Novartis AG to Acquire AveXis Inc Conference Call Morning - Final

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Presentation

OPERATOR: Good morning, and welcome to the Novartis analyst conference call. (Operator Instructions) And the conference is being recorded. (Operator Instructions) And the conference is being recorded. (Operator Instructions) A recording of the conference call, including the Q&A session, will be available on our website shortly after the call ends. (Operator Instructions) With that, I would like to hand over to Mr. Samir Shah, Global Head of Investor Relations. Please go ahead, sir.

SAMIR SHAH, GLOBAL HEAD IR, NOVARTIS AG: Thank you very much, and good morning, everybody, and welcome to our analyst and investor call. The information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Please refer to the company's Form 20-F on file with the U.S. Securities and Exchange Commission for a description of some of these factors. I also want to point out some important information about the planned tender offer. The planned tender offer discussed today has not yet commenced and our communication is not an offer or solicitation of an offer to purchase any AveXis' securities. On the commencement date of the tender offer, Novartis will file with the U.S. SEC a tender offer statement on schedule together with other materials and AveXis will file a recommendation statement on schedule 14D-9. We urge you to read these materials that contain important information when they become available. And with that, I'll now hand over to Vas Narasimhan, CEO, Novartis.

VASANT NARASIMHAN, CEO, NOVARTIS AG: Thank you, Samir, and thank you all for joining today's conference call. We're very excited about the proposed acquisition of AveXis. If you could turn to Slide 3, as I outlined in our Q4 conference call in January, we are on a journey to focus Novartis on an -- as a medicines company powered by data and digital. And already this year, we're off to a strong start to realize that goal. In January, we announced the closing of the AAA transaction to strengthen our oncology portfolio as well as a license share agreement with SPARK Therapeutics to market Luxturna outside of the United States as the first gene therapy for an eye disease. Then later in March, we announced the agreement to divest the OTC JV stake with GSK, pending the approval of GSK's shareholders. And today, we announced the agreement to acquire AveXis, which strengthens our neuroscience portfolio and also enables us to build a gene therapy platform.

Moving to Slide 4. I outlined as well in January, 5 key priorities to shape our future: Being world-class at operational excellence on our launches as well as driving productivity and margin improvement; breakthrough innovation, which is where AveXis will play a critical role as we continue to focus on high-end first-in-class innovation; a pivot to data and digital leadership; continuing to build our trust with society; and a cultural transformation. The agreement to acquire AveXis is really in line with our vision to deliver transformative innovation to patients.

So moving to Slide 5, a little more detail on the strategic rationale for this transaction. First, this is ***AVXS-101***, the lead molecule -- the lead medicine at AveXis is a potentially transformative treatment for SMA. It has the potential to be the first single gene replacement therapy, if approved, and it could save the lives of these children, improve motor function in children with SMA Type 2, and really addresses an area of significant unmet medical need.

It also provides us capabilities in gene therapy. We have a robust internal portfolio of gene therapies in ophthalmology and neuroscience in Novartis Institutes for BioMedical Research. And we look forward to using AveXis' capabilities in -- manufacturing capabilities and technical development capabilities to enable us to advance that portfolio. And finally, it supports our neuroscience strategy and our ability to expand our portfolio of medicines in neuroscience in areas where we have been a leader for over 60 years. Two new programs would enter our portfolio, a gene therapy for Rett Syndrome and a gene therapy for a genetically driven form of ALS, both with the potential to have IND filings later this year.

So moving to Slide 6, just a brief overview of AveXis. AveXis is a clinical-stage gene therapy company focused on neurological, rare and life-threatening diseases. It's based in Illinois. I'll go through later on some of the background on ***AVXS-101*** and the impressive array of regulatory notifications they have received, indicating the breakthrough nature of this therapy. And their focus is on an AAV9 technology, scientists at AveXis, including their lead scientists, identified that AAV9 is unique in its ability to address diseases of the central nervous system with a high affinity for

central nervous system cells. This enables AAV9 to be, we believe, unique in its ability to address a broad range of neuroscience-related diseases. Now for some of the transaction highlights, I'd like to hand it over to Harry, who'll go through them. Harry?

