Preliminary Results 2019

Thursday, 14th March 2019

Catherine Isted, Head of Investor Relations: Good afternoon, and welcome to Oxford Biomedica's Preliminary Results for 2018. I would like to thank you all of you in the room and those online and on the webcast for joining us today.

The word transformational is a word I believe is often overused. However, I do think it is correct to say that 2018 has truly been a transformational year for Oxford Biomedica. Not only have we seen our revenue grow by 70%, we have also become EBITDA and cash flow positive.

Importantly, this year, we have proved to the markets that our dual strategy is working with both large platform and pipeline deals signed. We are now building for the future in every sense of the word to maximise the opportunity for Oxford Biomedica in this new, fast-growing cell and gene therapy market.

With that, I hand over to our CEO, John Dawson, and CFO, Stuart Paynter, to go through the results and the outlook for the year ahead.

John Dawson, CEO: Thank you, Catherine, and I would add my welcome as well to all of you in the room and on the phone. We are delighted to present our results for 2018 today and we think we have had a very, very good year.

During the presentation, I will be making forward-looking statements which cannot be relied upon.

2018 Highlights

So into the meat of the presentation. Firstly, the 2018 highlights, three parts of that this year: the delivery on the dual strategy; strong financial growth; and building the future.

Dual strategy

Our dual strategy is somewhere we have executed perfectly in 2018. We have three deals that we are very proud of: the first one with Bioverativ around haemophilia with a potential value of $105 million. The second one with Axovant for our Parkinson's therapy, OXB-102 as we called it, now AXO-Lenti-PD, at a potential value of $842.5 million. And the third one for cystic fibrosis, a partnership with Boehringer Ingelheim, the UK Gene Therapy Cystic Fibrosis Consortium, and Imperial Innovations. And this is quite a technical challenge for us, inhaled lenti for cystic fibrosis.

Financial growth

We had a strong financial performance in the year. Income grew 72% to £67.9 million from £39.4 million the year before, which was spectacular growth. EBITDA was £13.4 million versus last year's loss of £1.9 million, and cash at the end of the year was £32.2 million versus £14.3 million the year before, reflecting significantly improved trading performance and a placing of £20.5 million gross.

Building the future

Importantly we signed two new leases in 2018, firstly on an 84,000 square feet building, which would double our GMP suite numbers going forward in 2020. And secondly, another lease in December 2018 on a 32,000 square feet premises to establish a new discovery and innovation facility.

In terms of staff numbers, we grew from 321 to 432 in 2018, and we will be 600 by the end of 2019 to keep up with the growth in the business.

We signed an R&D collaboration with Microsoft during the year to improve cell and gene therapy delivery, using artificial intelligence and machine learning. And of course, we have huge expectations for 2019 of further deals around our platform and also for our proprietary pipeline.

Before I go to the next slide, I would just like to thank all of our staff, our wonderful staff, back at Oxford Biomedica who worked so hard to achieve these results in 2018.

Strategy: Leveraging our LentiVector-enabled Delivery Platform

Still the backbone of our company is our LentiVector delivery platform. There are four main pillars to that; IP, patents and know-how; facilities, about which I will talk at length in a few minutes; expertise – brilliant people in the business, up to 600 by Christmas; and one of our real differentiating factors is quality systems, which is so important to attract new businesses to work with us.

Within two parts in the business; partner programmes and OXB products. We have learnt a long time ago the importance of remaining at the forefront of the LentiVector field. We have to keep innovating around our platform. And we are working very hard to get better yields in our bioprocessing, quicker analytics, better analytics, and lower the cost of goods for the benefit of patients.

Partner programmes are so useful to us. We have many income streams from those; process development fees and incentives, bioprocessing revenues and royalties, the all-important royalties. Customers that fall into these categories would be Orchard, Sanofi, Novartis, Boehringer, and, of course, the UK Cystic Fibrosis Gene Therapy Consortium.

We are investing now in internal and external assets, looking to take those forward to early clinical stage. Here, we can get deals that would give us upfront payments, milestones, royalties and development funding. If you do a deal like Axovant, you have the ability to get revenues from manufacturing as well, so a very important part of our business in that respect.

