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Novartis AG (NVS) CEO Vasant Narasimhan - CEO on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-22-19 Earnings Summary

Slides

EPS of $1.41 beats by $0.06 | Revenue of $12.17B (-4.75% Y/Y) beats by $501.83M

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Novartis AG (NYSE:NVS) Q3 2019 Results Earnings Conference Call October 22, 2019 8:00 AM ET

Company Participants

Samir Shah - Global Head of IR

Vasant Narasimhan - CEO

Harry Kirsch - CFO

John Tsai - Head of Global Drug Development & Chief Medical Officer

Marie-France Tschudin - President of Novartis Pharmaceuticals

Susanne Schaffert - President of Novartis Oncology

Conference Call Participants

Operator

Good morning, and good afternoon, and welcome to the Novartis Q3 2019 Results Release Conference Call and Live Audio Webcast. [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

Thank you very much,. And good morning and good afternoon, everybody. Thank you so much for taking the time to join us for the investor call.

Before we start, I'll just read to you the safe harbor statement. 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.

And with that, I'll hand across to Vas.

Vasant Narasimhan

Thank you, Samir. And thanks, everyone, for joining today's conference call. As you saw earlier today, we announced what I think are really excellent results demonstrating the strong operational performance happening at Novartis, our continued progress on our innovation as well as continuing to drive our strategic priorities, which we believe will drive sustainable long-term top and bottom line growth.

When you go to slide - the first slide, Slide 4, just to give a little more color on what you all saw earlier today. We had double-digit top and bottom line growth in the quarter. Sales were up 13%, core operating income up 18% and core margin up 1.4%. Harry will go through these numbers in more detail along with describing in a bit more detail as well our guidance increase where we increased both sales and core operating income guidance for the year.

Equally as important, we had strong innovation performance in the quarter. When you look at it, we're on - we are on track to potentially have 4 or potentially 5 new molecular entities approved in the United States, which really shows the kind of innovation power we have in the company. Beovu was launched in the U.S., ofatumumab, of course, compelling efficacy in RMS and then a number of other key milestones, many of which we'll go through over the course of this call.

So turning to the next slide. One of the most important trends we want to start highlighting is how our key growth drivers are increasingly contributing to our overall sales performance. When you look at Innovative Medicines sales 9 months to date in 2019, we've grown now to have 28% of our sales coming from our key growth drivers. And many of these key growth drivers have very strong underlying dynamics, as we'll talk about on the next slide.

In addition, our growth contribution is primarily coming from these growth drivers. We do have some, of course, Gx erosion and then some other benefit. But overall, the primary contributor to our growth year-to-date has been these key growth drivers, most of which are recent launches.

Now if you go to Slide 6, you can see in a bit more detail, we had broad-based strong growth across our growth drivers across the portfolio, whether that was in Pharmaceuticals with Cosentyx, Entresto, Xiidra, Zolgensma in our cell and gene therapies effort and in oncology, where also you see broad-based growth. So I think when you look at it overall, we're firing really on all cylinders as a company in terms of driving our in-line brand and launch brand.

Now if you go to the next slide, Slide 7. Diving in deeper into the individual products, let's start with Cosentyx. And in Cosentyx, we once again had a very strong quarter with 27% overall sales growth, driven by both strong ex U.S. and U.S. performance.

Now I'll first start talking a bit about dermatology. There, we see the market growing at 17% from a TRx standpoint, and Cosentyx continuing to grow ahead of the market at 32% despite intensifying competition. So we believe we're well placed. We also believe we will be well placed next year to maintain our first-line positioning, and we'll be happy to answer more questions about that in the Q&A.

And then when you look in rheumatology, we also are continuing to have a strong growth based on our strong underlying data where we grow 36% versus a market that's growing at 15%. We had some positive news as well with additional CHMP opinion on the higher dose as well as the PREVENT trial meeting primary endpoints at 16 and 52 weeks.

To go into a little bit more detail on the next slide on where Cosentyx is building further positions in the market, our non-radiographic axial SpA data clearly shows the potential of Cosentyx to move into a broader range of patients with ankylosing spondylitis.

When you look at the left-hand side of the chart, you can see there are 3.2 million patients with psoriatic arthritis, 1.7 million patients with ankylosing spondylitis and then an equal number of patients with non-radiographic axial spondyloarthritis.

When you look at the biologics penetration in this kind of early SpA group, there's biologics penetration of only 4% to 8%. This is an exciting opportunity for us now to take forward around the world.

We're also well positioned beyond just the current rheumatology indications. When you look at some of the data readouts we have, but importantly, additional clinical trials we have in Hidradenitis Suppurativa pediatric indications as well as additional new studies starting in rheumatology, including giant cell arteritis. We feel very confident in Cosentyx' longer-term trajectory and we look forward at R&D Day to give you more color on some of those additional indication programs.

Now moving to the next slide with Entresto. With Entresto, we continue to see strong underlying dynamics. Entresto revenues were up 61%, with growth -- strong growth both in the ex U.S. and U.S. When you look at weekly TRxs, we are up 51% Q3 2018 to Q3 2019.

