Allergy Therapeutics

Interim Results 2019

Wednesday, 6th March 2019

Introduction

Manuel Llobet
CEO, Allergy Therapeutics

Opening remarks

Hello everybody, thank you very much for coming here. We have today for the first time, WebEx, so hello also to all the people that are following us through the WebEx. As usual, Nick, our CFO and myself, CEO, presenting half year results for Allergy Therapeutics. You can see this slide that we have titled '20 Years of Growth and Innovation.' When we finish the fiscal year we will have executed our 20th business year, so since we were reborn as Allergy Therapeutics. If we had to summarise words in this 20 years, probably that would be the best sentence; 20 years of growth and innovation.

First half highlights

We will review today in slide number 3, a little bit of the business, first half highlights, commercial overview and preparations for the US, also will update you on the pipeline, Nick will take us through the financial results and we will wrap up with a summary and outlook for the rest of the year. In slide number four, you are very familiar with these slides; these are the three engines[?] of growth, the three development areas of the company, expanding the business in Europe what we are doing, we keep growing this average growth of 10%, as you know the markets in Europe are mature and not growing 10%, so this growth is driven by market share gains. We are taking around about 1%, one market one point a year, if it's a year [inaudible] towards pollen allergies, maybe it is going to be more than one point, if it's weak pollen seasons, maybe a little bit less, but on average around one point a year. The pipeline with these two blocks, the late stage assets, the Pollinex, Quatros and the early stage assets which are the two exciting projects around how [inaudible] vaccine, and preparation for the US entry.

Background

So before giving you a little bit of flavour around these three areas, just to again celebrate these 20 years, we were spun out from GSK in 1999, and a DNA of a blue-chip huge corporation, but in fact we were a very small unit and a very small company with very limited resources, so this combination was not easy to manage. There are plenty of milestones we have just put here some snapshots but we started with operating in few markets, in 24 we were operating nine markets. We have presence now in more than 20 markets, in 2005 for example we were 250 employees, we have more than doubled this headcount today, in 2007 just before the big crisis started we were selling 25.7 million and we are well above double this amount. I think this shows that we have been in a tough period because we had the economic crisis that had big impacts on reimbursement in many European countries, and a major regulatory change in the specific immunotherapy field, the company has been expanding at all levels, I mean industrial operations, hiring, generating hundreds of high quality jobs, developing new products, very focused on science and investing heavily in R&D. So, we are proud of this journey that has taken us to this 20th anniversary and we are very excited because we truly believe that the best is yet to come.

Highlights of the first six months

If we look at the highlights of this first six months, the phase three/four PQ [inaudible] is progressing, the PQ phase three readout, we confirm that will be released before the end of this month. We grew 10.6% to 46.7 million. In Germany we adjust our reference market; we typically inform Germany in the interims and global market share in June. We [inaudible] market share in Germany, pre R&D profit increased 27%, strong cash balance of 31.6 million held by strong cash generation and also the [inaudible] fundraising in July.

European business

In terms of the European business, nothing really new to say. All the markets are performing well. It's a healthy growth in the sense that it is not explained by only one market or one product; all the markets in general are growing. All the [inaudible] are performing well, probably [inaudible] driven by the ultra-short course products as Pollinex or Pollinex Quatro, but also very interesting growth from Acarovac and Venomil, which are within the four fastest growing products in the company. If we look at the [inaudible] of growth, you just can see here, will complete in June two decades of double digit composed annual growth rate, and that is driven by our front centre of convenience. As you know it, the core of our philosophy is to develop convenient products that the patients can complete. It is also driven by our superb supply chain that has been probably the most reliable in the market, or one of the most reliable in the market, along with very well trained and motivated salesforce.

US

In the US, this graph here, these figures you have also revealed, so maybe just to comment here, that the dynamics in the US are moving towards pharma grade products. the new guidelines on USP for compounding vaccines for allergies will be published in June. These new guidelines will require sterile conditions, will require people more prepared, higher quality requirements, so that is going to stretch the day to day practice of the allergies in the US, and in some way, fits well with what we are going to propose then that it is [inaudible] GNP manufactured and registered products for that market. We've been progressing with the preparations for the phase three for Pollinex Quatro. We believe that we are in good shape to start properly the final phase three this year, and will keep you posted on any progress on that [inaudible] and big milestone for the company. If we look at the pipeline here, as I said, I mean the late stage products are progressing well, PQ Grass on its way to be started this year, PQ Birch in Europe read out before the end of this month, the house dust mite state of the art vaccine will also read out before the end of phase one, for its phase one study. The peanut scaling up, it's progressing well; we are taking this part very seriously; we really need the totally robust CMC package and a totally robust manufacturing process before we get into humans, but our ambition is to start the first study in humans in 2019 with a small prick test study by the end of this calendar year. So, that is basically the overview of the business on the trading and [inaudible] development. I will now handover to Nick for the financial figures.