HARRY KIRSCH, CFO, NOVARTIS AG: Thank you, Vas. Good morning, everyone. Thanks for getting up so early with us on this call. Let me just make some brief comments on the financials. As you can see on Slide 7, the consideration is that AveXis' shareholders would get $218 per share in cash. That values the company at about $8.7 billion, fully diluted equity basis. The company has about $0.5 billion cash, so $8.2 billion of enterprise value.

Now on financing. We do intend to redeploy the proceeds of the sale of our OTC joint venture stake to fund this acquisition. In terms of the financial benefits, we expect that the acquisition assets will contribute to group sales starting in 2019, and then a significant ramp up as of 2020 on its way to become a multibillion blockbuster peak sales asset. We expect significant accretion to the group core operating income and core EPS as of 2020. In 2018 and 2019, we see a slight dilution in earnings per share and core operating income, mainly to ongoing R&D programs. We estimate this to be around 1% points of core operating income each in 2018 and 2019. We do expect significant returns well in excess of cost of capital. And finally, we expect closing in mid of 2018. And with this, already back to Vas.

VASANT NARASIMHAN: Thank you, Harry. So what I'd like to do now is walk through some of the natural history of SMA as well as provide some context on the data that AveXis has generated to date.

If you move to Slide 8, the natural history of SMA Type 1 is quite severe. 90% of children will not survive until 2 years of life or become ventilator dependent. And when you look at the endpoint-free survival, you can see that there's a rapid deterioration in these children already at 6 months of age and as -- once they reach 2 years of age, it's very minimal survival. In addition, most motor milestones that are expected in healthy babies are not met with SMA Type 1. So it is a devastating disease for parents, for families. And so it's one of the leading cause of genetically associated deaths in infants in the United States and in Europe. So it is a very important disease to address.

If you move to Slide 9, SMA, as a disease, covers a continuum of different types. We estimate there is currently about 23,500 patients worldwide in established markets. Those -- of course, with screening those numbers are variable, and we'll see how they evolve. Type 1 SMA indicates the -- a patient has 2 copies of the SMN2 gene. Onset is usually early, before 6 months of age, as I said. And these are the patients, who are over 90%, will die by age 2. In SMA Type 2, again, a very severe form. Patient have 3 copies of the gene. These patients will never be able to walk without support, most will never stand, 32% die before age 25 and most require lifetime support from families as well as the medical -- and medical institutions. Type 3 and 4 SMA are less severe. Type 3, in particular, is of note because it could be a future of relevance for these kinds of therapies. With Type 3 SMA of 3 or 4 copies of the gene, patients can typically stand unassisted and walk independently, but they lose their ability to walk over time. And I think screening, of course, as I said, will increase. Now if you go to Slide 10. We do expect over time that U.S. newborn screening could transform SMA care. You could imagine a world that has therapies like AVXS become available, there would be newborn screening at birth and then treatment to enable as many neurons to be preserved as possible. And there's clear progress on this at the moment for U.S. federal and state newborn screening.

So when you think about how to model a medicine like this, you have the new patients who are incident for the disease, you have the prevalent pool of patients at various age groups who are looking for the best possible treatment to enable a normal life. And then in the future, you have the power of newborn screening to identify as many patients with any SMA -- SMN abnormalities in terms of number of gene copies that then you could treat over time.

Slide 11 goes through a little bit of the mechanism of disease and the therapeutic strategies. Normal individual: There's a primary SMN1 gene that produces this critical protein for neuron function -- a motor neuron function and also normal individuals have SMN2 backups, multiple copies of the backup gene. In afflicted individuals, the primary SMN1 gene is not present and patients have variable numbers of the SMN2 backup copies. Now currently, the

approved therapeutic strategies are to, in fact, supplement the lack of SMN protein by using various approaches that add SMN protein into the patients over time, but these require chronic treatment because the underlying disease has not been [tackled]. With gene therapy, ***AVXS-101***, you reintroduce the primary SMN1 gene to enable normal -- hopefully, more normal production of the protein, enabling neurons to function appropriately.

