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Oxford Biomedica

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Jem de los Santos: Good afternoon, everyone. My name is Jem de los Santos. I'm with the Healthcare Investment Banking team based in London at J.P. Morgan. Very pleased today to present Stuart Paynter, the CFO of Oxford Biomedica.

[applause]

Stuart Paynter: Thank you very much. Thank you for sharing some interest in Oxford Biomedica. Let me take you through a brief presentation on who we are, what we do, the successes we've had, some of the challenges we face.

I'll try to spend 25 minutes doing this and then we can, hopefully, have a few questions. If there's anything I say that doesn't make any sense, please interject. Let's make this a bit interactive.

Going past the forward-looking statement slide, who is Oxford Biomedica? We are a pure-play CDMO and we are focused on the cell and gene therapy area.

We've only recently transformed the company into that business model. Previously, in the incarnation of Oxford Biomedica for the previous 20 years, we were a hybrid company, both doing our own therapeutics and doing CDMO services.

We've decided that the work we've done over the 25 years, especially in lentiviral vectors, really lends itself more to working with clients in order to help them solve their problems, develop their products, than it does to develop our own therapeutics. It's very difficult to balance both.

We are pure play. We are focused on the cell and gene therapy area. We're not a viral vector CDMO as such, although that's the major service we provide. We say we're a cell and gene therapy-focused CDMO. We're pretty unique in that aspect.

In terms of capabilities, we have the capabilities to go from very, very early stage with our clients, from identifying the genes of interest, right the way through to commercial GMP manufacturing.

We have been working with Novartis for 11 years, but actually doing their commercial manufacturing for Kymriah since August 2017 when that product was launched in the US. We are still the sole global vector manufacturer for that product.

In terms of our technologies, we go across the viral vector types, so long legacy in lentiviral vectors, which is what we're probably best known for. Over the past couple of years, we've made some acquisitions and licensed some technologies, giving us significant capabilities in both AAV, and adeno as well.

During the COVID period, we manufactured the AstraZeneca COVID vaccine, which was an adeno vaccine. That gave us experience both in commercial manufacture of adenos and access to an adeno platform, which we now use.

As I said, products on which we work are now commercially approved in more than 40 countries, and that is Kymriah.

One of the USPs we have is that we can help our clients from a regulatory perspective, do the filings and get approved in many, many countries around the world. We understand the regulatory landscape for cell and gene therapy.

We've got nine GMP suites across Oxford, UK, Bedford, US, which provides us with plenty of capacity. We've successfully made 340 plus batches of viral vectors.

We'll come on to this later, but one of the reasons we win in the field against much bigger competitors, and we'll go through some of the competition as well, is that people do ask what your track record is, and that's a substantive track record for a cell and gene therapy viral vector CDMO.

We've got 24 clients, 41 programs, marking the beginnings of a very nice portfolio. Always looking to add to that.

One of the key things as a CDMO you need to be is flexible with your scheduling, and you need to be able to replace products which either fail clinically or get deprioritized, etc. Whilst your clients can be tinkering around with their decision making, you have a solid basis on which to grow.

Then, at the bottom, there you just see some of the names we work with, all the way from Big Pharma, Novartis, BMS, Boehringer Ingelheim, right down to some of the smaller emerging biotechs you see there.

What's the plan? Since we made this transformation, and we announced a right-sizing of the company late last year, which we believe will save an annualized £30 million, we've outlined the sustainable growth plan, which we're putting in place.

We've right-sized the business to give it a CDMO base rather than a hybrid company base. All that has happened in 2023, and it will be accounted for in that period, so 2024 is a clean run for us.

We set out our strategy, which I'll take you through. A strategy is nothing without a strong implementation plan, and we've been working very hard on that.

Then, key is the pathway towards profitability, because we are a CDMO focused on cell and gene therapy, which is a maturing market. We'll take you through some of those numbers.

We have no other modalities we work on. In terms of some of our competitors, some of the bigger guys like Lonza, Thermo, for example, Catalent, they have multi modalities they work on. This is just one of them.

We are focused in this area, which is both a strength and a bit of a risk, but we'll go through why we think we're going to both mitigate and leverage that risk to give us extra focus.