Financial Figures

Nick Wykeman

CFO, Allergy Therapeutics

Opening remarks

Thank you very much Manuel, if we move to slide 12, the P&L for the half year, completed 31st December 2018, we have had sales of 46.7 million, as Manuel has already mentioned, that is a growth of 10.6% over the similar period last year; there is no currency effect in this year, which is a good strong performance. Gross margin at 37.3 million, the gross margin percentage of 80%; we have commented that the margin is likely to dip in the second half of the year; that commonly happens, and I might remind you that over 60% of the sales occur in the first half of the year. Overheads of 21.6 million, that is only just slightly above the last year, and as we have indicated in the outlook for the year, we are expecting high expenditure in the second half of the year; that is mainly due to phasing, on the basis that there is quite a lot of activity around congresses and various other things in the second half of the year, as well as some additional Brexit costs. Research and development for the half year was 5 million; you would expect that would have a fairly low spend rate at this level before we start to gear up towards the phase three grass trial which Manuel has already talked about, for the US, where we will start work towards the planning of that in the second half of the year, so you should expect us to be spending probably more than twice that in the second half of the year.

Operating profit

So, overall we had an operating profit of 10.7 million in the six months, which is up 4.3 million from the prior year. One mention we also use, which is our operating profit pre R&D which shows the underlying trading of the business, that was 15.7 million which is up 27% on the prior period, so showing good leverage.

Sales

Moving on to slide 13, that is the sales slide, that will give you a bit more flavour about the sales. As Manuel has said, we had good strong growth across the markets, particularly in northern Europe, Germany, Austria, Switzerland and the Netherlands, and I think it is fair to say that the birch season has been very strong, the grass season was not as strong as we were expecting. I think it is quite strong, but due to the very hot dry temperatures, that actually reduced and you can see that if you look at the IMS data for the German market, you can see all products in the grass area in the German market did not perform as strongly, in comparison with the rest of the competitors, [inaudible] and that is why we continue to take market share in Germany. As Manuel has already mentioned, we perform particularly well in the ultra-short course products, as well as venom and the Acarovac product which continues to perform very strongly in the Spanish market and in Austria.

Net revenue

As you can see, the net revenue constant rates as I mentioned before, 10.6% up, there was no FX rate for this year, exceptionally I think in the previous years we have had quite large movements in [inaudible] this year there is no FX effect.

Balance sheet

If I move on to slide 14, which is the balance sheet, I think the main lines to highlight here are the inventories, you will see, at 9 million up from 8.4 million at the half year, end of 2017, December 2017. That is the stocking which we have mentioned in relation to Brexit, so we are building up stock in our Spanish facility, the manufacturing facility in [inaudible], so that we have product on the mainland continental Europe in case of a hard Brexit. The cash balance, as Manuel has mentioned, 31.6 million, very strong, driven by the successful fundraising that we did, but also by the underlying strong trading for this half year. The debts position, slightly down, we have repaid a bit of the debt at 2.8 million at the half year.

Cash flow

Moving on to the cash flow, that is slide 15, the main thing to note here is obviously strong positive net cash driven by a combination of the very good trading, as well as obviously as I mentioned, low expenditure in R&D in the first half of the year which we are expected to reverse in the second half. Obviously the successful equity rate which raised 10.2 million net in July of 2018, leading to a strong cash position at the end of the half year. I will hand back to Manuel for the summary and outlook.

Manuel Llobet: Thank you Nick. Right, so in 2019 you have the new flow that we expect and we have already commented, birch resolves before the end of Q1, Acarovac, before the end of H1, [inaudible] house dust mite, that is a phase two study that we will run under the TAV programme; we will start it also this year, second half of this year. PQ Grass, for Europe and US initiation, around autumn this year and first in human phase one study for Polyvac by the end of the fiscal year, so an interesting new flow, almost every quarter will have something to say in terms of progress of our pipeline. So, in summary, we believe that the outlook is positive, we have, as I said, good new flow that trading is going well; we expect to finish the year in line with market expectations. We are growing faster than the market, and I think we have been preparing the company for the next stage, now the next big thing should be to move forward towards the US market, and we look at the future with confidence and excitement. So, that's it; thank you very much for your attention, I'm happy to take questions if there are any.

