Oxford Biomedica

Transcript

Moderator: Good afternoon, ladies and gentlemen, and welcome to the Oxford Biomedica preliminary results 2021 conference call.

Moderator: At this time, all participants are in listen only mode. Later, we will conduct a question and answer session, and instructions will follow at that time.

Moderator: We will only be taking questions from the phone line today, and any questions submitted through the webcast will be answered after the call. As a reminder, today's conference call is being recorded.

Sophia Bolhassa...: Welcome everybody and thank you for joining us for our preliminary results 2021 conference call. I'm Sophia Bolhassan, head of investor relations, and I'm joined here today by Roch Doliveux, chair and interim chief executive officer, Stuart Paynter, chief financial officer, and Kyria Mitrophanous, chief scientific officer.

Sophia Bolhassa...: I'll now hand over to Roch to begin the presentation.

Roch Doliveux: Thank you very much, Sophia, and welcome everybody to the 2021 financial results for Oxford Biomedica. I will just share with you a couple of slides on where is the company, and then, let Stuart highlight the financial results and Kyria and Stuart talk about the future.

Roch Doliveux: First of all, I'm clearly delighted about the 2021 performance, which was clearly exceptional due to several factors, the most important one being the large scale manufacturing of the adenovirus-based COVID vaccine from Oxford University/AstraZeneca. And I'm proud that we have successfully manufactured over a hundred million doses of the AstraZeneca vaccine.

Roch Doliveux: And just for the sake of... Because I know several of you had questions or comments, just to highlight that we do expect to continue activity with AstraZeneca this year. We are in advanced stages of discussion, and the discussion around how much and when, and not if so, just want to be very clear on that. The underlying business, if I could have the first slide, please.

Roch Doliveux: The underlying business is growing very nicely, brought in new customers. Can I have the first slide please? So, we are indeed delivering on our strategy to become a global viral vector. I think we are in a very unique position in the biotech space of being an innovative CDMO and an innovative service providers to sell therapy companies whether biotech or large pharma, and what's make us unique is our proprietary platform, our IT, our knowhow, for which customers are willing to pay royalties. The strengths of our quality system audited by large pharma and regulatory bodies all around the world, and our expertise.

Roch Doliveux: And the same recipe of success applied to our AAV business with the plug and play platform that we acquired in Boston earlier in 2022. If I could have the next slide, please. The three reason to really invest in Oxford Biomedica is the fact that we are a leader in viral vectors. Today, we're a leader in lentiviral vectors, and we aim to become leader in the largest of the viral vector, and the fastest growing which is the AAV business by the acquisition of our new platform which has record setting quality and yields performance.

Roch Doliveux: The second is the fact that we have a diversified business of both process development. Again, a lot of the innovative and the IP is coming through this activity, but also, manufacturing revenues, and then, the ability to have a long term upside from our proprietary pipeline, which will require external funding, and we'll come back to that in the Q&A, I'm sure.

Roch Doliveux: And last but not least, the fact that we have an amazing management team with an operation on infrastructure that has delivered, I think, the delivery on the lentiviral vectors, on the adenoviral vector, and now, on the AAV is truly unique. And the fact that we have commercial supply capabilities for both small biotech and big pharma is a huge strength to build in.

Roch Doliveux: And just want to highlight, before I hand over to Stuart for the financial results, that we really believe that this unique platform-based innovative business is coming at the right time of a challenging biotech market for companies not to reinvent the wheel and consider go to Oxford Biomedica as the place to go for any of their process development and manufacturing topic around viral vectors. And as you know, viral vectors is the key to unleash the potential of the vast majority of cell and gene therapy products.

Roch Doliveux: So, as you can hear maybe from my energy, I'm even more bullish than I was when I joined as chair two years ago and great progress have been made to maximise the potential of this company to become global viral vector leader now across the world. Now, to Stuart for the financial results 2021.

Stuart Paynter: Thank you very much, Roch. I'll ask the presenter just to forward on the slide to page six.

Stuart Paynter: So, this is just a bit of a highlight as to where we've been in 2021. So, we really wanted to present the business with a state of play at the strategy which Roch's just given, a little bit of a backward look at 2021 financially, and from an operational perspective. And then, something about the transformative acquisition we just made in Oxford Biomedica solutions and the impact that's going to have on the future and some of the other opportunities that are in front of us.

Stuart Paynter: So, on slide six, this is the start of our look back at the year of 2021, which was a year of substantial growth for us. So, revenues grew 60-plus percent to 143 million pounds from about 87 the year before. Of course, that was largely driven by the large, as Roch said, the last scale manufacturer of the Oxford AstraZeneca vaccine, which we've done at a high throughput, high cadence, and also, with some very nice success in terms of completed batches and yields, which AstraZeneca have been very kind to us to say that we were towards, or at the top of their league tables in terms of those key performance indicators.

Stuart Paynter: You know, interestingly, you'll see the disproportionate impact of the increased revenue throughput as we get to the P&L a bit later and the EBITDA generated. It really does illustrate the fact that commercial manufacture high throughput, commercial manufacture really is something to be learned from and aimed for in the world of innovative services, which we find ourselves in. The more commercial products, the more high throughput products you can get, the more efficient you're going to be utilizing your footprint and your fixed costs, essentially, which is what we found.

Stuart Paynter: We signed two new partnerships. In fact, three new names have appeared on that sheet since this time last year, Arcellx, Cabaletta being the top two. Immatics being another interesting small biotechs in the lenti field, who, as Roch mentioned, have gone down the CDMO route, looking to utilize our expertise to help them achieve their clinical goals, which is exactly where we want to be.