Moving to Slide 12. ***AVXS-101***, therefore, has the potential to be the first gene replacement therapy for SMA. It consists of an AAV9 capsid shell as well as a self-complementary DNA technology, which was another breakthrough associated with the ability to use AAVs. And the human SMN and 1 transgene, as mentioned, which will enable stable functioning of the SMN gene.

Moving to Slide 13. This is the data that was presented last year in the New England Journal of Medicine. On the left-hand side, you can see the ***AVXS-101*** clinical study results where 100% of patients survived the study period and are -- have continued to survive to this day, achieving the vast majority of normal motor milestones, so really a true breakthrough. On the right-hand side, you see data from another available medicine. And you can see the control group, how -- typically what you see with these patients as well as that medicine's performance.

Important to note, there is a lot of differences in study design, so extremely difficult to make cross-study comparisons depending on the time of treatment and in various endpoints used. But you can see the data here and both datasets are available on -- at the New England Journal of Medicine.

Now moving to Slide 14. You can see the outstanding performance of the medicine on achieving motor milestones, in particular patients who are treated at 4 months of age or younger achieve all of their major motor milestones and it's largely on track. And this is -- as AveXis noted in their Q4 conference call, continues to be the case as they continue to follow-up these patients. Additional long-term data will be presented at AAN on April 25. And AveXis will be releasing that data at the appropriate time.

Slide 15. ***AVXS-101*** has an expanded clinical development program. The data we just showed is from CT-101, the first study you see at the top. Ongoing studies include long-term follow-up of the CT-101 study as well as the ongoing STR1VE study, which is an additional study in SMA Type 1 in children less than 8 kilograms with IV dosing. In SMA Type 2, the STRONG study is currently ongoing. This uses intrathecal dosing and single-dose, again, in children who are greater than 8 kilograms and have SMA. Also, planned are presymptomatic SMA Type 1, 2 and 3 to take advantage of the potential of newborn screening, the SPR1NT study as well as an all comers pediatric SMA Type 1, 2, and 3, the REACH study also planned for start later this year.

So moving to Slide 16. After a regulatory update in the U.S., the medicine was granted Breakthrough Therapy Designation and with the approval to initiate additional studies. A pre-BLA meeting is planned for Q2 of this year and a BLA submission is planned for the second half of 2018. In the EU, the medicine has received PRIME designation, which is also similar to Breakthrough Therapy Designation. Scientific advise has also been received and the file submission in Europe is planned for the second half of 2019.

And finally, in Japan, the medicine achieved a Sakigake designation, which is a designation that indicates, again, a breakthrough therapy in the Japanese context. Pre-submission discussions for the medicine are planned in Q3 of 2018.

So Slide 17. One of the other things we were very impressed by was AveXis' significant progress in manufacturing capabilities. They have a impressive facility in Libertyville, Illinois, and they're planning additional facilities for capacity build out. They have manufactured clinical supply, they have executed process validation, they're building commercial launch inventory and they're preparing for their BLA submission and pre-license inspection. We view this as well as an important capability to add to Novartis as we continue to build out our own portfolio of AAV-based therapies.

So moving to Slide 18, and building on that point, we believe AveXis offers an attractive gene therapy platform for us. In addition to AveXis' internal programs, which I'll say a word about, we have programs in hearing loss with an AAV5, that's in Phase Ib. Another program in retinitis pigmentosa with an AAV8 also in Phase Ib as well as a range of additional programs through our Homology Medicines collaborations and other collaborations that all take --

enable -- all require the ability to produce AAVs. So having this manufacturing capacity and expertise, we believe will help us accelerate our entire portfolio of gene therapies in our core therapeutic areas of neuroscience, ophthalmology and oncology.