Q&A

Speaker: Manuel, [inaudible] positive manufacturing operations, I wonder if you could give any more colour in terms of where peanuts [inaudible] allergy?

Manuel Llobet: Yeah, well in terms of manufacturing it cannot be manufactured in our facilities. So far we are working with a specialised CMO in Germany, and the plan, if everything goes well, is to keep working with the CMO. If at some point volumes are really, you know, big and justified [inaudible] about building our own facilities, but that's really long term and subject to a successful output of that. It is very sophisticated to the manufacturing of this vaccine, extremely sophisticated, I would say. It is this BLP structure, it is a synthetic [inaudible] protein from the peanut allergen but it's constructed in the same chemical entity. Maybe when we finish the scaling up we can provide more details about the process and what it is about.

James Mainwaring: Thank you very much, probably one for Manuel and one for you Nick. Just first, you obviously talked a bit about Brexit costs and being [inaudible] business we have obviously seen inventories step up a bit to sort of 9 million. Just help me to get a sense of the magnitude of any further changes in that or kind of is that reasonably well stocked in Europe now?

Nick Wykeman: We will see further stock increases, probably something about similar to the same or a bit more in the period but obviously by the time we get to the next supporting period, end of June, there will be a certain amount of destocking although we will be in the low season at that stage, and really that stock could work its way out through the next season up to December next year. So, probably by [inaudible] probably we will see at least the same effect again in the level of stock.

James Mainwaring: And then probably a question for Manuel, obviously there has been some concern that the delay in birch could be due to negative read out, obviously everything is still blinded. Just kind of want to get your thoughts on, you know, if the worst did happen and it was inconclusive or negative, kind of what your plan would be after that, and if it was taken in context, that the sort of TAV process continues to see products drop out and it could get to a point where lots of products – I mean there are no products left in Europe, so just trying to get what your worst case scenario would be.

Manuel Llobet: Well, there are registered products that are protected, we have for example Pollinex trees that cover the same segment that Pollinex Quatro birch, so that part of the market eventually could be protected by Pollinex trees. And I mean we are a research company; we did everything which was in our hand to write a successful study. I think there were points that allow us to be optimistic, like very successful phase two studies, higher dose, we had a good pollen season but we are, in R&D and especially in allergy studies, you can never guarantee, and you have seen some of our recent registered product competitors, they have been registered with some successful and some unsuccessful phase threes. We have had also an unsuccessful phase two for grass, and we rotated, and we got a successful output. So, I would not like to have an unsuccessful or inconclusive result, but if we have it, we will need to analyse what happened and if proceeds and it is appropriate to [inaudible] the study.

Thank you very much, that is very useful.

Speaker: Manuel, just focusing on your comment about the new legislation in the United States, I mean obviously it's not overly relevant for you at the moment, but is there not a risk that the regulators bring in that change and then it leaves the market short because they have not actually got any products that are formerly approved for use, so how the allergists going to cope, with the lack of sterile product and –

Manuel Llobet: There is a risk that a small practice will not be able to cope with that or over they can organise what's happening also is that there are some CMOs offering services to small practices to do the compounding, and say, 'Look, we will invest 1 million, we need to invest in a sterile area with laminate floor, with everything according to the new guidelines and we will have everything for you and just bring us the prescription and we will give you the vaccine.' But that will imply sharing margins, so of course it is going to have an impact, I

think big practices or hospitals maybe it is not going to be a big issue, but it will have an impact and this is why maybe it is a nice combination for poly-sensitised complicated patients, they just carry on with these compounding vaccines and for patients that respond to major allergens or mono-sensitised, we will offer them a portfolio of very strict GNP manufactured products.

Speaker: Secondly, could we just focus a little bit on the legal case that you have embarked on; I appreciate that there is probably a limit to what you can say, as it is under legal jurisdiction, but can you sort of indicate which trial it refers to, and I suppose I am guessing it is probably the phase two US, given that the costs are all in dollars, and secondly, could you explain a little bit why there is a differential between what you are claiming from the other party and what they are claiming from you because the differential implies that you are trying to get all your money back and they did the trial; it might not have been a good outcome, but a little bit more on what that is all about.