The clear strategy. The transformation which I mentioned has taken place now. We are now right-sized as a pure-play cell and gene therapy CDMO, and we believe now is the right time to do that.

The market is high growth. As you can see, some of those numbers, it's roughly weighted 20 percent CAGR. Adenovirus is coming down, as you can see on that slide, but that's because of the vaccine.

Both AAV and lenti, the two prevalent viral vector strains, they're growing very, very strongly. We expect them to continue throughout not just the next three years, but as you can see there, it's a '20 to '28 CAGR. That's significant growth.

The quality and innovation-led strategy we have is super important. Over our time period when we've been working with lenti and on lenti, we've made some significant strides in both the ease of manufacture, the purity, the efficacy of our viral vectors. We've just launched the fourth generation of viral vector, which I'll take you through soon.

We've been working on viral vectors for more than 20 years, and we've had individuals with us since that time working. The innovation is super important to bring down the cost of these therapies to the payer and, ultimately, get more patients treated. We know this is an important issue in the industry right now.

Quality, of course, is everything. Focus on quality, both in terms of the quality of the product, the regulated quality of the product, but not just that, the quality of the operations. It's the right-first-time attitude, the client-centricity.

We want to be seen as a high-quality player. That, of course, enables you to be on the premium end of pricing, which everyone aspires to be with the technologies you have.

We know we've got proven platforms and differentiated platform technologies. As you can see from the client roster we currently have, we're looking to grow that client roster, but people do come to us because they know that our vector system does work and has been on the market for the longest time of anyone with the lentiviral vector on the market.

The goal for the company is to become multivector, multisite, so we want to be able to do everything, everywhere.

That speaks to the client-centricity of the new strategy, focused on what the client wants, especially for process development clients typically want to be close to the work that's going on. It's very, very important for them to be in full control and understanding, working with us in a partnership.

Obviously, the global footprint is very important. We're just about to close a deal in France, which I'll take through on the next slide, which does make us genuinely internationalized.

We need to integrate very, very closely, share both technologies and know-how in a controlled, secure way in order that we can fully leverage the 700 people we currently have and another 140, 150 coming with our French acquisition.

The implementation plan. Let's start with commercial. Until a couple of years ago, we were probably the company that did business on a word-of-mouth basis in a very, very big licensing deal-type way. A business development type model that we were running, and we've switched that into a commercial model. We've invested in that area.

A couple of years ago, we had four people working in our business development team. Now, we've got 15, 16 people. We've heavily invested to give us the share of voice and feet on the ground to match some of the bigger competition that we see. That's paying dividends in the increases in orders that we're seeing.

Orders, obviously, is a key metric, key barometer for where your revenue is going to be next year. We've seen some strong order growth in 2023, which we're confident we can continue into '24 and beyond.

We've concluded this workforce reorganization. It involved a good number of colleagues leaving us to right-size this into an efficient CDMO.

When you're running a dual operation like we were, both a CDMO and developing your own therapeutics, you build an infrastructure which is difficult to manage because they're doing lots and lots of different things and there's multi-skill. We're trying to focus the skills, so everyone's doing one of two things well and there's a whole bunch of new ways of working, which we're integrating right now.

With the experience of our top management, we've all got significant CDMO experience in order that we can morph ourselves from one thing to another.

It's extremely important. It's a transformation that will take place over the next couple of years. The right sizing has been done, but the transformation just starts.

We are currently transferring our technology from Oxford, the lenti technology, into Boston. We'll do the same into France when that deal closes because we are seeing the demand for our lenti products outstripping the capacity we have in Oxford to be able to serve from a PD perspective.

We are relatively capacity-constrained on the process development side in Oxford. We'll be opening up new latent capacity both in Boston and France in order to serve those clients.

It's an interesting aside, but I often hear talk of overcapacity in the market for cell and gene therapy. To one extent, it's true. From a GMP perspective, there is overcapacity in the market.

There's plenty of facilities with bioreactors that can make use of gene therapy theoretically, but where there's undercapacity is on the PD side.

Certainly, we are at capacity, and others just don't offer that same service, which is why we think we win. I'll take you through some of those USPs that we have a bit later on.

Importantly, just at the end there, we're talking about the ABL deal. We've acquired ABL Europe. That deal should close in the next couple of weeks. We've got all the regulatory approvals we need now. We just need to go through the ending process.