Deal 1: Sanofi (Bioverativ) Haemophilia Partnership

The Bioverativ deal is a product development agreement for Factor VIII and Factor IX for haemophilia A and B. It is a non-exclusive IP license. And the deal structure here was $5 million upfront, with over $100 million potentially for development, regulatory and sales milestones.

We receive royalties from the sales from the drug launches and can get slightly higher royalties should we embed further IP. These deals can take up very long time. This one took us up to 18 months to sign. And just before we signed it, literally two weeks, Sanofi bought Bioverativ.

These things can be very catastrophic at times, so we were very happy to see this go through two weeks later. And we were very grateful to Bioverativ having pre-cleared the deal with Sanofi, so that happened very quickly afterwards.

So the work we do currently is in process development stage for haemophilia A and B to allow successful production of materials for clinical development. Just to give you a feel for this market, sales of products in this area were $6.7 billion in 2016, set to grow to $8 billion by 2026. And a very exciting area to work in.

Deal 2: Axovant Licence Agreement

Onto the second deal with Axovant around our Parkinson's drug OXB-102, now known as AXO-Lenti-PD. It is a worldwide licensing agreement here. Headline value of the deal was $842.5 million. We got a $30 million upfront here, $55 million was specified for development milestones and a further $757.5 million was specified regulatory and sales milestones.

It is our own drug here, so the royalties we get are higher than we would normally get in a partnership deal. We get tiered 7-10% on sales. In March 2019, Axovant reported their data from the first cohort of the Phase I/II trial and are now planning to move into the second cohort of treatment in the second quarter. We are very excited about where it could go.

Products in Parkinson's in 2016 sold $3.1 billion, set to rise on our forecast to about $8.8 billion by 2026. It is a huge market to aim for.

Deal 3: BI/UK CFGTC/Imperial Innovations

And the third deal of the year was with Boehringer, UK Cystic Fibrosis Gene Therapy Consortium and Imperial Innovations around cystic fibrosis. This is a process development agreement. We are currently responsible for process and the analytical developments, scale up of manufacture and generation of material for tox studies.

This has an exclusive option and license agreement with it and the terms are undisclosed currently. Our work here is in pre-clinical with plans to manufacture materials for toxicology studies. And again, this is a very active, growing market. In the seven major markets, sales were, in 2015, $2.2 billion, forecast to rise to $8.6 billion by 2025.

Building the Future – Capacity Expansion to 226,000 sqft

Our current footprint, that is our 2018 footprint before future building, was 110,000 square feet. By the end of 2019, that would have grown to 226,000 square feet. You know about our previous buildings, our head office in Windrush Court with laboratories. Harrow House has two GMP suites. Yarnton, another GMP suite. Both of these are FDA and MHRA approved.

Now we are investing for the future. The first deal was the 84,000 square feet building for more GMP suites, four of those with two fill and finish suites as well. We will finish building in 2019 and have these running and producing vector in 2020. And more recently, we signed another lease for our discovery and innovation facility. This will have non-GMP research laboratories and space and offices, because the rate of growth we have, we have to find desks for people to sit at, effectively. Huge growth, but we do believe this is going to take us to a place where we can satisfy our demand in the future.

Extensive Lentiviral Vector Clinical/Pre-Clinical Trial Activity

The next slide talks about the number of trials starting each year using LentiVector. You see that it is ever-growing and has been heavily driven by some of the CAR-T programmes. If we look at the graph on the left-hand side, it also breaks down for you the number of trials in each type of phase starting each year.

The bottom line is a selection but not all of the companies working in pre-clinical and LentiVector with our clinical trials. The circle should indicate the guys we are working with. Now very, very pertinent to us were the comments by Scott Gottlieb, the FDA Commissioner, back in January. He talks about by 2020, having another 200 IND applications per annum, to supplement the 800 already in place, and further on by 2025, 10 to 20 cell and gene therapy approvals each year, massive growth. Hence, we are building our business, and we predict internally that the market for LentiVector manufacturing by 2026 could be as much as $800 million. That could be dwarfed by the success of the cystic fibrosis or haemophilia programmes.