Stuart Paynter: We want to be helping companies both big and small, and we do have the big pharma endorsement, achieving their goals, and ultimately, providing with a solution from very early stage process development, all the way through to commercial manufacture, which is, of course, is the goal to help our partners get right the way through their program. At which point, the royalties, which Roch, mentioned, again, start kicking in.

Stuart Paynter: We've also, post-balance sheet, completed as well as moving from pure entity into adeno, which was done in 2020, we've now completed the full suite of viral vector types in terms of our investment into AAV in North America, in just outside Boston. Yeah, we think that's a really smart use of the pandemic efforts that we've put in, the success we've had in that area, and really, crystallizing that into something that's going to be really, really interesting and transformative to us in the medium to long term, which is our entrance into the AAV business, and leveraging our technologies and our brand across lenti through adenovirus with AstraZeneca into AAV.

Stuart Paynter: And Kyria will take you through some of the technology points a bit later on. So, if we just move on to... Oh, 0.4, not to be underestimated on this slide about the

strengthening of the board. And Roch's been in a... Since his two years as chair has been slowly transforming the board into real world-class gene therapy expertise on the board, both clinical, technical, manufacturing, financial. And so, we think we're in a really good governance place now to drive the future growth of the business in the right way, in the right way for FTSE 250 company to do it.

Stuart Paynter: So next slide, I'm not going to take you through all the points here, but I'll let you read through them. You know, the three key points for us are always revenues. And we've been through the revenue growth that we've achieved in 2021. EBITDA. And that number was about 35 million for the year of 2021. Like I say, driven by that efficiency where we were generating through the high throughput campaign of adeno viral vaccine. And then, how we are transforming that EBIDA into cash generation.

Stuart Paynter: So, you'll see that we had 35 million of operating cash generated from the business to 25 million of operating cash generated from the business, which was substantially more than the previous year. And that enables us to make interesting choices, both in terms of how we fund the business and how we, then, reinvest it into the business, whether it be into R&D for future innovations, or where it's necessary, into lab expansion, capital expansion, to further forward our infrastructural footprint.

Stuart Paynter: Worth mentioning that we did the deal back in September with Serum Institute to fully fund the phase two of Oxbox. So, many of you will know, many of you have visited the Oxbox facility in Oxford and know that there's 25 to 30,000 square feet of fallow area there, which was deliberately designed for a futureproof expansion plan. We believe the time is right to yeah, to be looking at delivering Oxbox phase two. So, we will have an offering to our partners, which is multi-scale, all the way from 50 to 1,000 litter and beyond in terms of the GMP capacity we can offer.

Stuart Paynter: And that provides a commercial solution, not just for our existing partners on lenti, but it provides a solution for AAV as well, and then, potentially, other vaccine work, which we can do. And we've recently signed a memorandum of understanding with Serum on how a future collaboration will look. We're very excited by that in terms of us helping them with their strategy of building up their capacity and capabilities in the UK for vaccine manufacture.

Stuart Paynter: The other area, of course, all importantly is cash. Cash at the end of the year was north of a hundred million pounds. Cash at the end of the first quarter was 144 million pounds. Of course, that was after some quite big inflows and outflows, having transacted the deal and a capital raise in order to fund the deal, as well as some loan financing.

Stuart Paynter: So, you can see we're still in a strong net cash position at this juncture. You know, this was a sort of bridging loan to get us through the way that the capital raise was put together in the required circular. But we've come out of the sort of pandemic period with an acquisition, which we are really excited about and a strong financial position.

Stuart Paynter: So, if we just scroll to slide eight, please. Many of you have seen the slide before. This is the six monthly view of revenue growth. The blue on the top chart being the underlying business, and the purple being the more lumpy milestones and license fees. And you can see that we get something very regularly. In fact, every six months, that we'll see some of that purple stuff coming through, very difficult to predict.

Stuart Paynter: The underlying business is slightly easier to predict. And you'll see there that, looking back to the first half of 2015 when we pivoted to be an innovative service provider, initially, just for Novartis, there's some substantial growth kept off in a year of 2021 with north of 140 million.

Stuart Paynter: You know, the seasonal split there is a lot to do with the throughput of vaccines in the first half, and the arrangement with AstraZeneca on pricing, et cetera. So, we are, again, very proud of that underlying growth, and we expect that to, you know, post-pandemic and with the acquisition we've made in the medium to long term to continue very, very aggressively.

Stuart Paynter: The bottom chart, operating EBITDA. You know, we've communicated this for a while now, that now is, we don't consider now to be the time to generate, to be our aim to generate EBITDA. EBITDA has come from the good delivery that we've made this year, and it gives us those flexible reinvestment opportunities, whether that's to strengthen the balance sheet, or whether that's to invest back in R&D.

Stuart Paynter: But we are absolutely committed as an innovative service provider to generating the next trache of innovations, which is going to enable this industry to make a really big impact in healthcare and bring gene therapies, not just to very rare diseases, but beyond that, to more prevalent diseases in a cost-effective way. And we believe we've got a really big part to play in both. Yeah.

Stuart Paynter: Making it more robust as a process, cheaper and safer. And we're excited to be able to do that in both lenti and AAV now.

