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VIDEO TRANSCRIPT

AWS Webinar: The Power of a digital thread in pharma
Date: 10/13 @ 11am ET

Speakers:
Stuart Henderson: Client Account Lead at Accenture
Barry Heavey: Managing Director at Accenture
Chris Kopinski: Business Development Manager at AWS
Dan Sheeran: Director at AWS

Fierce Moderator: Ross Youell

Ross Youell:
Hello, everyone. Thank you for attending today's webinar, The Power of a Digital Thread in Pharma, presented by Accenture AWS Business Group. I'm Ross Youell, and I'll be moderating this webinar. Our speakers today are Dan Sheeran, healthcare and life sciences director, AWS; Stuart Henderson, global life sciences industry lead at Accenture; Chris Kopinski, business development executive, AWS; and Barry Heavey, managing director, Accenture. You can read their full bios on the left side of your window by selecting the speakers tab.

Ross Youell:
Just a few technical notes before we begin. The webcast is being streamed through your computer, so there is no dial-in number. For the best audio quality, please make sure your volume is up. This webinar is being recorded and will be available on-demand within 24 hours after the event. Time permitting, we will follow the presentation with a Q&A session. Please submit your questions using the questions and answers tab on the left side of your screen.

Ross Youell:
Okay, now let's begin. Stuart, please go ahead.

Stuart Henderson:
Thanks very much indeed, and welcome to this webinar. I'm delighted for us to have this conversation today. I want to start off with a very positive note in terms of what I hop you get out of today. And the conversation today is going to be building upon what is an extraordinary 24 months for our industry in life sciences in terms of the amazing accomplishments we've done in the light of the pandemic. But in the context of that, it's also highlighted some of the bottlenecks that we've got to address.

Stuart Henderson:
And so today, we're going to talk about those bottlenecks and how to address them. Let me start though with kind of just some of the high level views on what's going on, because I think it's important to put it into context of the amazing achievements of this industry that we work in is doing. First, I want to put it just kind of a broader view on the overall portfolio. We take the whole portfolio of the industry and we categorize it into different structures. And one of those groupings is we call new science.

Stuart Henderson:
New science essentially is assets in the pipeline that are new modalities. They are new mechanisms. They have a technology associated with it potentially. There's unmet need, significant unmet need, and there's essentially a classification that with put on the whole of the industry pipeline. And we classify that in terms of what of that will drive revenues. New science, as a part of that portfolio, that

industry-wide portfolio, is growing. And it's increasing the amount of tech in there, and the amount of capability that is going to be driving that revenue.

Stuart Henderson:
So we see almost 81% of biopharma revenue is going to come from that ... Growth is going to come from that group which we call new science. And the net present value's increased. This is a real reflection on the scientific advancements that the industry's made. And it's extraordinary. And so in terms of science, especially tech in there, it's important because six to seven times, companies, they're excelling in new science and spending six to seven more in terms of dollars, six to seven X more in dollars on the digital side of their portfolio. So that's the first is new science, more important than ever. There's much of that research that's available on our website for you to look at.

Stuart Henderson:
Secondly, there are way more treatments in development, but they're way more complex. We're looking at biomarkers. We're looking at far more stratification disease. And so in terms of phase two and phase three, we see the number of procedures that are in those have increased by 44% since 2009. So it's really important that not only we've got great new science, but it's way more complex. But despite all that, treatments are coming to market faster than ever. It's an extraordinary time, more complex, more science, more tech, but yet it's coming together faster in the market.

Stuart Henderson:
So this is, from an achievement perspective, for you as industry leaders, it's an extraordinary achievement, and we wanted to kind of just start off with a highlight there. But I want to put it in context of, in actual fact, what did you need to do to overcome and achieve that. And there's really three orthodoxies that we've seen you as industry break in the last 24 months. The first orthodoxy is that drug discovery is a process you can't change. We can't change the way we discover medicine. I'm going to use three examples to tell you and show you how industries change that.

Stuart Henderson:
If we look at three companies, Recursion, Insitro, and Escientia, Recursion defines itself as the industrial revolution of drug discovery. Insitro talks about itself being the convergence of human biology and machine learning. And Escientia is an AI-based company, which is actually delivered the first AI drug into clinical trials. These three companies have done an extraordinary job of taking what is an enormously difficult process and bringing tech into it. If we think about every cell in our body has 21,000 genes, and we talk about how many proteins they code for and how many proteins they interact for, it's a great example of where tech and scale tech can make a difference. But you've changed that orthodoxy, and we've seen those deals happening, and we see these companies making great strides.

Stuart Henderson:
Orthodoxy two is we can't deviate from in-person clinical trials. It's very clear at the beginning of the pandemic we had a lot of clinical trials that were either all virtual or all in-person. We had very few hybrid. In actual fact, the concept of hybrid clinical trials really only penetrated to any great scale during the pandemic. And so what we're seeing is a far more thoughtful approach to the increase in terms of the number of clinical trials that will be done with a virtual aspect to it, even at premier sites.

Stuart Henderson:
You see companies that were kind of in the wings pre-COVID, pre-pandemic, now very central to the strategy of every single clinical trial organization, whether it's the likes of Science 37, whether it's the DASO metadata, whether it's Medable, Viva, or THREAD, we're seeing just an extraordinary progress in terms of the capabilities they have to enable clinical trials to be virtual. And by that hybrid, what we mean by that is of a certain number of visits, some of those will be in-person, some of those will be in-person at a local site, and some of those will be

entirely virtual. So we've seen orthodoxy two blown up.