Platform Pipeline

Turning to our platform pipeline. We are still working on two drugs from Novartis, one we cannot talk about. Hopefully, we will be able to talk about it later in the year when they go into the clinic with that. There is the new deal with Axovant there. We are manufacturing for them. They fall into the platform part of the business as well.

We have two drugs in Sanofi's hands at this point in time, haemophilia A and B, going forward with those. They are in the early stages. Orchard are going from strength to strength, having IPO'ed this year. We have three drugs with them, ADA-SCID, MPS-IIIA, and one currently undisclosed. And of course, our new collaboration in cystic fibrosis.

Product Pipeline

On the product pipeline, we now have three drugs partnered with other parties; AXO-Lenti-PD with Axovant, and of course Sanofi Stargardt and Usher Syndrome 1B. I should comment, of course, about the press release earlier in the month that we expect to see Sanofi wanting to re-license these drugs, and should clarify how we see this happening.

They are now looking for a new partner. We expect to be the CMC partner for new partner they take and of course that could be very good for us. I would heighten and show the GSK to Orchard transfer, which was very successful. We expect to part of something like going forward. Both are very exciting drugs which have a place in the market.

For our proprietary unencumbered assets, we have a few of these which I will talk to you about. Corneal graft rejection, OXB-302, the CAR-T 5T4 for liquid tumours, OXB-201 for wet AMD, two new ones for retinal diseases, LCA10 and RP1, and we are now looking at ALS as well.

And the big drive this year was to bring new ideas forward. We have seen what we can do with platform ideas, and also the platform is so important to us to drive the business forward and create value. So we are working very hard internally to create new ideas, and we have a long list of things we are working on. Some strict criteria what we will take forward, but there will be more drugs appearing in the coming 12 months.

At that point, I will pass it to Stuart to talk about the financials.

Stuart Paynter, CFO: Thank you, John, and my welcome to everyone on the phone and in the room as well. So it falls to me to take you through the 2018 financial highlights.

2018 Financial Highlights

As John mentioned, we are very proud to say that we have grown extremely strongly through the year. So both revenue and what we call gross income, which is revenue and

other operating income, have grown more than 70%. And a large chunk of that is from the licensing deals we did with Bioverativ and Axovant, which are very positive.

The operating expenses have increased by 38% to just under £32 million and this is a consequence of, as John mentioned, us really increasing the headcount to be able to cope with current and future demand. We are a growth company and we are investing in our infrastructure very aggressively in order to see us as continued market leaders in our space in the vibrant gene therapy field.

Of course, what those two things do, increasing your revenue and increasing your costs, when you increase your revenue more than your cost, this leads to a much more favourable EBITDA number. So we were about £13.4 million for the year. You will recall at the half year, we were just under £12 million, so the second half was also EBITDA positive. And it is important that whilst we are aggressively investing back into the business, that we are also keeping a prudent view on how much money we have to spend on that. So we are managing that very closely, as John mentioned, and we will come to it in the outlook. We are looking to be at 600 people by the end of the year.

The operating profit was slightly higher at £13.9 million, slightly unusually, because we recognised about £6 million of revaluation on the Orchard assets that we hold. So we hold, post-IPO, just under 900,000 Orchard shares. And I think this is a really nice validation of the strategy of working with both big and small companies. We signed a deal with Orchard a long time ago when they were the seeded VC-round, novel gene therapy company. We have helped them get to the position in the market, they are today with their successful IPO, as John mentioned. And with their ADA-SCID product, we hope they will be the second LentiVector products onto the market, probably in early 2020.

And so it is shown that we can both work with big companies and if the science is good, we will work with small companies and potentially take equity stakes. We will be more flexible in the deal structures that we have now.

Licensing income was £18.3 million from Axovant and Bioverativ deals; £10.2 million on the products and £8.1 million on the platform in terms of how those revenues were split. And, of course, that leads to a positive cash inflow in the year. So the other thing we did was in order to fund our 86,000 square foot facility for the new GMP suites, we did a raise back in February-March last year, a very successful raise of £20.5 million. And now we have got a fully funded pathway to expanding our capacity capabilities.

How that played through to our cash position is we are north of £30 million as at the end of the year. We are expecting with the spend for OxBox, which is what we are calling our facility, to start really in earnest towards the end of last year and the first six to eight months of this year. We are expecting to go through quite a lot of cash, but again, that is fully funded.