That's going to bring us this extra PD capacity. 25 years of experience as a CDMO, 140 CDMO experts coming from both Strasbourg and Lyon, two sites, some significant capabilities, and capacity that we're going to open with that deal.

Having a site on mainland Europe is important because the EU does offer some pretty nice incentives for European biotechs to manufacture on mainland Europe. That should be a real benefit to us in terms of grants offered to our clients, should enable us to make a big impact in that marketplace very quickly.

We'll transfer the lenti platform over there. I think that will be an exciting acquisition for us, and it was a pretty good deal. The enterprise value that was assigned to that was five million euros. They're already producing somewhere in the teens in terms of revenues, broadly break even.

Institut Mérieux, who's the current owner, will take a 10 percent stake in Oxford Biomedica. They're both buying the market, and they'll buy some of those shares for cash as well. Very, very good deal for us, and that should be closing in the next couple of weeks.

Pathway to profitability. Now, we're a pure-play CDMO. There are only two reasons for a pure-play CDMO to exist. The first is to serve your clients and ultimately serve those patients who need these treatments very badly. Secondly is to make money. We can't avoid this, and we're not going to avoid it. In fact, we're going to meet it head-on.

This is where we think our finances are coming out and looking. The important is the purple thing down the right-hand side. We're going to end roughly £90 million this year, is the guidance we've given in 2023. We are confident we can grow. None of these numbers, by the way, include the French numbers. We won't include those until we close.

30 percent revenue CAGR for the next three years. At the end of that time period in 2026, we expect to be making a 20 percent EBITDA margin or above. That's where we come from. 90 million and loss making this year to broadly break-even next year, to 20 percent EBITDA margin in 2026, having more than doubled the revenues in that time period.

The orders we've signed this year support that and the strength of the pipeline beyond that supports that, as well as the quality of the products already in our pipeline. You'll see a snapshot of those momentarily.

This is super important. Now, we need to give clear guidance to the market. Post the French deal closing, we will come out and re-guide and give 2024 guidance. Then we need to update the market on a frequent basis the progress we're making.

Let's dive a bit deeper into the commercial strategy, which is, where are we going to win? Revenue growth is just about everything in this industry. There's lots of prospects out there and opportunities. How are we going to grab them? How successful have we been so far, and why do we think we're going to win in the future?

This is a snapshot of the client programs we currently have as of September 2023, client programs, 41. That's the beginnings of a nice portfolio for us. Then, you can see that 41 listed out in terms of the progress or the relative advancement of those programs.

That first one is what you'd call pre-clinical. The second block of 14 is Phase 1, Phase 2. The third block with 1 in it is Phase 3 or nearing BLA. Then, the last one is commercial.

The quality of the products we have and the partners we have do lead us to believe that in the next three years, significant progress is going to be made in that internal pipeline. There's going to be drop-offs. There always will be. All of those 25 aren't going to make it through.

With the probability weighting, we believe that we can get to the end. Of course, for every CDMO, for any CDMO, but especially for one in the cell and gene therapy area, those commercial products are gold because that gives you the predictable routine manufacturing.

When I say routine, it's routine in order. It's not routine in ease. Manufacturing that you can build your basis of your plan on every year. That's how you become efficient. You absorb overheads, and you become profitable.

We've got enough programs entering those two late-stage areas now. Progress has been made since September 2023 that we're confident that we can get to the end. By 2026, we'll have more than one in each of those areas. We will be able to generate a plus 20 percent EBITDA margin at that point.

That isn't the end, by the way. That just indicates that, even in 2026, this market won't be fully mature. That maturity will come somewhere down the line.

We know that gold standard CDMO, EBITDA margins are probably somewhere in the 30s, mid-30s, towards the high 30s, depending on the products. That requires a mature industry. We don't quite know how long it's going to take to get there.

By the time we get to 2026 we're happy to re-guide. We're happy to keep on driving those efficiencies to get more and more profitable. We don't see any reason fundamentally why cell and gene therapy can't be as profitable as other advanced therapies manufacturing.

Why do we think we win? This is the list of these differentiated platform technologies we have. A couple of my commercial colleagues are sitting in the room. The first question they're asked is, "What's your track record?"