So moving to Slide 19. AveXis also plans to advance 2 new gene therapy products into the clinic in late 2018. AVXS-201 is for Rett Syndrome, this is a rare neuro-developmental genetic disorder. It's caused by an X-linked dominant mutation for CPG with a median age of diagnosis, again, in childhood of 2.7 years. They're well on their way to getting the IND filed for this medicine. As well as the AVXS-301 for genetic ALS with a certain mutation type as well. This -- of course, as you all know, ALS is a debilitating disease that impacts patients as they progress in life, and just another exciting opportunity. As I mentioned both medicines, the plan is to submit IND applications in late 2018 and early 2019.

So closing on Slide 20, our expected next steps. There'll be long-term data for ***AVXS-101*** at AAN on April 25. The pre-BLA meeting is planned for Q2 2018 with the file submission in the second half of '18. EU file submission, as I mentioned, in the second half of 2019 and the ongoing recruitment of the clinical development programs. As Harry mentioned, Novartis -- and Samir as well, is to commence a tender offer for the outstanding shares of common stock of AveXis. We expect closing in mid-2018, subject to success of the tender offer and satisfaction of customary closing conditions. So with that, I will hand it back to the operator and ask for questions. Thank you.

Questions and Answers

OPERATOR: (Operator Instructions) And we will take our first question from Richard Vosser with JPMorgan.

RICHARD VOSSER, SENIOR ANALYST, JP MORGAN CHASE & CO, RESEARCH DIVISION: A few please. Just thinking about the screening program, just thinking about potential costs to health care systems and how do you see it working? Would you think about all newborn babies being tested? Just trying to get at sort of how easy is it to identify these patients today? How easy was it to recruit the clinical trials? You've given us the -- second question, you've given us the prevalent population, but the incident population would be useful, if you could give us those numbers as well. Is it for Type -- for both Type 1 and Type 2? Are we looking at about 1,000 to 1,500 U.S. or -- sorry, those -- the geographies you've said for the incident population for Type 1? And then finally, just thinking about your M&A strategy, previously we've been looking at both on this $2 billion to $5 billion, clearly this is a decisive move slightly above that range and a strategic move. Could you just talk about some updated thoughts on the M&A strategy?

VASANT NARASIMHAN: Thanks, Richard. In terms of screening programs, this is -- this would be a part of routine screening. There's no major or additional costs that we're aware of that are associated with this screening. I mean, this is readily identifiable once implemented as part of newborn screening, which is normal course, in the United States to screen for genetic illnesses. So we do expect over time, especially with therapies now available for newborn screening to be put in place. Our overall strategy for the medicine is to initially launch in SMA Type 1 under 8 kilograms, potentially a broader indication as well pending the discussions with the FDA, expand into greater M&A programs for the older kids who have SMA Type 2, get the indications for newborn screening, which would then enable the medicines to be used for all children who are identified in the U.S., and hopefully, Europe over time. In terms of the epidemiology, I'll hand it over to my colleague, Janneke van der Kamp, who's our Global Head of Marketing for pharmaceuticals. Janneke?

JANNEKE VAN DER KAMP: Thank you, Vas. So your question on the incident population. The incidence rate is between 1 in 6,000 and 1 in 10,000 newborns. Those are the data coming from the SMA Foundation. So indeed, like Vas said, there is, of course, one population that we expect to be treating and then indeed in the established markets, we have the preference population of 23,000 patients. So that's people living with SMA today, and we also expect to treat many of those. Maybe to add one point to your question around cost. Of course, you asked about the cost of the screening, but maybe another important point to note around cost is that in the U.S. if we look at patients that are diagnosed relatively early with SMA, the median cost to the system is around $150,000 per year per patient. So that's what's the -- an SMA patient's cost today to the system and that's excluding medication cost.