Stuart Henderson:
Where we're going to focus today is on orthodoxy three. And I'm going to hand you over in a moment to Barry Heavy who's gonna kind of talk about this. And the concept is we can't rapidly scale manufacturing for new modalities. Now, in some respects, we would argue that we've seen an extraordinary achievement just in the last 12, 24 months with the scaling of vaccine supply, especially in the mRNA space. We've seen hundreds of millions of vaccination treatments, or vaccine treatments rolled out around the world. It's extraordinary to think how quickly that scaled and how rapidly it is. But there are bottlenecks.

Stuart Henderson:
And the conversation today, I'm going to hand it over to my colleague, Barry. He'll talk about those bottlenecks and how you can go about addressing them. So without further ado, I'm going to hand it over to you, Barry.

Barry Heavey:
Thanks very much, Stuart. Great to be here. And yeah, I mean, to pick up on that point, I think there's been enormous progress in challenging that orthodoxy three that Stuart mentioned. But there's also continues to be challenges. New science never sleeps, so there's constantly new modalities coming to market. Companies have a wider and wider variety of products to handle. And there's been high profile cases of companies in recent years where they've had big challenges and delays in launches because of issues in manufacturing, or delays in just ramp up into the market, the addressable market, because their ability to actually scale manufacturing was somewhat challenged.

Barry Heavey:
So there's been a lot done, but there's a lot more to do. And I guess we want to ask the question today, what if we could do things like accelerate early process development? So it can take six months to a year to just even develop the early stage manufacturing process through your pre-clinical studies, or your first in-human trials. And then when you've got that done, you've got to start again and start scaling up the process and understand all of the variables that might change when you do that. And that keeps happening, that kind of re-development of your manufacturing process has to keep happening as you scale from clinical production through launch and into commercial production.

Barry Heavey:
And what if you could accelerate the pace which you can do each of those incremental step changes in either at the scale of your process or the efficiency of your process? Taking three, six, eight months off what might be a twelve months normal cycle time. And when that adds up, you're seeing potentially enormous value in terms off taking process development and manufacturing of the critical path that it may come on because we're seeing the acceleration that Stuart outlined in the other orthodoxies in drug discovery and clinical development.

Barry Heavey:
What if we could rapidly scale up the efficiency of manufacturing? There are companies now, biotech drugs, protein-based drugs with monoclonal antibodies happening in the market for over 30 years now. But we're only finally seeing companies really maximize yield of the manufacturing process. And there's a small number of companies who are running at 10X the yield in their manufacturing process as the rest of the industry. Those companies have really understood the biology of the manufacturing process and got to a better control of it using data.

Barry Heavey:
And you can imagine if that happened in the car industry, if one automotive company was saying, "We can produce 10X the number of cars per month from the same square footage as all of our competitors," it would be an enormous disruption in the industry. But that's what's happening in this industry at the moment. And I think it behooves all of the companies to try and kind of accelerate the rate at which they're increasing efficiency, even if nothing else, for the sustainability of manufacture.

Barry Heavey:
What if we could have a Turbo Tax kind of approach to making filings and interaction with regulators who are getting approval for these chemistry manufacturing and control dossiers associated with our manufacturing process? And in actual fact, in some cases, the regulators are leading the industry on this. So the FDA in 2019 already launched their CASA program, which is around the management of knowledge, and the sharing of knowledge, and structured applications for CNC filing.

Barry Heavey:
And finally, a constant pain point in the industry is that handoff between different teams as the process, as we described, evolves from pre-clinical to small scale clinical batches, to large scale clinical batches, to commercial. And every time there's a handoff between those teams, these complex, delicately controlled processes that maybe not all of the variable are fully understood yet have extremely high risk of changing and not performing as expected and causing concerns from the regulators and so on.

Barry Heavey:
So the solution that today has really been kind of really heavy and of human intervention and managing those challenging transfer points between groups, either internally in companies, or between companies and their third party partners, either CMOs or collaboration companies. So our question is how can we address these?

Barry Heavey:
So it's a nice aspiration to talk about these priorities. But we want to talk next about some solutions that we think would really help accelerate these. So we talk about this idea of the digital thread in life sciences, which is effectively our definition of this is that it's a truly digital solution that accelerates the scale in the supply of complex treatments, from the clinical trial right through to commercial launch and production, and right through the life cycle of the product.

Barry Heavey:
So again, we can only achieve this kind of acceleration and see this handover between groups by harnessing enormous amounts of complex scientific and engineering data on the process from inception, right through, perhaps 10, 15 years of supply of the product in clinical and commercial manufacturing. Furthermore, we would say that, again, it's a nice aspiration, but we believe there is a solution. And we believe that this solution can be developed by building on established tools. We're not coming saying there's a new magic bullet solution, a single solution that can suddenly solve this problem, this orthodoxy that's persisted in the industry for all time.

Barry Heavey:
Or rather, we believe that the technology now exists to harness the existing systems that companies have invested in, like their ERP systems, their backbone systems, their GXP manufacturing and quality control systems, but then on top of that, using modern tools, like cloud, like AI and ML to really unlock value and help make faster decisions in extremely complex contexts, and lower the risk of noncompliance and under-performance in the supply chain.

Barry Heavey:
So again, somewhat aspirational you could argue, but let's look at some examples. So this slide is really ... I touched on, in one of the earlier slides, the stress that exists in handoff of these complex, delicately controlled, manufacturing processes for these exquisitely complex molecules from one team to another. And this case study really touches on that. And this is with a company that really were a kind of ... They epitomized the embracing of new science. It's well kind of chronicled that this company has one of the most exciting pipelines in the industry.

Barry Heavey:
They've gone from bringing in about 70% of their revenue from four or five products. Now they have almost 15 products bringing in 70% of their revenue. And they have a huge growth in novel modalities like biologics and so on. And actually, our friends at FiercePharma have shortlisted for a number of awards in recent years for a number of their new molecules that were launched that