Whenever you interact with a client, they want to know whether you've done it before. What they want to do is leverage that experience you have in problem-solving. Solving their problems in a very fast, flexible way through process development and helping them get to the end with the best probability of success, all important for our clients.

We really do pride ourselves on giving a client-centric experience. They're not just a number to us. They're not going to go into a shed to be forgotten about. We work very closely with our clients. Our NPS scores tell us that they enjoy that experience.

The track record is all important, so 25 years of lentiviral vector experience, 340 GMP batches. On the AV side, the team that we inherited from the Homology team which we're transforming into our US site CDMO, have made 45 batches of AAV. Now, they need to go out and make batches of AAV for others.

We're not as advanced as we are in the lenti space, but it's a great technology. We've been successful in signing clients onto that platform. We want more work to do in that area.

We believe we can accelerate clients' timelines. One of the other things that we think is occurring in the industry is that the FDA, in public statements, have said that they'd really like to see a five-fold decrease in cost of goods, in cell and gene therapy products, to the payer. Of course, the only way you can do that is to drive down the cost of sales.

The suggestion made directly from the FDA was you need to centralize activities at reputable CDMOs. Where they have platform technologies which are proven, there may be some interesting ways for them to accelerate timelines for clients using those platforms.

Long way to go between them saying it and it becoming policy, but it's a really exciting time for a company like us with a very established platform.

If you can accelerate a client's timeline even by 6 months to approval, or by 12 months, we know that biotechs are running at about \$100 million a year in terms of cost base.

That's so significant. We're not niggling around with prices of batches here. This is a massive chunk of cash they may be able to save. The FDA making signs that they want to help the industry get better and get cheaper, and we'll keep a watching brief on that.

I did mention TetraVecta™. This is our fourth generation of lenti-vector. That was launched last year. Increased packaging, potency, quality, a whole bunch of novel IP in there.

We've inherited the dual plasmid system from Homology, which is a pretty good system. Like I said, we're investigating with about 10 clients at the moment, early stage. We believe this can make a difference to other AAV clients as well, so this is being aggressively marketed.

Then, the regulatory achievements, like I said, it's no small feat to help a client through an IND submission, a BLA submission, an ODAC meeting like we did with Novartis.

We've got some really, really nice experience at both doing that and getting people, getting Novartis specifically, approved in more than 40 countries around the world with Kymriah.

Helping them actually amend regulatory filings as well when they swapped from an adherent process to a suspension process a long time ago now, 2018. All the regulatory paperwork needs to be amended, and we helped them with that.

This is the last slide, and this is an embodiment of our CEO's transformation strategy. When we

look at this slide, he really wants to take a company which has done good things, and he wants to make this company a great thing.

We've got this concept of a flywheel. As you see there, you start at the top with the people, because without people, every company is nothing. We have great people now. We want to be able to attract, develop, and retain those people.

Now, we're going through this process of operating in this client-centric organization. A lot of the changes that have been done at the end of 2023, and ways of working coming into 2024 will really give us the discipline of a CDMO, which we're getting from senior management.

A lot of good CDMO experience coming there, and we need to organize ourselves in a way which is entirely consistent with the client's experience. Then we'll be able to deliver those client experiences, deliver them great product, on time, a quality experience.

Then, from that, we'll be able to expand the existing partnerships and attract new clients, because this is a small world.

We've been successful without really marketing ourselves because people in one company have had a great experience, moved to another company, or speak to someone in another company, and word of mouth really works well.

That added to an aggressive marketing campaign should allow us to really maximize those opportunities, generate the increasing returns for reinvestment, both in technologies, and anything that better serves clients.

At the moment, we work mostly on viral vectors, but like I said earlier, we're a gene and cell therapy CDMO. We don't rule out anything that's sufficiently adjacent to our existing technologies and capacity or infrastructure to enable us to easily move into it.

Other technologies, which are potentially non-viral, which can be made in the same sort of GMP suites, etc., could be open to us to invest in with those increasing returns. That, again, enables us to become the best company with essentially a great outlook in order that we can attract the best people.

We think this is like a flywheel, it's a virtuous circle. We're working on all of these. This is how we're going to run the business.