Nick Wykeman: I will answer that question, I will respond to it, shall I say? I apologise, we cannot really say any more because it is part of an active legal case at the moment and we are not allowed to disclose parties or indicate. I think if we were to indicate the trial, you would probably be able to work out who the party was. So, I am afraid I will not be able to say anything more than what we have disclosed in our press release.

Speaker: Would I be right in assuming it is a US trial?

Nick Wykeman: I cannot comment any further, I am sorry, I apologise my hands are tied on this one, sorry.

Andy Smith (Edison): Could I come back to more boring financial results for Nick's benefit? So, I know on the commentary around cost of goods, that your 10% revenues increases were due to volumes, and I wonder if there is any visibility you can give us on whether those volumes are more doses per patient or more patients, because one has a higher SG&A than the other.

Nick Wykeman: I think it is fair to say that the majority of it comes from the patients. There is a certain amount in relation to the mix of the different products that we are selling. As Manuel talked about, we have had particularly strong sales of our [inaudible] product which is for the bee and wasp bite, and that one is a longer course; it is a more traditional type of approach, so in a way it is tough to give an exact figure, but certainly the significant majority of it is due to gain of patients, and this comes back to the point that Manuel made earlier that we are gaining from our competitors, so if I talked about the German market this year because of the weaker grass, the market itself has not really grown this year, and we have been taking market share from others. So, that hopefully gives you some flavour.

Paul Cuddon (Numis): Thank you, just extending on that, are you effectively taking share because products are being taken off the market, or are you finding that you are capturing share from the likes of Alutard? I think you cited you were the number one in Germany for [inaudible] in October, so just to try and understand the wider dynamic with products coming off.

Manuel Llobet: Well, there are products coming off as a result of the TAV, and we are always trying to feel this space. Also remember that the TAV and the relation in Europe has

not been only about clinical data but also about better quality requirements, spread specifications, and some products have been taken out, not because of lack of being able to provide clinical [inaudible], because of manufacturing reasons, supply chain – we have seen programmes in some of our competitors and that also – we have tried to take advantage of that, so the TAV removals because of [inaudible] clinical but also because of supply chain issues and also, as you know, there are some key competitors, really trying to switch all their products towards oral treatments, and that is also leaving us space to grow in prescribers that do not want to move to oral treatment and prefer to remain in subcutaneous treatment. I would say that our philosophy has been to stay there, all the time with reliable supply chain with all the products in the market, and every opportunity we have had, we have taken to increase an improve our market position.

Paul Cuddon (Numis): And then on the peanuts trial moving into kind of human later this year, that is one that does not have to kind of wait for pollen seasons; it is a challenge based model, so how creative can you be in the clinical trial process to get efficacy data kind of within a two-year timeframe? Could it be much faster than studies?

Manuel Llobet: I think, well – if you want to comment something after me, but that is great that we are not constrained by the season. I think the studies will be more complex because of the safety issue and therefore maybe a little bit more time in preparing and taking all the measures to be sure that the studies are safe, but the fact that they are out of the season and the fact that maybe there is some sense of urgency from a regulatory perspective, maybe we could have a clinical development plan faster than the classical ones on pollen. Would you like to add something here?

Nick Wykeman: No, I fully agree with Manuel's point, I think due to the variants of the peanut we have to progress cautiously but obviously we are already talking to KOLs, we will be talking to the regulators to see if there is an accelerated path that we can look to. But we have first got to get through obviously the scale up which is absolutely critical to ensure that we have a product that we can manufacture on a consistent quality basis, but that is progressing well at the moment.

Paul Cuddon (Numis): It would be wrong to assume we could have efficacy data in patients on this within two years?

Manuel Llobet: At least at phase two probably we could have some efficacy indication, yeah.

Paul Cuddon (Numis): Thank you.

Christian Glennie (Stifel): Just on the US piece, a little bit more, if you can, in terms of the nature of your FDA interactions, the discussions that are ongoing there and the state of play and then linked to that clearly is your preparedness for launching a phase three in autumn, you know, September/October; have you appointed CROs, far down that track? Obviously there's a timing element that you need clarity on the trial design but you also need to lay the groundwork, so how confident are you around those discussions and your preparedness for that phase three?