And it is worth mentioning that we have also been very, very well supported by the government in the last 12 to 18 months. We have been the beneficiaries of two Innovate grants. One for the advancement of capacity for viral vectors and the other one for the digitisation of the process and analytics, as John mentioned. And that really concluded in the deal that we announced earlier this week with Microsoft. So the government has been very supportive and we appreciate the support.

Gross Income and EBITDA

So if we flip over now to slide 14, what you can see is what I have already talked about. So on the top, we talk about gross income there. That is both revenues and other operating incomes, which is now very small. Accelerated growth, very impressive growth. We know that we are a growth company and top line is key for us. So we will continue to, as John mentioned, aggressively pursue opportunities in the marketplace, to sign new deals to allow us to grow our revenue base and reinvest that revenue back into the platform.

It is worth mentioning at the half year, if you recall the more predictable element of the revenue is the blue line. That is the bioprocess and commercial development revenues. And we highlighted the seasonality at the half year. It is worth mentioning that in the second half of the year, we grew 64% in the bioprocess and commercial development revenues on the first half of the year. So we promised you an uptick and an uptick is what we delivered.

And then the EBITDA, of course, we have long being a product development company back in the years we are looking at there, 2014, 2015. And in 2016, we successfully pivoted our strategy in order to help Novartis pursue its goal. And you can see that that has paid medium and long-term dividends, and it has enabled us to have the financial strength to have much more optionality now, moving forward.

Segmental Analysis

So on slide 15, we just take you through the segments. It is clear even in 2017 that the platform stood alone and made a positive contribution to the business. That is been fortified in 2018 with the new deals we have signed, which has enabled us to expand the commercial development piece of our business very aggressively. It is worth mentioning that we have three clean rooms currently and they are running at capacity and they have been for a number of years. So we are still slightly constrained by the capacity we have.

We have invested to remove that constraint by the early part of 2020. So we are, through 2019, still going to be slightly artificially constrained there and we should see the shackles come off in 2020 for revenue growth.

The other area we had constraints was laboratory space in order to do some of the analytics. And, as John mentioned earlier, with the new facility we signed for innovation and discovery, we have taken the constraints off our lab space as well. So we think we are well set for the future.

And then you see on the product segment, that is necessarily going to be more lumpy. We signed a very good deal in 2018, of course, as John has gone through, with Axovant genetic therapies. You can see on the operating loss line, the operating profit this year and the EBITDA that these have sensible investments we continue to take.

So, obviously, as I mentioned, we are going to try and identify those things that are going to help us grow and invest in those in a very strategic and controlled manner.

Outlook

Taking you to the outlook for 2019, the gene and cell therapy space is still very vibrant. We have seen a number of deals take place in the last few weeks. So there is a lot of interest from big pharma in the space, a lot of investment going into the area. We see our

strategy as being very, very capable of taking us forward and maintaining and growing our marketing leadership in the Lenti space.

We expect to see Novartis bioprocessing and royalty income going up, of course, as Kymriah is rolled out around the world. We have multiple revenue generating partners beyond Novartis, including some of the ones we have talked about, like Orchard and Sanofi and Boehringer Ingelheim. And there is an expectation of new, additional platform partnerships to be added during the year. Certainly there, as we know, we have always had trouble giving you exact date and times of these deals, but we have a vibrant pipeline of opportunities which we are still bullish about closing.

And, of course, what we have done with Axovant is we have validated our strategy of the hybrid model. Of course, that is a single point and we understand we have got to continue that trend. And with that in mind, we still have ambitions to out-license one of our products this year as well.

In terms of the infrastructure, in 2019, as we have gone through, we expect work to continue on the new manufacturing facility, again, completely fully funded. And that is on track for completion and validation in the first part of 2020. We have already occupied the building in the office space. We know that the cost growth in the business to 600 people will be required to meet the anticipated revenue growth that we have. It is not good enough to add resources post these deals. We need to have the capacity for the big pharma guys and the smaller entities to be able to do their work in a timely manner. It is a competitive marketplace and one of the USPs[?] we can give people is the ability to take their product to market faster than our competitors.