Stuart Paynter: Slide nine is our P&L. We show, you'll see revenue, we've already talked about. Costs will go up, of course. Cost of goods with the increase in revenue. There's been a shift, as you can see there from by-processing costs into cost of sales, given the extra efficiency we managed to create, and the absorption of those overheads into cost of sales. R&D expenses have gone up as we continue to

invest. This is absolutely the right thing to do and what we're committed to do for the next few years. Administrative expenses have increased, too, as we have built the governance around a company which is going to springboard now from the lower ends of the 32/50 with, with really significant growth ambitions that the board has set us for the next three to five years. We're set further in terms of building that back office, the control environment, the governance structures, to be able to make the next leap forward.

Stuart Paynter: Obviously, there's various headwinds in the marketplace as well in terms of supply chain and inflation running. But we are in a financially very robust position to be able to not just cope with those changes but actively push the agenda forward with a multi-geography approach now that we're taking.

Stuart Paynter: So, onto slide 11, this is more of a future look now. So Kyri will take you through some of the science in one or two slides' time, but I just wanted to reiterate we've gone through this a couple of times now, why we wanted, the board and the executive team here wanted to make the leap into AAV. Having seen the performance levels in Adnote which was brand new to us, we were convinced that the technologies, the knowhow that we have in having worked in lenti, which is a very tricky place to be for the last 20 years really does lend itself well to that transfer of knowhow across that modality through Adnote and into AAV.

Stuart Paynter: So here, I think we've made a smart acquisition in a very smart way of a fledgling innovative service provider who are currently just providing services to a single client, which we have received the contract for with the latent capacity we can build up very quickly. If we would've done this organically, it would've taken us a few years. We believe this is a really smart way to make an impact in the AAV field with the best in class plug-and-play platform. But the reason we were doing this is because you'll see in that top graph, the lentiviral area is growing at 17% which is not too shabby. And we're already very, very ensconced in that market, but you'll see the levels of activity going on in AAV. And furthermore, AAV really does have a problem with some of the CMC that the FDA has identified, which we truly believe we can form part of the solution for.

Stuart Paynter: So, we believe the time is right for us to bring our knowhow, capabilities, technologies, and ultimately our brand and big pharma endorsement into this area. When you see the market sizes, it makes a lot of sense. So, we will continue to deliver on the alignment in integration and ultimately delivering new customers into that part of the business. And it's going to form part of the growth strategy for Oxford Biomedica Group for the next two, three, four years. And everyone's aligned both the management at Oxford Biomedica Solutions, we, Oxford Biomedica Group and Homology are all aligned that in the next three years. The job of Oxford Biomedica Solutions is to bring clients on and generate

revenue and essentially grab the biggest portion of this market share we can as the market matures. So, I'll hand you over to Kyri who'll take you through some of the science and the technology that we are excited about in the next two slides.

Kyria Mitrophan...: Thank you, Stuart. So, slide 12, please. So today I'm going to share with you some of our plans for future innovation around our platform technologies, as you were saying. These are focused on realizing the potential of avian and lentiviral vectors to revolutionize medicine. Then, I will describe how we are strengthening our product pipeline, first with the continued development of OXB-302 for acute myeloid leukemia. Second, with the application of lentiviral vectors to modify the liver for therapeutic benefit. And finally, the development of in vivo CAR T therapy, a very exciting area.

Kyria Mitrophan...: So first, on platform technologies, our expertise, IP and investments make us well leading producers of lentiviral vectors. In the last few years, we have leveraged this expertise into other vector platforms, as we've heard, with our very successful manufacturer of the Oxford AstraZeneca COVID-19 vaccine. Our long term goal is to become vector agnostic, and to that end, together with Homology Medicines, we've established Oxford Biomedica Solutions a high performing full scope, AAV manufacturing and innovation business near Boston.

Kyria Mitrophan...: We see clear areas of synergy between our current capabilities and our new AAV expertise in Oxford Biomedica Solutions. And I'm really looking forward to the exciting developments we will make by combining our strengths. By improving the amount and quality of vector we can generate, we are opening up new therapeutic indications for both AAV and lentiviral vector products.

Kyria Mitrophan...: Right now, we are focusing co-development activities initially in four areas. First, transfection. Both AAV and lentiviral vector production currently rely on transient transfection. For lenti production, we have learned to make stable transfection mixes that are particularly useful at large scale in GMP. By optimizing the transfection conditions and also switching from three to two plasmas, Oxford Biomedica Solutions have increased the potency of the AAV particles produced. These are the ones that have the vector genome inside them, they're the ones containing the therapeutic genes. Combining these technologies of stable transfection mix, superior transfection conditions should allow further improvements in titer and quality of vector produced, both for AAV and lenti thereby obtaining superior cost of goods.

Kyria Mitrophan...: In terms of upstream and downstream production, we will look to combine two industry leading technologies. 2,000-liter transient transfection and perfusion technology for improved quantity and quality of vector. In addition, the trip system allows for the production of high-titer AAV and lentivectors, irrespective

of the transgene. In terms of analytical testing through Oxford Biomedica Solutions, we have a full suite of analytical methods for AAV characterization and product release. By combining this with our state-of-the-art automation and vector characterization, we expect faster and more efficient testing, characterization and also batch release.

Kyria Mitrophan...: Now we recognize that having the right production cells is key to a successful product and OXB has developed screening technologies for obtaining high-titer production cells, production cell lines for lenti and also developed methodologies for making a stable lentiviral vector producer cell lines. We can apply these learnings to AAV production to meet the expected and current high demands for AAV and lenti.

