues as we learn more about how our tissues are accepted and function in humans. Finally, one of the reasons we've chose the liver as our primary target, it's a large homogeneous regenerative organ, and often the first steps you learn of the fact that you've got an impaired or seriously dangerous or alarming liver function is when you're down to 10% or 15% remaining functional capacity of your liver. And then you're on a pretty short list, often for transplant or serious intervention. Conversely, therefore, our theory is that, perhaps small doses or patches providing incremental benefit around that time frame may help walk patients back from that transplant event. And that's pretty much at the core of our strategy. Ideally, our patches might be able to maintain liver function indefinitely. So lots of potential there. And I remember the first part of your question, sorry. We're using the same composition and design for our patches across multiple indication areas. And I think that's quite a nice synergistic and derisking approach. And we believe the FDA is quite intrigued by that process because, in essence, they only need to learn and work with us to characterize one approach, and then try that in any condition where the liver is otherwise healthily functioning with the exception of one misforming -- one deficiency, one missing enzyme.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay, that's great. And then just one big picture question around your liver disease modeling studies. You had mentioned in some of your prepared remarks earlier about the existing animal models that often don't answer some key questions around liver function. And I was hoping that you could elucidate exactly what kinds of those questions would you be referring to?

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

Well, it's interesting. Yesterday, we had one of our clients address our employees, Vice President, 30-year veteran of the pharmaceutical industry with several drugs on the market under his belt. And this client is working with us, in our -- with of our NASH model. And we asked him, why work with Organovo? You're already in the clinic. What differentiates us from either classic 2D screening models or animal models? And he looked at us and said, because you're allowing us to work in dynamic human tissues. It's as simple as that. Animals are not good predictors of humans as we know. Even if they give you some ideas of where the drug may perform, they can be way off in terms of what dose works, how doses combine, how they metabolize, et cetera. And these are all the kinds of things that we're looking to try improve upon with our tissue platform.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay, great. I did have one other question just as an (inaudible). I was wondering if the FDA technical guidance that was released back in December on 3D printing technology, does that type of guidance apply to you? And if so, were there any surprises or material changes to what you would have been expecting?

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

The answer is yes. You know the guidance is something, by the way, we'd like to see we played a role in providing advice and feedback into that process, and we're delighted with the FDA's recognition of the importance of not only 3D printing, but complex tissue and tissue engineering solutions as extremely promising, particularly for a number of unmet disease areas. And so as I mentioned, in parallel with that guidance, right around the same time that they surprisingly quickly gave us our Orphan Drug Designation, I'd mention probably a couple of months faster than we were expecting to hear from them, but perhaps because they wanted to end the year with a lot of messaging around the same topic. That's when the Head of the FDA office said, we're looking for a whole range of ways to encourage clients to progress these technologies focusing on

unmet disease areas. And as I mentioned also, as an added bonus, if they have a particular benefit in pediatric orphan disease areas, even better. And that's where we're starting with our approval.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay. All right. One last one, then I'll jump back into the queue. This is for Craig. I just wanted to make sure I heard this correctly, the cash burn run rate through the end of calendar year 2018?

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

Yes, that assumes that we are able to continue to vail ourselves of some modest continued ATM activity, combined with the burn rate trajectory that our operating cash flows are already on, that we effectively would not be in a position to have to do any type of larger financing during calendar 2018.

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

And just to add, the implication there is also that we would end 2018 with an adequate cash reserve for our forward mission.

Operator

(Operator Instructions) The next question comes from Matthew Cross of JonesTrading.

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

Great to see the shift towards disease modeling as being reflected in your revenue mix so quickly. That said, you've taken the revenue estimates for fiscal 2018 towards the lower end compared to last quarter. And I'm curious if that's reflective of an expected change in grant revenue? Or if the disease modeling projects, which you're, as you said, now making up the majority of service revenues or longer term projects relative to toxicology and so the bulk of those revenues is just yet to be realized?

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

I think part of our client tightened guidance is just practically speaking, we had a $2 million spread in the range. And with one quarter left, clearly, we have a much clearer idea of what part that range will fall into. So we just wanted to tighten that guidance. I think as I mentioned on the last call, a lot of our projects are binary in terms of which quarter they fall into. And so our ability to predict at the tightest level often comes down to sometimes 1, 2 or 3 projects finishing early or finishing a month later than expected. There is a fair amount of experimental wrestling that we do here. And while we have a pretty good idea of timing and outcomes, still there's time line variability. And so I think the breadth of our revenue range and the ability to predict even into the near term is affected by those binary outcomes. But we don't see that as a result of lack of client interest or lack of traction in the business model.

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

Sure. Got it. And then second question I had was, I was hoping you could kind of building off of Reni's question, as far as the FAH program and then data that maybe coming later this year. Given that you guys recently received the Orphan Designation for the Alpha-1 antitrypsin program, I was wondering if you could discuss what work may still needs to be done for the FAH program to potentially pick a designation for that one as well?

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

That's a great question. I probably think it's premature to give any guidance on that. But just to speculate because we're using similar materials and approaches, and since -- so you could imagine that the safety side of our database is complementary to what we've already created in and upon which the FDA has already opined. There should be a pretty straightforward path for us repeating the process that we do with Alpha-1 antitrypsin. So depending on how the animal model data comes out, it's certainly reasonable to expect that we would be looking at teeing up this second indication for an IND check program. Sure. And as I mentioned, FAH is also a pediatric orphan disease. So it's best I can imagine, and it would fall in the same criteria that the FDA used to approve the Alpha-1 antitrypsin Orphan Designation.

Operator

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