And, of course, we mentioned the modest investment back in our pipeline programmes there. We are very excited about the internal pipelines. We have some very good candidates we are looking to screen and bring forward. And as we mentioned to at the half year, we now have the latitude to take these forward ourselves into early stage clinical studies through Phase I/II to look to generate the next incremental piece of value. So the next value inflection point is what we are after. Some good human data really does give you a really marketable asset.

So that is where we are for 2019. And with that, I will hand over to John to talk about the news flow.

John Dawson: Looking forward, we can see a lot of things happening over the next 12 months. The second CAR-T programme from Novartis should go into the clinic. And we will see higher royalties coming in from Novartis with the uplift of sales from DLBCL as well. Orchard Therapeutics will file their BLA for ADA-SCID during 2020. And we continue working with Bioverativ and Sanofi to take forward haemophilia A and B to have materials ready for clinical trials in the next 12 months.

Of course, our expectation is to sign further deals around our platform; very, very important to drive the business to keep that revenue growing. But we have to invest further in our platform to improve the volume and yield from bioprocessing and efficacy of vector transduction of target cells in the business too, key to our business going forward.

In-house products, we will see AXO-Lenti-PD moving to cohort two of the Phase I/II trial. And we have huge expectations around doing another pipeline deal of our products going forward as well. And I think this could be a very exciting for Oxford Biomedica as it stands, going forward.

Q&A

Amy Walker (Peel Hunt): The release mentions that bioprocessing revenues rose 15% in the year to 2018. Based on your commitments, as you see them right now, what do you expect that figure to be for 2019, particularly in the context of the commentary around capacity constraints?

Stuart Paynter: As you know, and you are probably frustrated, Amy, we do not give that level of guidance down to the individual revenue lines. We do expect to see some growth but we are not going to see the sort of growth that seven clean rooms against three clean rooms gives you. As we move forward in the year, it is public knowledge that we are currently running two cell factory, two process A suites and one process B. One of those suites is being validated for process B now, so it will be two and one the other way.

And the process B does gives us opportunity to run more campaigns. So it is a shorter campaign, which produces more material. So to that degree, we can still squeeze growth out. We would not give a percentage growth number, but we can still squeeze growth out until we are deconstrained in 2020 with new suites coming on line.

Amy Walker: And about de-bottlenecking, Stuart, how material is that? Can you give us any feeling for – just from capacity footprint perspective, can you put the percentage on what that does for you?

Stuart Paynter: It more than doubles our capacity. So we have got three clean rooms now. We will have seven clean rooms at the end of the process. All of the clean rooms going into the new facility will be process B. They are all bioreactors. So, of course, we need to be able to fill those and we will staff up in a controlled manner in order to run one, two, three, four clean rooms when the demand is there. So it is going to be slow ramp. It is not going to be an immediate double the revenues, but it enables us to sign new deals on the platform now with the ability to satisfy the demand in future.

Amy Walker: Okay. Picking up on that, in terms of signing new deals, can you help us understand what the main bottleneck for the rate of deal signing is? So it sounds like capacity you have got some flexibility. So what is it? Is it the number of targets? Is it your bandwidth to do the due diligence? What is the key thing that is the rate-limiting step to new deals?

John Dawson: Most of the time it's feasibility testing. Most clients want that to work on their drug to make sure we can work with LentiVector. We very, very rarely fail that, so that is not a concern. It just takes time. And then we can negotiate it afterwards. I can take you back, for example – I cannot take you forward. Bioverativ took us 18 months. Some deals have taken us a year sometimes. It is very hard to predict exactly when they get signed as well. What we do know is we are very busy. We have a lot of feasibility ongoing and we do expect to sign further deals this year, but I could not give you a time on it.

Amy Walker: Last one, just on the debt and the capital structure. What are your options for reducing the debt burden and what is the timeline for repayment or refinancing or whatever option you are keen to use?

Stuart Paynter: Again, there are no board decisions made on this. So we can give you an aspiration. So we see the debt as being absolutely necessary for the growth of the business back in 2015 when we took the first debt out, and then we refinanced that debt in 2017, as everyone knows. That debt and the finances at the time enabled us to become the company we have become, but we do acknowledge that it is now a debt which is not in line with the risk profile of company we now are.