Kyria Mitrophan...: I'm looking forward to sharing with you the exciting technologies and innovations that will arise by combining the strengths that we have brought together in AAV and lentiviral vector, ultimately leading to the development of life-saving products for our patients. Now, please, can you move on to slide 13?

Kyria Mitrophan...: So first is with a great pleasure that we welcome Dr. Ravi Rao to OXB as our new Chief Medical Officer. Ravi brings with him a wealth of experience gained through senior roles at Sobi, GSK and Roche. Ravi is responsible for developing the OXB therapeutic product strategy, both by building on our existing product pipeline and further evaluating novel areas of opportunity.

Kyria Mitrophan...: We have undertaken an internal review of our preclinical programs. This is ongoing, but I will share some of our latest thinking. Our lead clinical product candidate OXB-302 for the treatment of acute myeloid leukemia is in late preclinical and progressing well. We're developing a new set of products to target the liver that play to the strengths of lentiviral vectors. The liver is a continually dividing organ, and because lentiviral vectors integrate into target cells, a one-off treatment is all that may be required to give lifelong benefit. Now, large quantities of high quality lentiviral vector is required for liver gene therapy, which OXB is particularly good at making.

Kyria Mitrophan...: And finally, we're developing an exciting new innovation, the generation of CAR T cells in vivo. The aim with in vivo CAR T therapies to remove the need for all ex vivo cell processing, by directly administering the lentiviral vector into the body. We expect to be able to treat many more patients and treat them as a first or second-line therapy, rather than third or fourth. This should give better clinical outcomes. To ensure that we adequately resource this new pipeline, we are deprioritizing OXB-203, 204 and 103.

Kyria Mitrophan...: Finally, on the 31st of January 2022, Oxford Biomedica was informed by Sio Gene Therapies of their intention to return the rights for [inaudible 00:27:13]. We planned to out-license the program to a suitable partner.

Kyria Mitrophan...: Thank you, and I'll hand over back to Stuart.

Stuart Paynter: Thanks, Kyri. If we just go on to slide 15, we're just going to cover a bit of outlook and use flow for the year 2022. So, the outlook is that we expect that the revenues will be slightly lower than 2021. As we work with AstraZeneca, as Roch said, to sort of reassess their supply needs going forward, we fully expect, and there will be vaccine revenues in the year 2022, but not at the same throughput levels as 2021. We do expect the number to be significantly more than the year 2020.

Stuart Paynter: We are going to see the impact of the integration and alignment of Oxford Biomedica Solutions into our numbers, which will, as we've highlighted during the deal stage, this is an innovative service provider in waiting as it were, and we need to bring them up to use the latent capacity in order to get them to a profitable state and that will take a few years. We've fully funded that by injecting $50 million into the business at the time of acquisition. So, we tried to be entirely transparent about that but as we are building up their customer base, there will be some losses which we will consolidate into the group accounts, which will lead to a slight negative EBITDA number for 2022. We expect that alignment transition sort of integration period, to be over in 12 months. We are making sure that the business has the latitude to run itself.

Stuart Paynter: Absolutely according to the demands of the business, and we're making sure that we take the best of both cultures, shared technologies and do those things, which will make us strong. This was not a cost synergy play, of course. This is a new business into a fast growing area, so we need it to be agile, well-funded and have the resources it needs to make an impact in that marketplace. What that leads onto is our approach for CapEx in the year of 2022 is going to be relatively cautious. As you'll know, we did the deal back in September. We've asked with Serum Institute of India to fully fund the 50-million pound expansion of Oxbox phase two that's in the planning stage. Now, the main cost on that is not going to be until 2023 and beyond.

Stuart Paynter: But we are making sure that we are integrating the solutions business priority. Number one, making sure that we are aligned to our existing customers and future customer needs on the lenti side as well, and making sure we're fit for purpose for the future in terms of full scale manufacturing up to and beyond the 1,000 liters. So, we'll make those calls as we see fit at the board level and make sure that we are spending our net cash judiciously in that sense. Again, we expect two customers two come on the AAV side in Boston. And on the lenti

side, we expect to continue and build on the momentum of 2021 in terms of new customer signatures, both new deals in terms of expansion of existing customer work and complete new customers.

Stuart Paynter: We believe the outlook is very strong for the year and we find ourselves in a position where, of course the capital markets are relatively soft and have been since mid-November last year, but in that timeframe, we've had the financial robustness to do a transformative acquisition, and we're still in a strong net cash position coming out of that six-month period. So, really, really strong performance. We are excited about where we're going in the future and we put the building blocks in place, we believe, to be able to make a really big splash across the cell and gene therapy industry and becoming a securely set vector agnostic in that sense.

Stuart Paynter: So, if I ask to go onto the last slide, which is a repeat of the first slide that Roch went through. Again, not to be underestimated, the big pharma endorsement, very important, the risk-mitigated approach to cell and gene, we're not taking those big clinical risks that you see some companies have. And ultimately, the scale we have now achieved of close to a thousand people across two continents, audited by the FDA and many other regulatory authorities, Japanese FDA, and MHRA, this is a real barrier to entry. So, we really believe we're in a strong position now to serve our customers, keep on innovating and, ultimately, to aggressively grow the business in the medium to long term. And with that, I'll hand back over to Roch for closing comments and to open the Q&A.

Roch Doliveux: Thank you Stuart for clear and Kyri also. Exciting future which started already. So, the floor is open for question.