VASANT NARASIMHAN: Great. Thank you, Janneke. And then, Richard, lastly on M&A strategy. As we said, our goal is to continue to build on our core medicines -- as a medicines company powered by data and digital. With the exit of the GSK stake, our intention was to redeploy the capital into our core -- in its core therapeutic areas and to build new technology platforms. A deal like this sits right in that sweet spot. It builds our neuroscience pipeline as well as gives us a new capability in gene therapies, which then we can use to expand in our other core therapeutic areas. Looking ahead, we'll continue to look at opportunities that are value-creating for shareholders and the company as well as patients in this kind of bolt-on category. So we'll continue to assess opportunities as they arise, and of course, keep you all informed.

OPERATOR: We take our next question from Matthew Weston with CrÃ©dit Suisse.

MATTHEW WESTON, MD AND CO-HEAD OF EUROPEAN PHARMACEUTICAL EQUITY RESEARCH, CRÃ©DIT SUISSE AG, RESEARCH DIVISION: Three questions, if I can, Vas. The first is on the revenue ramp. So Janneke has kindly given us the cost per patient, but obviously, with gene therapy, one of the things that all governments and funding bodies are going to have to come to terms with is, is how to reimburse potentially a one-time treatment that leads to a cure. Now I'm not asking for your pricing strategy, but I'm sure in doing the due diligence for the deal you've thought about the revenue ramp of the product. Looking at consensus, AveXis numbers that seems to be an immediate jump basically to $1 billion of revenue on launch of 101. And I wondered whether or not you are prepared to comment on whether or not you thought that was a reasonable move or whether or not you expected that we needed to think of a more phased revenue ramp as we enter an entire new technology? Secondly, around -- following on from Rich's question around M&A strategy. I know you've pitched this as a neuroscience deal, but really it's a move, as we see it, into rare disease. Do you want to comment as to whether or not you see a broader move into rare diseases or whether or not you feel that Novartis' current infrastructure and infrastructure you can build organically is more than enough for you to satisfy your strategic goals? And then the final question is around manufacturing logistics and data. Often times when we see a large-cap pharma acquire biotech companies, we see that they have to revisit data whether it be around manufacturing infrastructure, regulatory requirements, and it's whether in your due diligence, your confidence that in this case you can meet the relatively rapid filing and approval goals that are baked into the market?

VASANT NARASIMHAN: Thanks, Matthew, I appreciate the questions. First on revenue ramp. What we've guided to in our announcement, there is a significant revenue ramp from 2020 forward. In my view when you look at the situation with SMA, the currently marketed medicine is already reimbursed across the United States by private insurers and by Medicaid as well as almost all major European markets. So in this case, given the severity of the disease and the desire to help these patients, ***payers*** have already made the decision to invest. And when you look at the amount they're investing over time for the existing medication, it's quite significant already. So we believe, in this case, that decision has already been taken. And I believe over time, the issue here is not ***payers***, ***payers*** appreciate that when you deliver a potentially curative therapy that takes out cost out of their health care system and enable people to live, hopefully, a more normal life, they are willing to pay and they see the value. Our goal will be to take an approach on pricing that's focused on value, so value-based pricing, ensuring we're cost effective, ensuring we have appropriate programs in place to enable access. But again, in this case, we think that the road work has been in -- put in place and now we can hopefully with the closure of this deal be able to bring AveXis forward across those markets. In terms of M&A strategy, the way we look at it in certain areas such as neuroscience and ophthalmology, there will be a pivot to rare diseases and gene therapies. We believe the monogenic, genetic disorders, potentially polygenic disorders can be addressed with gene therapies, that's why we made the move with Luxturna to license Luxturna outside the United States for ophthalmology, that's why we make the move here. We believe the science is very [trackable], the efficacy is quite significant. So when I think about rare diseases, I try to put it in the lens of, is this in a therapeutic area where we already have a significant presence that we can leverage in both neuroscience, ophthalmology, you can argue with pediatric ALL, and CART, and oncology. These are rare diseases, those diseases that fit into our therapeutic profile. We have a lot of capability in this given our work with Ilaris. Ilaris, of course, is treating CAPS in hereditary periodic fever disorders, has been incredibly successful as well as Sandostatin in some of our rare drugs in oncology. So we have this rare disease capability as well. But I would say, we would assess each opportunity with the lens of, is it a technology that we're interested in? Does it fit in our therapeutic areas, and do we think we can generate value for Novartis patients and

our shareholders. And lastly, in terms of manufacturing logistics, we've done a very careful due diligence. We believe the company has done a great job in terms of its work on validating its batches and validating its process, gearing up and being ready for FDA inspection. So we feel comfortable based on all we've seen where we are. And I think, given our experience in Morris Plains with our CART therapy, we have a pretty good understanding of what it take to get through an FDA inspection for one of these medicines.