So we are actively looking at the corporate structure we have in order to make us a stronger company and release us from these legacy issues that we have. No timelines yet, but I can tell you that it is being actively looked at.

Philippa Gardner (Jefferies): On the Sanofi assets that they are looking to re-license, how actively is Sanofi actually pursuing re-licensing? And are these assets that you might consider bringing back in-house and doing some further development on and then looking to re-license yourself? And then my second question is just on your cost base and you talk about growth this year with the 40% increase in employees. How should we actually think about the R&D and the G&A lines for 2019?

John Dawson: First part on Sanofi, I will take it. I will pass the second part to Stuart. For Sanofi, they are very active. They have quite a big data room ongoing, with a lot of people in that. We find these assets very attractive and is something we could consider. We have not done so yet, but we are expecting to get partnered. We are expecting it to be very attractive in the future. And these drugs do cure a lot of unmet medical need at this point in time. So we see them having a very attractive future. Stuart?

Stuart Paynter: So in terms of the cost base, very good question. We are looking and we have added a whole bunch of scientists into the organisation, which is what you would expect from an organisation like us. We have reached a bit of a tipping point in the size of the business where we have had to add some strategic G&A cost into the mix. In 2018, John successfully employed another three members of the senior executive team. We were five and now we are eight. Some of those are in the R&D line but this is part of the company we need to build infrastructure around.

So, as you look at this going forward, I think you will expect to see a bigger increase in the R&D lines because the vast majority of people will be working scientists. But that is not to say that we will need to make some strategic G&A investments as well.

Stefan Hamill (Numis): I will try and do three. So on bioprocessing volumes, could you just clarify – it sounds like you are going to make quite a significant internal improvement before the new capacity comes on. Will you be able to achieve that in the first half?

Stuart Paynter: So, as you have seen this year and I highlighted in the presentation, the first half tends to be seasonally slightly suppressed, given the cleaning schedules. So once a year we have to close down the clean rooms, and it is usually just after Christmas, and it has been. We took that opportunity this year to switch our Yarnton facility from a cell factory to a bioprocessor, so that is going to get to validation.

So I would say the first half of this year is not going to see a big increase because, first of all, we are making that change and that makes us do validation batches. And, second of all, it is a seasonal effect of the GMP cleaning schedules we have to do. Certainly, about the second half that should be a validated facility, and we should be seeing the new norm in terms of the amount of throughput we can put through our existing three clean rooms with two bioreactors and one cell factory.

Stefan Hamill: So just expanding on this capacity constraint issue, has it actually held back on the deal side, the business development side?

John Dawson: No. So we would have been constrained by the end of 2019. Hence, where we took action to start building in late 2018 to be ready to use the new facility in the first half of 2020.

Stefan Hamill: So deals that land now will land clearly after the seven clean rooms are ready.

John Dawson: Yes that's correct.

Stuart Paynter: I think we have said this. Stefan, it is typically about a year between signing the deal and doing the process development work before you need GMP facilities. So, you need GMP batch facilities. You need to do your testing in GMP facilities but by the time you actually need to make a clinical batch, usually it is a year to 18 months. So any new deals now will form part of the OxBox estate, the new facility estate.

Stefan Hamill: So in theory, it could accelerate?

Stuart Paynter: Yes.

Stefan Hamill: Okay, second question.

Stefan Hamill: Just on Sanofi. The wider significance was that those assets were the most advanced ocular Lenti assets and there was an overlap. You announced two new Lenti ocular assets prior to us finding out about this news. Can you give us some comfort there is no clinical or technical red flags coming out of that decision by Sanofi?

John Dawson: Absolutely not. It is the portfolio they reviewed and categorised their spend as to what was going to get the best returns in the future, and very much like GSK, they came out of rare diseases. They have come out of gene therapy and ophthalmology to give it to a player that better suites that business going forward.

Stuart Paynter: It is more of a commercial business.

Daniel Wilkinson (Edison): I am going to try to squeeze two questions into one to start with. On about growing the work force, operationally how is that going and have you had trouble acquiring talent at all?