Moderator: If you wish to ask a question at this time, please signal by pressing star one on your telephone keypad. Please ensure the mute function on your telephone is switched off to allow your signal to reach our equipment. Again, please press star one to ask a question. We can now take our first question from Alistair Campbell of Liberum. Please go ahead.

Alistair Campbe...: Oh, thanks very much for taking my questions. I've got a few actually. Can I start with just thinking about some of the R&D collaborations you've signed during last 12 months? I mean, deals with Circularis Virca. Obviously, looks like those are deals intended to improve your internal productivity and yield. I'm just kind of intrigued, do they come with any significant economic pay aways or profit shares that we should be aware of which could influence the economics of business going forward?

Alistair Campbe...: Second question, well, I'm going to try my luck. I'll probably not have much, but just thinking about Novartis, increasingly they seem to be pointing towards their

new T-Charge technology as the key to truly building a successful CAR-T portfolio. They had data from one of these projects late last year, which is kind of a Kymriah upgrade, and the data look pretty good. And they're talking about moving that into registrational trials this year. And doing a bit of digging around, it looks like that's also powered by lentiviral technology. I mean, would I be foolish to assume that you are involved in that? And just to confirm, any future products that come from that Novartis pipeline, would they be on similar economic relationships or arrangements that you currently have with Kymriah? Thanks.

Roch Doliveux: Kiri, you want to take two questions and maybe Stuart can come in.

Kyria Mitrophan...: Yeah. So, in terms of the... Thanks for the question, Alistair. The collaborations you outlined with regard to Virica et cetera, are, as you say, to strengthen the platform with regard to lentiviral vectors. Can we improve the quality and quantity of vector that we manufacture? I don't want to disclose any of the financial terms. I don't think that would be appropriate to do that. With regard to your question regarding T-charge technology, I think we'd have to defer to Novartis to confirm that they're using lentiviral vectors, but most CAR-T therapies are using lentiviral vectors, if I can say that. And in terms of the financial terms for CAR-T therapy, Stuart, I'll ask Stuart to comment on that.

Stuart Paynter: Yeah. I think you're right, Kiri. I mean, T-Charge is something that Novartis would need to comment on. It's still in its investigational phase, as you mentioned, Alistair. We've got a long, well-trodden path with Novartis now about how we work with them, and we've been working with them for the best part of seven or eight years, and we wouldn't expect a big difference between the economics of Kymriah, et cetera, to anything new we work on them with. They're still going to utilize our platform to do that. So, yeah.

Stuart Paynter: I mean, just to comment on the research pieces that you mentioned, Virica et cetera, I mean, Kiri's absolutely right. Kiri and this team are extremely clever people, but we can't make every single innovation necessary to continue at the cutting edge ourselves. It just can't happen. So, what we do is, Kiri and the business development team scour the world for some of the best innovations ongoing. And we look to catch them early and build collaborations, tech licenses to technologies, which will then fortify our platform and our offerings going forward.

Stuart Paynter: So, we're trying to do this in a smart way. We're not trying to do everything ourselves. We're trying to look at the important stuff ourselves, but we're making sure that we are leveraging these really smart, innovative, small companies who can help us fortify our platform, which ultimately is going to be the key to the offering, whether it be AAV or lenti. If we are going to be an

innovative service provider, we need to be offering the latest technologies to our partners in order to give them a robust, safe, high yield process, which they'll pay for.

Alistair Campbe...: Can I just slip in one cheeky last one, which is just, I think you referenced CMC issues that the FDA seemed to have identified with AAV, and obviously you're hoping to address those. Can you maybe touch on some of the key areas you're looking at there, where you think you're going to have technologies that can improve the quality of AAV?

Roch Doliveux: I think the core, and when we disclose about the acquisition of the Homology plug and play platform, is, the ratio of full to empty capsid is one of the array. It's not the only one, but it's one that got a lot of airtime because the quantum is so important of difference. The average I think of the industry is around 70%. So that means you have 30% of empty capsid that just do nothing except compete for the efficacy of the field capsid and add to the toxicity. And that's one area where we feel we have a leading edge with our AAV platform and where more is to come.

Alistair Campbe...: Okay. Thanks very much, Roch.

Roch Doliveux: Thank you.

Moderator: We can now take our next question from Miles Dixon of Peel Hunt. Please go ahead.

Miles Dixon: Hi there. Thank you. I read in the RNS this morning that you were... I think the quote was that you were working hard to bring in additional partners in FY '22 for the US AAV footprint. I think it's all wrapped up with... Can you give us an update on how the integration is going? I know it's still early. But also, where you see the maturity of the BD function in the US in bringing those additional partners in on top of the 25 million from Homology. Thank you.

Roch Doliveux: Thank you. So, the interest in the platform is very strong. We have several CDA sign, we have several business propositions, so all that in a matter of less than two months. Several business proposition already out. So, I'm very confident with the guidance we've given that by the end of the year, we bring two new customers in. The integration is not so much an integration because we have a LV business, and we have an AAV business. So, the key area really is about innovation. And I think Kiri talked about it. He has a slide where he shows... And there is already work that has started on a few of this work stream that Kiri highlighted about enhancing each other's innovation.

Roch Doliveux: It's about sales and marketing, clearly. We have the sales team common to all our platforms. I mentioned the very strong momentum we're having there. And

of course, we're mindful of the cultural sensitivity. You bring two different cultures together and we want to keep the best of both, but at the same time, this is not a big pharma integration. This is an add-on strategy business, which is fully accountable for the [inaudible 00:41:20] with align incentives to our three year target. And so, everybody's incentivised the same way, so it makes things very easy, I should say.