We believe that once we go around this circle a few times with increasing our NPS scores with our clients, optimizing that organization, being commercially savvy and commercially successful, and the P&L tells the story, this will start running itself.

This is how we turn the company that was Oxford Biomedica hybrid into this quality and innovation-led cell and gene therapy CDMO that we want to be.

I'm going to stop there. We'll sit down and take some questions. Thank you for listening.

[applause]

Jem: Thank you very much, Stuart.

We're now going to move on to the Q&A portion of the presentation. Please note that if there are any questions in the room, there is a microphone in the back that you can get ahead of asking your question. With that said, are there any questions in the room for Stuart at this time?

[pause]

Jem: Great. I think I saw one in the back.

Audience Member: How would you characterize utilization of your current capacity, and at what point do you need to invest materially more in infrastructure?

Stuart: I don't know how close I've got to get to this mic, but I'll sit here.

It's a great question. Unfortunately, it doesn't have an easy answer.

Suffice to say, I did make the point that there is overcapacity in GMP. If GMP is the capacity you're talking about, we don't need to make a material investment under current assumptions until 2029 in further GMP capacity.

We have enough GMP capacity, both with the US, the UK, and soon with France, to see us through our aggressive growth profile from a revenue perspective for the next five years.

That being said, if we are more successful than we think under current assumptions and we sign

bigger deals, it's a great problem to have.

We do have an already planned expansion to GMP in the Oxford facility in a fallow space, which is being planned, it's going in for planning permission, and it's going to be held for execution when we need it.

We've tried to mitigate the risk. We never want to be at capacity on GMP. We always want to be ahead of the game and investing before it happens, but we've put that mitigation in place so we're going to be good.

Under current assumptions, like I say, we have an aggressive growth profile, doubling revenues by 2026 and beyond, not including ABL. No further investment until 2029.

Jem: Are there any additional questions from the room?

Audience Member: I presume that the number of the clients from 2022 to 2023 include the number of the clients that the ABL and your joint venture already had. Is that right?

Stuart: Nothing on this presentation includes ABL, but yes, in the US. The US-owned entity, the US site is included, not ABL.

Audience Member: It looks like during that time you lost one of your commercial clients. Could you share the background of it?

Stuart: That was the AstraZeneca COVID vaccine. I think everyone's glad we lost it. It was one of those things that we were running full bore. The experience that the COVID vaccine gave us is just worth talking about briefly.

As well as giving us experience with adeno, which now we have access to a platform which enables us to produce adeno for our clients - it's a smaller market but it's there - it gave us the experience of running at a capacity which is unbelievable. We're running 24-7 three suites.

We don't really think any gene therapy client is going to tell us to make as much as you can, don't stop. It just showed what happens to a CDMO when you can be efficient in that way and really sweat your assets. Of course, now we've got some significant CDMO experience in CEO and some of our major C-suite individuals.

That's exactly what we're looking to do, sweat the assets and be as efficient as we can be in a market that's still maturing, and we should bear that in mind.

Jem: I think I saw one question in the front.

Audience Member: I want to know your anticipation for the long-term growth potential of the lentivirus market. What do you think is the most major constraint for the lentivirus market has to grow in the future?

Stuart: You saw the numbers we threw up there. It's 18 or 19 percent CAGR until 2028. Obviously, when you go out that far, there's a bit of guesswork involved there, but we think it's going to significantly grow.

There are enough clinical trials ongoing in both AAV and lenti, more than 1400 I think, to know that this is going to be a part of the healthcare landscape for the next 10, 15, 20 years.

Where are the risks in that? Well, there are risks of adverse events, as you can imagine. We've made some really good progress in terms of safety and other quality, purity issues with TetraVecta™ and our platform in general over the years. You're always at the mercy of adverse events. We haven't seen any yet.

We're building that real world...Say any, we haven't seen any fundamental adverse reactions to lenti yet. We think it's a proven technology for treatment now, and there is enough CAR-Ts especially out there to make it absolutely a part of the landscape. It's got good prospects and a growth profile.

Probably, the biggest single thing in terms of opening a market is China, which is the second biggest market in the world for lenti after the US. We are examining our strategy to potentially take our technology into China. The two markets, China, and the rest of the world, are almost mutually exclusive.