OPERATOR: We take our next question from Michael Leuchten with UBS.

MICHAEL LEUCHTEN, CO-HEAD OF PHARMACEUTICALS RESEARCH OF EQUITY RESEARCH, UBS INVESTMENT BANK, RESEARCH DIVISION: It's Mike Leuchten from UBS. Two clinical questions, please. One, is your view that the direct administration of the transgene trumps the splicing approach or can you comment on potential combination given you have branaplam in Phase I/II testing in your own pipeline? And then secondly, have you -- do you have any view as to whether there is potential for retreatment with the AAV9? And I'm thinking about antibodies here that might deny the ability to do that.

VASANT NARASIMHAN: Thank you, Michael. In terms of the potential for complementarity, I mean, I think, our view is that this therapy will become the front-line therapy, because of its ability to address the underlying basis of the disease. And then, of course, the patients and parents will have to determine and as well as clinical data -- as well as the physicians, most importantly, as well as the clinical data how additional therapies could be used to further augment the patient's overall functioning. We view our current internal oral drug LMI, which is quite early, really it's something that's complementary to this kind of a gene-based approach for patients. The approximate 10% to 15% of patients that have AAV antibodies, alternative therapies are going to be required. And so I think, having something like our LMI molecule will be complementary to what we have here with the gene-based approach. In terms of (inaudible) , we don't know how retreatment would work. As I said, we know that there's about 10% to 15% of patients in SMA 1 and 2 that have AAV antibodies. And so those patients will need an alternative approach as well as we also know that pregnant mothers can transfer AAV antibodies, so those antibodies have to be cleared out. So there could be roles for other medicines to bridge to the gene therapy. These are all things, I think, that will be worked out over time as we generate more and more data.

OPERATOR: We take our next question from Michael Leacock with MainFirst.

MICHAEL RICHARD LEACOCK, DIRECTOR, MAINFIRST BANK AG, RESEARCH DIVISION: I have 3 brief question, if I may. Firstly, on the follow-up compounds, the Rett and the ALS compounds. I understand that they are licensed in to AveXis rather than owned by AveXis. Is that correct? And will your purchase of AveXis make any difference to that ownership? Secondly, I think there was a quote about the 1 in 6,000 to 1 in 10,000 children born with SMA. Is that for all types of SMA? And if so, what proportion of those patients or children would be SMA Type 1? And thirdly, given the innovative nature of the product, how long do you think it would be before the Type 2 development could lead to a product in the marketplace? And so how long would it take for you to get approval for Type 2 following a Type 1 approval?

VASANT NARASIMHAN: So thanks for the question. On the first question on the licensing into the 2 molecules, I'll hand it over to our Global Head of M&A, Nigel Sheail. Nigel?

NIGEL SHEAIL: Yes, it's correct that the programs are licensed in, but AveXis has the rights to those programs. I think that's actually also true of AveXis 101. And in our modeling and financial assessment, we've included the relevant costs of royalties and other associated payments with those licenses.

VASANT NARASIMHAN: Thanks, Nigel. And on the incidence on the split between SMA 1 and 2, I don't know, Janneke, if you have that information handy.

JANNEKE VAN DER KAMP: Sure, Vas. That is actually on Slide 9 of the presentation. If you -- there's lot of numbers on it, of course, but you can see there in the road assess, incidence split, that's off that incidence number that I just mentioned, about 60% is SMA 1, 27% SMA 2 and 13% SMA 3. Now with the advance of newborn screening, as Vas mentioned, in the U.S., we, of course, expect that there could be growth in that diagnosed rate early -- for early patients coming from the Type 2 and Type 3 pool.