Stuart Paynter: And Miles, if I could just add the investment we've made in sales. We use the term BD. We used to use it. We use it slightly more advisedly now, right? We've got sales function, a commercial function. And then we have a BD corporate development function led by... One's led by Jason Slingsby, the BD in corporate development, the other led by Dave Backer, who is someone based in California, who came from Elevate but very used to the AV field, an expert in AAV.

Stuart Paynter: So, we are trying to speed up that sales cycle by making it a more commercial process rather than a big deal every time we do a deal. We've invested in both an east coast and a west coast rep reporting to Dave. So, we have moved from, basically, in the last two years, Jason, and a couple of colleagues based in Oxford, to a truly international sales team, and Jason with his BD and corporate development hats on led the process that got us Oxford BioMedica Solutions. So, we have bifurcated that area and we've made those investments in order that we can drive quicker and more volume of sales.

Miles Dixon: Thanks, Stuart. I'd noticed earlier on you talked as well about the increased cadence of deals. I wondered if you cared to comment, not just in AAV, but more broadly across the group, how the profile of those deals and the type of companies that you're working with has changed over the last 18 months in particular.

Roch Doliveux: I can say that the momentum is much stronger than pre COVID, so pre the big focus of the company on the vector for the vaccine. So pre that focus, our momentum on the lentiviral space is much stronger now. And the profile of customers is very different at this stage, because in LV we're established, so large companies are a target in addition to innovative biotech in the AV space.

Roch Doliveux: The first two customers that we expect are small customers that will validate the fact the performance that was done on the clinical batches for Homology as a customer can be validated to other customers before big pharma, or, yeah, big biotech aligns with us on the AV. But I'm very confident, because I'm impressed to see that even large customers are interested at this stage in the AV. But to set up your expectations, I would expect really the first two deals to be smaller deals to validate, and that's our assumption before large customers come in, whereas on the lentiviral space, you should expect more big customers also.

Miles Dixon: Many thanks, Roch. I'll get back in the queue.

Roch Doliveux: Thank you.

Moderator: We will now take our next question from Charles Weston of RBC. Please go ahead.

Charles Weston: Hello. Thanks for taking my questions. Perhaps I can just start by following up on Miles on new business development. You mentioned that the first couple of deals in the US might be smaller ones. Beyond that, would you be targeting late stage clinical or potentially even commercial products that could have quite an immediate impact on revenues? Well, clearly, you'll be targeting them, but how likely do you think it is that there'll be a material mix of those larger projects rather than the earlier stage ones that of course take longer to come to fruition?

Roch Doliveux: Yeah, it's a great question. The one that take longer, and the earlier stage are the one that lasts long also, because you don't compete on [inaudible 00:45:45] compete with the CDMOs. You basically set the process, how people solve their issues, and then they stay. And as you've seen in our customer retention on the lentiviral space, so I expect the same dynamic there. That being said, I think it will take a while before we get large manufacturing scales. When I say a while, not this year and maybe not next year, so it will take probably a couple of years before we get large scale AAV in the activities.

Stuart Paynter: And-

Stuart Paynter: Hi, Charles. Just to follow up on Roch's answer there. In terms of the investment, we're making in Oxford in Oxbox phase two, that space is going to be genuinely flexible advanced therapies manufacturing space. So, we will credibly be able to offer a solution from early stage commercial development process development in the US for AAV and in Oxford for lenti and adeno, all the way through clinical supply, all the way to a genuinely FDA approved commercial facility. So that really is a differentiating factor for us. So, we are making sure that any future builds have that sort of strategy in mind, the long term in terms of multi-scale, all the way up to 2,000 litre, potentially, commercial manufacturing that's been FDA approved.

Charles Weston: Understood. My second question is on the R and D, your product R and D. Has your strategy evolved further in terms of your thinking on, at what stage you're likely to want to take assets before out-licensing them? And if you can just provide a split between the product and the platform R and D expense in the P and L, that would be helpful.

Roch Doliveux: I'll answer the first one, and let Stuart come in on the second. We have not yet an answer to your question and that... Ravi, who joined as chief medical officer,

that's his first job, is to provide an answer to your question. That being said, one thing that is pretty clear is that we plan to expand the product side through different type of funding and innovative approaches rather than self-financing. And the fact that Ravi works part-time, for 50% of his time, for Oxford BioMedica and 50% of his time for SV Venture, I think is a good indicator of the type of thinking we have on the financing.

Roch Doliveux: You know, how do we move ahead the product? It's not just a question of financing. It's a question of management focus. Our focus in the next two to three years is entirely on delivering on the lentiviral vector platform and the innovation around it. So, the challenge is how do we keep on moving our assets without distracting management attention nor financial resources? And that's something that, again, we're working on. Stuart, you want to add, or correct?

Stuart Paynter: Yeah. To the second part of your question, Charles, in the appendix here, we've got a segmental split, which shows that the product R and D roughly mid to high single digit millions of pounds for the year. The remainder is the R and D we spend on the innovation services part of the business. I do want to address something that we did say at the half year about segmental reporting. We're going to do something different. Actually, we decided to postpone that given the acquisition of solutions to make sure that we don't have to do it twice, we're just going to do it once, and to see how that fits in best. And we can present that with transparency.