John Dawson: That is a very good point. We have worked very hard in 2018 to create the right culture, to have the right values and mission statements as well as the right reward systems. We have had no issues in recruiting the people we have needed so far. We bumped from 321 to 432 in 2018, it went smoothly. It is a lot to go for. It is a lot to get

your arms around, but it has gone extremely well, and we have some brilliant people back at base. And we expect the same to be true in making 600 by year-end this year.

Daniel Wilkinson: Thinking about the costs of that, your admin expenses only grew about 5% this year, where you went up by 35% in personnel. Is that mainly weighting to 2019 in those costs?

Stuart Paynter: There was a suppression in the admin numbers because we recognised that FX gain in those numbers. So, the real growth numbers were a little bit higher on the admin side. But yes, of course, there is an annualised effect of bringing on new people very quickly. So it is a bit difficult to forecast but we expect to see a continued annualised effect and by the time we hit 600, like I said, by that time we have fully grown into our shoes. So at that time we will have more constant cost base, but it is going to be an annualising effect over the next year and a bit.

Daniel Wilkinson: Okay. And then just a bit on the capacity side. I know you have gone on this a bit. But with Novartis, are they demanding more at the moment than you can give them or have you got it pretty well planned out for next 12 months to two years?

John Dawson: Pretty well planned out. We have the forecast for the next couple of years and we know exactly what we need to do and we have the ability to do it.

Gary Waanders (Bryan Garnier): Couple of questions. Mostly around the theme of how long. So I noticed the statement in your announcement today that you are the only FDA-certified Lentiviral vector manufacturer.

John Dawson: Yes. Commercial sales, actually.

Gary Waanders: So how long do you think it might take before that position is threatened? Is it alternative Lenti manufacturers or is it actually the field moving away from those sorts of vectors?

John Dawson: That is a very good question. First of all, we have to pick up the second one as well with ADA-SCID and Orchard. We expect them to actually have that held for quite a long time to come. We do not see anything coming too quickly after that. Bluebird might launch something with other processes and they will be FDA-approved as well. I am thinking about that probably around 2021, I believe that could be the case.

As far as competition goes and things to take away from LentiVector, in the things we are working today, we have potential competition coming in the future from other LentiVector manufacturers. There is no signs you can do what Lenti can do with other things at the moment. AAV had this space of course, but the two can be complementary in the market.

Gary Waanders: And the other one was around the CF programme. There are obviously quite a lot of technical hurdles to get a Lenti inhaled. How long might it be before that programme gets into phase 1?

John Dawson: That is going to be a period of time, and I would say we have not got a exact date yet, so I would not share that with you. But it is something we are working quite hard at, and we are pretty pleased with the results so far.

Julie Simmonds (Panmure Gordon): Firstly, just on the staff you have, how many of them are involved in working on your programmes and how many of them are involved in working on your partners, so that is development?

John Dawson: So the beauty of the hybrid model is they do overlap sometimes. So we can work on both firms. We have people in manufacturing doing our assets and other people's assets too. As far as discovery and research is concerned, we have dedicated people in that, but we do learn from the other part of the business too. So if you work for somebody else, you learn a great deal about that and can think about doing our own drugs in that area too afterwards.

So we do not split them out as you have asked the question there. But I would say discovery and research on the platform, and also around the products, with probably the 600 by year-end, I will put it probably between 75 and 100 people working on discovery and innovation.

Julie Simmonds: Okay. And just secondly, obviously, Axovant put out some news earlier this week on the Parkinson's product. Do you have any comments on the data compared to what you have seen previously?

John Dawson: Encouraging. Early stage, but encouraging.

Brian White (Cantor): A couple of very general questions, if you do not mind. Just in terms of when you are speaking on a platform. So when you are speaking to potential partners, are they agnostic to the particular vector or are they wedded to a particular vector?

John Dawson: It depends upon what they are working in. If they are working in CAR-T systems, they cannot go to AAV, for example, so yes. But in other areas you can work in with AAV or Lenti. People have their choices to make. But certainly, the people come to us tend to want to work only in Lenti and we have a very good track record to prove that we have done it before and can get people to market generally quicker with our processes to other competitors.