And as you can see from the slope of the line, we just have this continued solid steady uptake in TRx in the U.S. and we see a similar trend in other key markets around the world. Now both PROVE-HF and EVALUATE-HF provided additional mechanistic support for Entresto, and we see that increasingly influencing guideline bodies around the world. FDA also approved a pediatric indication for Entresto in Q4.

Then moving to the next slide. When you look at the PARAGON-HF study, which we read out in Q3, and I think many of you already know these results as described at ESC, the preserved ejection fraction heart failure population is a population that currently is completely unserved.

And these patients are looking for some treatment option. We narrowly missed the primary endpoint on the overall population, but we had important subgroups, including the subgroup of patients with an ejection fraction up to 57% as well as female patients in the study with significant benefits.

So after discussions with the U.S. FDA, we now plan to move forward with a regulatory submission for inclusion of data into the label in Q4 2019. We're continuing to engage in discussions with Europe at EU and other regulators to discuss how best to take forward

this data. We are determined to try to find a way to reflect the benefits of Entresto in a broader patient population in an appropriate way.

Now if you go to Slide 11. Zolgensma, off to a strong start, as you saw year-to-date with sales of $175 million since launch. A few comments on access. I'm very proud of our access efforts within our team in the U.S. They've done an outstanding job. Getting now access is 90% of commercial patients and 30% Medicaid patients with a policy in place. Importantly, we are now still seeing 99% final approval rates for patients that are on label after we go through the appropriate appeals processes.

We are seeing solid demand in a broad base of institutions, over 50 treating institutions now in the U.S., including many leading academic centers of excellence have prescribed now Zolgensma.

And when you look at the patient profile, we're seeing patients across SMA types, the incident and prevalent populations as well as 50% patients coming from switches from the previous -- currently licensed product, nusinersen.

So if you go to Slide 12. Looking forward for Zolgensma, I think a general comment I'd say is you can expect -- given that in Q3 we worked up through some of the pent-up demand for the product, much of which we had also addressed through a Managed Access Program, but there was some pent-up demand still we were working through in Q3. We expect Q4 to be broadly in line with Q3 for Zolgensma. But then moving forward, we see opportunities both in the U.S. and outside the United States.

First, in the U.S. we expect that newborn screening climbs from 30% of newborns to 70% of newborns or higher by the end of 2020. This will be an important additional growth driver for Zolgensma. We also -- and we know that 2/3 of incident patients treated in states with newborn screening are getting Zolgensma. So I think this is an important trend for us.

We also expect Medicaid policies to increasingly come into place over the coming 12 months, including in Florida, New Jersey and Michigan. And many of you saw our interim STRONG data, which really showed, I think, the strong profile of Zolgensma in SMA Type 2 patients with impressive scores on the HFMSE scoring for patients 2 to 5 years of age.

Right now, from a regulatory standpoint, we're awaiting FDA feedback on the IT filing approach. We have provided FDA with the data set that we recently presented and are discussions with the FDA on the appropriate approach to filing. For Zolgensma in the

current IV indication, we expect CHMP opinion in Q1 2020. I know there are questions surrounding that.

The primary reason for that were an extensive set of questions with respect to the manufacturing in CMC. We've now submitted those responses, but we need to continue to work through these responses with EMA to get to the final positive opinion.

And then in Japan, we expect a decision in first half 2020. We importantly have early access programs now in place in France, Portugal and Germany. So overall, I think Zolgensma, well on track to reach our longer-term aspiration.

If you move to Slide 13, Beovu is off to a strong start in the U.S. When you look at the U.S. launch at AAO with a highly competitive label, we're very excited about this medicine. We see it as a medicine that provides benefits both with the possibility for patients to have fewer intravitreal injection but also important data with respect to visual and anatomical measures of the disease. You have longer treatment intervals achievable without compromising efficacy.

That's a key differentiator for this medicine. We have supportive label language on visual and anatomical measures, which will enable us to discuss the important data we have both with respect to retinal fluid and -- central retinal subfield thickness. And we have an overall safety profile in line with comparator products on the market.

So taken together, we think this is a very compelling case. We can say that at least the early signs are very positive on how the launch is already going. So we look forward to keeping you up-to-date on how the Beovu U.S. launch progresses.

Now if you go to the next slide, we also have a broad comprehensive clinical trial program ongoing to look both at potential new indications as well as to better profile Beovu in the core AMD indication.

A few things to highlight here -- and of course, we're happy to provide more details in the R&D Day on this overall program -- but when you look at the TALON study, it's a head-to-head superiority study of Beovu versus aflibercept evaluating treatment interval duration in an identical treat-to-control regimen, I think this is a study which shows our confidence in the overall profile of the medicine.

We have the MERLIN study, which is a head-to-head noninferiority study to cover the q4week population, which we believe will be a small portion of patients that will need q4 dosing, but nonetheless one patient population we want to address.

We also have a head-to-head superiority study ongoing in PCV, which is another opportunity for us to continue to differentiate the medicine.

I think the key message here is we have confidence in Beovu, confidence in the potential of this medicine to be a significant advance for patients with these diseases.