VASANT NARASIMHAN: So -- and the last question Michael on SMA Type 2. So the initial filing will be in patients under 8 kilograms, so that's roughly 6 months of age with an IV formulation that's what the clinical trials to date have indicated. There is an ongoing study with single intrathecal, so into the spinal cord administration and that is in patients greater than 8 kilograms covering patients regardless of -- again, of the SMA type. We expect that study to enable a filing in the 2020 time line. So that's our -- how we've currently modeled that coming on board. But we have to, of course, see now, with the discussions with the regulators, how things unfold.

OPERATOR: (Operator Instructions) We will take our next question from Luisa Hector with Exane.

LUISA CAROLINE HECTOR, PHARMA RESEARCH ANALYST, EXANE BNP PARIBAS, RESEARCH DIVISION: I just wondered if you could comment any further on the competitive landscape on any of the gene therapy approaches that you're aware of? And then secondly, could you tell us how long the manufacturing process is and whether there's any particularly unusual steps within it? And the final question would be, given the dilution that you now faced your earnings from the consumer exit and a small amount from this AveXis acquisition midterm, will you be doing any incremental buyback to offset that?

VASANT NARASIMHAN: So thanks for the question. On the competitive landscape, there are, to my knowledge, a few preclinical gene therapies but I think it's too soon to comment on where those gene therapies are and how they might progress. So I think, we'll, of course, keep you updated as we understand the competitive landscape better. In terms of the manufacturing process, I don't know the answer to that off the top of my head, and I'll maybe just ask Nigel. Nigel, do you know by chance the detail of the timing of the manufacturing?

NIGEL SHEAIL: Sorry, could you repeat the question, I didn't catch the details.

VASANT NARASIMHAN: The question is what is the -- how long does it take to complete the manufacturing process and are there any challenging steps that might be worth noting?

NIGEL SHEAIL: Yes. So I think the manufacturing process takes about a month from start to finish. There are no critical steps in that process. The LIBERTY fill facility is already been established and is currently running at full capacity and has produced several batches on a very consistent and high-quality basis. There were also...

VASANT NARASIMHAN: (inaudible)

NIGEL SHEAIL: As you can say, we -- there were also plans to build a second facility, which will further increase capacity.

VASANT NARASIMHAN: Thanks, Nigel. On the topic of dilution, Harry, do you want to take that?

HARRY KIRSCH: I think -- thank you, Luisa. The question was on share buybacks. Now share buybacks will continue to be part of our capital allocation priorities. As you know, first priority being invest in organic business opportunities; the second being a strong and growing dividend of Swiss franc; third being bolt-on acquisitions like this one, for example; And fourth being share buybacks. Now we have not announced an additional share buyback program yet, we -- I expect share buybacks to be continuously part of the mix. But we would basically announce it separately, if it would become, again, part of our capital allocation priority in the near term. And we have an ongoing commitment to always mitigate any dilution from employee participation programs. We don't announce it, we just do that. So there's no dilution from that. But if we would enter another share buyback program to reduce the number of outstanding shares, we would do standalone or we would do an announcement.

OPERATOR: It appears we have no further questions at this time. And I would like to hand the call back over to you for any additional or closing remarks.

VASANT NARASIMHAN: So thank you all, again. I think you can see this is part on target in our strategy of building a focused medicines company as well as on target in our strategy in terms of our desire to bring breakthrough first-in-class medicines in our core therapeutic areas fits with our capital allocation priorities as we've laid them out. So we'll look forward to keeping you up to date on the progress of the transaction as we move to closing and as well on the progress of ***AVXS-101*** as well as our full pipeline of gene therapies. Thank you all for joining the call.

OPERATOR: Thank you. This concludes today's conference call. Thank you for your participation. You may now disconnect.

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