We do supply vector into China through Novartis because it's the drug substance rather than the drug product. We're allowed to do that. Taking our technology and the Chinese companies to benefit from that, it's something that we're looking to do being the second biggest market in the world. It will be remiss of us not to be doing something to address that opportunity for us.

Jem: Are there any more questions? I think we have a little bit of time so I may ask a few then.

Stuart, can you just comment on, I know you mentioned it already, but maybe just ongoing progress on the ABL acquisition?

I think you mentioned it was going to close hopefully in the next few weeks. Maybe an update on the integration timeline. How are you thinking about that post close?

Stuart: We believe it's going to close. All the regulatory hurdles have been met now. We're going through the administrative throes of closing a deal. We are extremely confident this will be closed.

Integration-wise, really important for us. They have some really, really nice experience. They've been a CDMO 25 years. They've got loads of CDMO experience, which we think will be additive to our culture, but we need to integrate properly to be able to really benefit from that in other sites.

The model that we're running as an operation now is going to be a site model. We're running the UK as a site, the US as a site, we'll run France as a site, all feeding up to the group. In that way, we really want to share technologies and know-how across those sites. We've got an in-depth integration plan that's going to run from the moment of close.

One of the first activities we'll undertake is to transfer the lenti technology into France because we do think there's latent demand from European clients and other clients to have their lenti made...Like I said, we're at capacity. Once we open up both Bedford in the US and the French site, we'll be in a strong position to make sure that we can serve those clients.

Integration is super important to us now because we want to take the best of the culture and the practices in France and integrate them into the UK and the US. This can't be an imposition. This must be a synergistic sharing. We're 100 percent focused on doing that. We've already got a team in place.

We've been allowed to obviously speak to our colleagues at ABL for a while now. Obviously, there'll be a name change very, very quickly. We all want to be part of the Oxford Biomedica family.

It's about, like I say, taking the best and making them feel like they're part of a team rather than they've been acquired, which is what we're focused on in the first few months.

Jem: Great. I think in 2023, probably one of the key transformations that the company's undergone is changes to the commercial team, which you touched on briefly during the

presentation.

Could you maybe comment a little bit more about these in detail, and whether you think that that's what's been driving the recent growth that you've been able to disclose on 50 percent growth in terms of contract orders and doubling of the amount of clients? Has that been a key factor?

Stuart: Yes. Before, we were relatively successful in attracting especially Big Pharma clients, just through the name of Oxford Biomedica and the fact that people move around between companies. If you give them a good experience, they're happy to come with you for the second time, even the third time in some instances.

Actually getting out to the wider universe of 500-plus clients in that universe, you really need feet on the ground, you need to be attending the right conferences, and you need to be offering your services in a cogent way, which is exactly what the definition of marketing is. What have you got, and how does it fit into the marketplace?

We've spent a lot of time under the stewardship of our new chief commercial officer, Sébastien Ribault, who came from Merck Millipore, formalizing what we think our USPs are, understanding where we're going to make the biggest impact, which conferences will make the biggest impact.

There are these trade conferences throughout the year and throughout the world, and you need to be at the right ones with the right people, and you need to make the best use of your time.

Sébastien has really brought a discipline into this area, which is a genuine commercial discipline rather than, like I say, a big licensing business development type approach that we previously had.

I would absolutely say it's made a significant difference, and we believe it will keep on making a difference because now, with the closing of ABL, this should open up a whole bunch of new clients to us in mainland Europe as well.

Feet on the ground in the right place, numbers of people from 4 to 16 in the last two years, an investment in marketing itself, and we really are aiming to make as much noise in terms of share of voice as some of the bigger competitors like Lonza and Catalent.

That's why we're winning clients, because we're really emphasizing the client-centricity we have, the quality of the experience they'll have, and obviously, the track record that we have.

They're the things that we've identified that people get us to that RFP stage, get us beyond the RFP stage and enable us to win more than our fair share of clients, which of course is always the goal.

We know the market is going to grow, but we need to grow faster than the market. We need to win disproportionately more than the market grows.

Jem: Great. Thanks, Stuart. I think we can wrap it up there. We're just at time. Thank you, everybody, for coming. Thank you again, Stuart, for the time.

Stuart: Thank you.

[applause]



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