Stuart Paynter: But as Roch said, the key for us is that these are very different risk profiles, these two areas of spend, and how best to both not just present, but to preserve and enhance the value of both of these propositions, innovative services, and our own products in order that it's very clear where investors' money is going and how we want to play this game, because there are genuine synergies in doing what we do and the ability to generate new products, and it's how to best give life to them. And so, they're not competing on capital with those areas that Roch mentioned have undoubted focus over the next two years, which is the innovative services piece. So that's Ravi's job, and we look forward to him getting his feet under the table, both here and at his other job at SV, and giving a proposal to the board in due course, where we will then look to execute the strategy.

Charles Weston: Thank you. And just a really quick last one, just for you, Stuart. Could you clarify why the revenue outturn for the year was less than the number that you indicated in January, please?

Stuart Paynter: Yeah, well, we knew that question was coming, Charles, because you put it in your note this morning. So, shame on me. I haven't got a response to it. So yeah, well, let me give you a bit of background. So, the control governance we have

over our revenues is that we tend to do quite big, complicated deals. The Novartis deal at the end of the year being a good example of such. As you'll recall, we negotiated back the non-exclusive rights to CD19 and two other leading CAR-T targets, back to Oxford Biomedical. So now we're free to operate in those areas, which we consider has significant commercial value. And the proof in the pudding is going to be in the first time we sign a deal around CD19 or those other two assets, those other two targets I should say. And we hope to be doing that in due course.

Stuart Paynter: On the flip side, we released Novartis from the capacity reservation fees and minimum call offs, more to a, yeah, pay as you go type arrangement, which we are currently with Novartis on that, gave them flexibility and that was worth something to them.

Stuart Paynter: As a governance, we have a revenue recognition advisory firm, a big four, that works with us on putting together the accounting papers around these complicated deals and advises us on both [inaudible 00:52:53] 15 standards and whatever the relevant guidance is around those revenue points. And we performed that control at the time. So, we did the deal, looked at the contract, wrote the paper, had it advised upon by another big four.

Stuart Paynter: And the final part of the control is obviously agreeing the trig with the auditors. And we were in a situation where we did a deal which was relatively unique. And we had a different interpretation, along with our advisors, to the interpretation which the auditors had. Now, this is getting to be a bit of an occupational hazard for a company that does complex deals. And there wasn't a good example, even in the guidance of a deal, anything like this. So, whilst we and our advisors, our big four advisory firm, believe that our initial belief of what the accounting would look like would stand, it was a debatable new point, novel point, that no one had come across before. And in depth discussions with our auditors, another number was agreed upon. So, whilst I won't go into the nitty gritty of the Qantas, because I think that's commercially sensitive, suffice to say that we ended up recognising slightly less than we initially wrote the accounting paper, and got advice that we could.

Stuart Paynter: But yeah, it is an occupational hazard for a company which does complex deals, which is another reason why my point earlier, we're trying to bifurcate those complicated BD commercial development deals from these commercial stroke sales deals. We want this to become faster and more standard and more predictable, rather than having to fair value 78 pages of a contract with all sorts of different bits in it, which often leads to consequences which in terms of revenue recognition we have to get advice on to take to our auditors. It's that complicated.

Stuart Paynter: So, for you guys and the general public, it really becomes very problematic in trying to assess where we're going to be from a revenue perspective. So short question, Charles. Long answer. Apologies for that. But that's the kernel, the essence of the issue that we faced.

Roch Doliveux: I think the important thing from us is that both from an EBITDA and cash standpoint, there was no change.

Stuart Paynter: Yeah. That's a good point. [inaudible 00:55:32] consensus, Charles. It was cash neutral. It was not a cash issue.

Charles Weston: Yeah. Thank you very much for the clarity.

Moderator: We can now take our next question from Joe of H.C. Wainwright, please go ahead.

Joe Pantginis: Hi, good morning, everybody. Good morning and afternoon, I should say, and thanks for taking the question. So, a couple questions. First with regard to the internal pipeline, and this is going off some of your earlier comments, I just wanted to take it a step forward. It's always been evolving your strategy with regard to the pipeline. So, if you just look at your most advanced right now, as of today, do you think you would take 302 into the clinic yourselves?

Roch Doliveux: Nope.

Joe Pantginis: Perfect answer. Thanks for that. So, I guess going backwards with regard to some of your prepared comments, when you look at the Axel PD program, I guess the first part of the question is how would you define the level of maturity for your discussions right now? And are there anything that potential partners might be considering? Because obviously the program has had a very positive evolution, especially when you look at the improvements you made over pro seven and the long term clinical data. So, are potential partners looking at anything beyond the current clinical data with regard to say commercial landscape or potential future vector improvements, anything that we need to consider?

Stuart Paynter: Cary, you want to take that?

Kyria Mitrophan...: So, we are in early stage formulations about discussions for the future. With regard to any additional technology improvements, obviously we've carried on developing the antiviral vectors and there are new improvements that we've made, processee and so on, that longer term can be incorporated to give an improvement in the cost of goods. So those will be factored in our discussions in the future. Yeah, I don't think we can say more than that. So, the improvements that we are making on the underlying lentiviral vector platform would likely

apply to [inaudible 00:57:52] PD and therefore can be incorporated to improve the cost of goods and quality, which will be of value as you get into a commercial stage product. It won't affect the current clinical plans because those are ongoing materials being made and so on.

Stuart Paynter: And maybe just to add to that-

Joe Pantginis: That's helpful and, yep. Sorry.