Brian White: Okay. And just in terms of comments about the expectation of platform delivery from new and existing partners, what proportion do you think are going to come from new compared to existing partners, John?

John Dawson: Because we have not signed the deals yet, it is tough for me to answer the question. But I can say we are working on both equally at the moment, of current partners who have other things for us to do, as well as new people coming in. I would say the demand of new people coming in and talking to us about what we can do for them, it is in its early stage of course, but it is quite significant.

Amy Walker: Just a couple of read-across questions, if I can, please. Novartis and their manufacturing situation, I think, I remember on 30th January they said that they have got an expansion of the viability specification in Europe and they expected the US to follow suite very soon. Has that happened yet? Do you know what the timelines for that are?

John Dawson: That is the one we cannot answer unfortunately.

Amy Walker: Okay. Can you answer if it did not happen? Or if it was delayed towards the end of this year, would there be any material implications for you and your budgets on bioprocessing?

John Dawson: Not at this stage, no, because everything we are making for them is set in stone at this point in time, as far as the batches are concerned. The need for them is still significant to meet the market. They have the data for paediatric ALL and DLBCL. So we do not see issues for 2019.

Amy Walker: Great. And then very lastly, Voyager in January increased its targeted enrolment for its Phase II trial, and I think the expectation is that that will therefore be fileable and they could be on the market 2023, 2024. Can you just compare and contrast – or do not compare and contrast, with that as background, what is your expectation, your and Axovant's, for when you might get to market?

John Dawson: Depending on the path we are taking and of our choices, that is a possibility to match or slightly upwards.

Joe Pantginis (HC Wainwright): Good morning and good afternoon. For John, and maybe Kyri if he is there, I am not sure if he is in the room, my question could be focused on Novartis but really for all your Lentiviral research and processes. But for Novartis as an example, without obviously giving up proprietary info, can you give a sense of how the Lentiviral programme has evolved between Kymriah and the next CAR-T you are working on, with regard to say efficiencies, manufacturing, vector design, etc. that allow you to be keep your leading status in being competitive and well positioned in the Lentiviral arena? Thanks

John Dawson: Kyri is not here, so I will do my best to answer in full. And if I cannot answer, we will refer back to him later. As far as the evolution of the process is concerned, we have moved with Novartis from the cell factory to the bioreactors, [inaudible] the bioreactors. And thereby we have moved and given them a much better cost of goods [inaudible] to the patients, so that step has been significant. We are continuously working to improve that as well and we have many potential advantages coming through in the coming years around our LentiVector platform.

Joe Pantginis: Got it. Thanks a lot, John.

John Dawson: Thanks Joe.

Caroline Palomeque (Maxim Group): Thanks for taking the question. Just wonder if you could talk about the parameters that you consider when looking to out-license some of your in-house assets, and will the focus be on ophthalmology or in the cancer space? Thank you.

John Dawson: We have enough for mind to both, of course, but what we have specialised in the past has been ophthalmology, brain and obviously the eye. Now we are looking at lung, liver as well.

As far as assessing what we license out and what we keep, then we got a host of the criteria. I could bore you with the day on that, if I tried to. But certain things we would look for like breakthrough status, we keep to ourselves. We have been looking to actually make sure it is something we can handle the size of trials. Ourselves as well, we have run people trials in the past. So looking at how we do the things and what we license out is a fairly

complex process. It takes a matter of probably a month or so to actually get to the bottom of it in each particular case.

Stefan Hamill: Just a quick one, on the announcement with Microsoft. Is there some proof of principle there in terms of the potential yield improvement that can be achieved by digitising?

John Dawson: This is just a deal for them to investigate what they can do with, obviously, your cloud, working with us around machine learning and artificial intelligence. And the idea is that we get so much data that it is impossible for the human to interrogate that adequately to see what you can do differently or what can affect the yields differently. So working with them, we can actually interrogate far more deeply and find ways to improve our volume and yields from these actions.

Catherine Isted: If there are no more questions from the room, we would like to say thank you very much for your time today, the people in the room and also on the line and on the web. And well, have a good day.

John Dawson: Thanks very much. Goodbye everybody.

[END OF TRANSCRIPT]