Manuel Llobet: I think we are confident; there is a lot of work behind the scenes preparing everything. There has been contact with FDA; we have had a phase two meeting that was delayed a little bit because of the [inaudible] down but it is going to have in a matter of days,

and we should expect, you know, good feedback because when you arrive to these meetings it is not out of the blue; there has been a lot of time and you have submitted a package and you have submitted a lot of information, and there is work with CROs and KOL network, so there is a lot of work behind this intention to start the PQ grass this year. Also the factories working on the [inaudible] batches, and I mean all the work that has to be done to start this year, it is underway but again there are always contingencies but if everything is okay, we will be able to start this year. And remember that is a very interesting study because it is going to be a study that we [inaudible] to support filing in Germany and the US, so it has to be in line with more than one regulatory agency and it seems to be in good place.

Gary Waanders (Bryan Garnier): Just a couple of questions if I may, firstly on the Brexit stocking, I imagine you are only able to stock product which is registered. So, the PQ sales across the category could be at risk of importation/exportation delays; would that be true?

Nick Wykeman: Yes, I think the basic position is that the approved products, they are the products that we are storing in Spain, but for the main patient products, they are only manufactured at the point at which the prescription is received and therefore they have to wait for that prescription to arrive, so like any exporter, there is a risk there that if a hard Brexit occurs and there are issues of getting across the border, that might affect us, but obviously we have been working very hard with our shipment agents to work out other routes and given the type of products that we have, and they are not particularly bulky and so on, there are many more options for us. If you are an exporter of steel or something like that, obviously it is a lot more difficult for us, potentially we could go air freight, there are also a variety of different methods we might use in order to get the product into the continental Europe, if necessary.

Gary Waanders (Bryan Garnier): Could there potentially be a shift of that late stage manufacturing of the main patient products into Spain, for example, or elsewhere?

Nick Wykeman: The Spanish facility itself for manufacturing is fairly small and quite specialised, so realistically that is not something that could be done in the short term.

Manuel Llobet: But what we have been doing is expanding materially the testing, the labs there. So, one of the key issues for us about – if there is a bad Brexit for us, or a hard Brexit is that we will have to double test all the products here as a third country, because we will become a third country and then in Europe, and that has been dimensioned in a way that we will be able to cope with all the continental Europe demand through the Spanish labs. Now, as Nick says, moving the whole factory, we would not be prepared, but there is some intermediate, we have not designed a plan yet because I think the contingency plan we have is sensible, it is the best we could do and we did everything we could to mitigate any damage. If you want zero risk then you have to make huge investments and then if there is a soft Brexit, what do you do with all those investments? So, I think the [inaudible] of it has been quite sensible but as Nick said, if it is a total hard Brexit, there probably could be some disruption, but we do not expect it to really materially affect the company.

Gary Waanders (Bryan Garnier): On the TAV as well, you mentioned a number 65 products still ongoing in the process, has Allergy Therapeutics cut any of the products that it had initially put into the process.

Manuel Llobet: We have kept all of them, but I think we are – I am not 100% sure but I think we are the only company that has been able to keep all the products in the market.

Gary Waanders (Bryan Garnier): And lastly, on the USP guidelines, it seems to me, if there is going to be pressure put on the compounders, in the US, that may indirectly force some kind of change in clinical practice and it may be beneficial for the tablet manufacturers, for example, if physicians are having to move from an injected product to an alternative, how long – I mean we have still got a phase three trial to conduct and that may take two years or three years before there is a result that results in a product approval, what sort of sense do you have of the way the clinical practice is moving in the US, is there any strong shift towards non-injected products?

Manuel Llobet: Well, if we look at the numbers of the companies that are selling tablets in the US, I would say no, we do not see any [inaudible] at all, we do not see any change of trend, the figures are not material for the size of the US market, but eventually, I mean in Germany the market is a [inaudible] market like the US and oral treatments are a little bit more than 20%, so that could happen in the US and would be good, I feel. I think in the meantime the allergists will try to find a way out like maybe the CMOs providing them the services of compounding for the practices that cannot justify an investment on sterile areas and so on. But yes, we cannot wait to launch the products in the market and offer our products to our [inaudible] there. Any questions from WebEx? No questions? Okay, thank you very much for coming, thank you for your interest, we will keep you posted and see you next time, thank you very much.

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