Stuart Paynter: Sorry, Joe. Yeah, Stuart, obviously we did a ton of work in the background in the three years that these programs with Axovant and then Sio. We successfully translated the adherent process to suspension, which it was vitally important for the cost of goods and was one of the key things. And we've got a nice sort of process working now. So ultimately these discussions for the return of rights are still ongoing. As soon as they're finalised, we've got one or two people who are interested in opening discussions in terms of having a look at the data and potentially discussing with us how we can partner to get this to the market. Obviously, Cary's been working on [inaudible 00:59:07] stroke, OXP 102 stroke XL [inaudible 00:59:11] PD for a long time. We really do, as you mentioned, Joe, we really do believe that this product needs to be put into patients to really test the thesis that this increases these dopamine levels and gives long-term relief.

Stuart Paynter: It's a very underserved market, and we believe we can still form part of this solution. We are pretty bullish about our opportunities to when it comes back.

Joe Pantginis: No, that's very helpful. Thanks for that. And my last question, I guess it's really a technical question for Cary, and obviously a lot of your processes that we've talked about at length in the past, are quite proprietary, but I guess I wanted to focus on one part that's intriguing, especially when you look at the trip system and the comment that the efficiency and quality and et cetera is irrespective of the size of the transgene. So obviously that's I think a very important improvement there. Any even high level description of that system, why you can make that statement?

Kyria Mitrophan...: So, with regard to the trip system, so the mechanism of action there is to suppress the expression of the protein during production. Usually, we find that depending on the transgene, that can interfere with the vector production, both with AAV and with lenti. It's not so much a size issue. So, it doesn't benefit in terms of the size, it benefits by the removing that protein in a number of ways. One is you get more vector particles, especially if that protein interferes with particle formation. The other is it isn't present in your downstream purification, therefore that protein, whatever it is, is less likely to interfere. And finally, as we touched on earlier, in terms of AAV and lenti, it would be best not to have the transgene present in your dose of vector to be administered. You are less likely

to get an immune response, an inflammatory response that could be problematic.

Kyria Mitrophan...: So, the trip system acts along in a number of different ways to improve the quality of the vector that is made. And that is both for AAV and lenti. And some of the data coming out of the AAB clinical trials indicate that the presence of the transgene can cause an inflammatory or immune response to the transgene, which can then contain a long-term expression. So that's where the benefit is from the trip system.

Joe Pantginis: Great. Thank you for all the colour, guys.

Stuart Paynter: Thanks, Joe.

Moderator: We can now take our next question from Julie Simmons of [inaudible 01:02:05]. Can you please go ahead?

Julie Simmons: Thank you very much. Just a couple of questions on Oxbox, if that's okay. Looking at the agreement you just signed with Zerum, you're looking at putting in two 2,000 liter scale reactors into there. What else are you looking at putting in that part of the facility?

Stuart Paynter: Hi, Julie. So, we're going through the planning phase at the moment, so yeah, you are right to suggest that we want to see that scale to give us full flexibility around commercial solutions for both AV and vaccine. And ultimately for lenti in the future, when the process becomes much bigger than the standard 200 litre process. We have about 25,000 square feet to play with. 2,000 litre suites are big, purely because of the water systems that need to go in, and of course the size and scale of the bioreactors themselves, and the fact that you need to have many bioreactors scaling up all the way through the process to 2,000 litres. So, we are currently in planning and seeing what we can fit in there comfortably.

Stuart Paynter: As you'll recall, the first part of Oxbox was built with the future in mind. So, we already have much of the utilities work done, which is really helpful when it comes to that process of planning. But we are doing that planning in conjunction with some of the people who have gone through this process before, particularly our partners at Zerum who have given us some really good technical advice on how to build fully flexible advanced therapies manufacturing spaces and get the most bang for your buck out of the floor plan. So as soon as we've got to finalised plan, we are happy to share. For the time being, we're looking at that flexibility, but you are right to suggest 2000 litres are definitely involved.

Julie Simmons: Lovely. Great. And then just on the fill finish suite, looks like you're going to be getting approval for that fairly shortly this year, I guess, from the time. Does

that help in terms of finding up new partners, or are partners currently reasonably comfortable with going elsewhere to get that part of the process done?

Roch Doliveux: Make it simpler for sure.

Stuart Paynter: Yeah. We identified long ago, Julie, that we essentially, Oxford Biomedica is subcontracted the fill finish. So, we were on the hook for it, and we weren't in control of it. And actually, it has given us various elements of issues over the years. So, in terms of our control, as Roch said, what we're looking to do is offer our partners complete control from getting the [inaudible 01:04:54] in, doing the production, all the way through to frozen vials. And that's what the fill finish will enable us to do. And you are right to say that it's going through its validation and process right now. We expect approval surely.

Julie Simmons: Brilliant. Thanks very much.

Moderator: Here's the question and answer session. I would now like to hand the call back to your speakers for any additional or closing remarks.

Roch Doliveux: Well, thank you very much for your time. We run a few minutes over, and thanks for your interest in Oxford Biomedica that meant there was a lot of question, and hopefully we shared with you the enthusiasm of 2022 and beyond with both our LV business and our AV business, which is starting on a very strong footing. And also, hopefully we've clarified the misunderstandings, perhaps around the activities around our vaccine business for this year, which is continuing again at a different level than last year, clearly. But we are continuing manufacturing the vaccine this year, and we are in advanced discussion with AstraZeneca on the how much and when and have great relationship with them. So, thanks for your interest again. And any question, feel free to contact Sophia, who will be delighted to provide you more answers if you have questions after this call. Thanks for your interest. Have a great day.