Now if you move to Slide 15. Ofatumumab also read out in the quarter with, I think, really extraordinary data. When you look at it, it now can be a high-efficacy disease-modifying therapy. But our goal will be to position it as being able to be used early and broadly.

We think of this as not a medicine we're focused on competing within the B-cell space. We want patients with RMS to have access to B-cell therapy as early as possible in their disease progression.

When you looked at the data, you saw strong efficacy results versus teriflunomide across a range of different endpoints, I think all of you have seen that data. Also a highly competitive overall profile, high efficacy, favorable safety profile, continuous -- convenient subcutaneous injection with an autoinjector and no need for an infusion center. And our plan is to initiate worldwide regulatory submission starting in Q4 2019.

One thing I wanted to clarify that may have been misunderstood from our press release, our U.S. filing is a filing. It's not a rolling submission. We only meant to imply that we will be rolling out our submissions around the world over the course of the coming months, but our U.S. filing is a straight filing, complete filing that will happen in Q4 of this year.

So moving to Slide 16. Now look -- turning to Mayzent. So with Mayzent, I think, as many of you have seen, very strong market feedback, very strong interest from physicians and patients. It has a unique label with unique data, the only medicine ever to be studied successfully in secondary progressive, active secondary progressive MS, with very strong data that we continue to roll out, including recent data on cognitive processing speed as well as a 4-year delay to the need to use a wheelchair. We are seeing strong interest in the medicine, 90% willingness to prescribe, over 2,600 of request forms now and 150 million lives with preferred and unrestricted access.

Our key goal now is to enable a more rapid onboarding of these patients. We're seeing right now about a 90-day lag between initial interest in the medicine and actually getting patients fully onboard with paid RXs. We expect to work hard to shorten that time line as well as work through the backlog of patients, drive an urgency to treat, simplify the onboarding.

And we hope then to be able to demonstrate further sales progress in the coming quarter. But overall, we think we're in a solid place with respect to how the medicine is being perceived with the foundations now put into place. We expect CHMP positive opinion in late Q4 of 2019.

Moving to Slide 17, now fevipiprant. Fevipiprant, today, we announced the results of the ZEAL 1 and 2 study, but it's important to note where ZEAL 1 and 2 fits into the overall program. Our core goal with fevipiprant was to study the medicine in severe asthma with a focus on high eosinophil severe asthma as other biologics have studied.

That is the core group of the LUSTER 1 and 2 programs, with a further potential to look at patients who are low eosinophils in that study. That is the core of the overall fevipiprant study -- program.

We also were asked to study, as is often the case with these programs, to study the medicine in less-severe patients using an FEV1 endpoint, and that was the ZEAL 1 and two programs in so-called GINA 3/4 patients, the kind of moderate severity asthma patients. And there, we saw no significant improvements in FEV1 on top of the standard ICS/LABA regimen, but we saw a very clean safety profile.

It's important to note we only took the 150-milligram dose into this population and we did not stratify for eosinophils as well. So right now, we are continuing to work through the completion of the LUSTER program and look forward to reading out that program in full in Q1 2020.

Now moving to the next slide. Now switching gears to oncology. While oncology had a broad-based outstanding performance with double-digit sales growth, I wanted to highlight the outstanding performance we had in terms of one of our launches, Piqray. So Piqray was launched as the first and only therapy for advanced breast care -- breast cancer patients with PIK3CA mutation.

When you look at the sales growth here, you can see a really strong uptake. 40% of patients with hormone-receptor positive/HER2-negative advanced breast cancer had a PIK3CA mutation. So really, our goal here was to ensure broad-based uptake of testing. And I think our teams in the U.S. have done an outstanding job enabling that testing to be broadly available.

We now expect CHMP positive opinion in the first half of -- CHMP opinion in the first half of 2020. And our focus is to take Piqray into additional indications, including programs in HER2-positive breast cancer, triple-negative breast cancer, head and neck cancers and

ovarian cancers. So you'll see us continuing to work to expand the utilization of Piqray. And we believe this medicine can be a blockbuster over time.

Moving to Slide 19. We also released additional data on Kisqali, demonstrating the overall survival benefit of this medicine, as the only CDK 4/6 inhibitor to demonstrate overall survival in 2 Phase III trials. One important element to remember about Kisqali is we believe that it's unique in its profile and its ability to agonize the CDK 4 part of this pathway.

And with that unique profile, we think that really enabled us to have a mechanistic differentiation for Kisqali. Now our goal right now is to continue to educate the physician community about the MONALEESA-3 and MONALEESA-7 data, particularly the 28% and 29% reductions in the risk of death. And we'll look forward to further differentiating Kisqali with additional readouts, including the MONALEESA-2 overall survival data, which we'll read out next year.

Now moving to Slide 20. If you look at our overall 2019 expected milestones, I think we had a great innovation performance year-to-date, and we hope to carry that forward with a strong finish to the year. You can see that we've reached nearly all of our milestones. A few milestones were pushed into the first part of next year. But overall, I think a very strong performance.

When you go to Slide 21, I wanted to just highlight a few of the catalysts. We expect a number of key approvals next year. Importantly, ofatumumab and Cosentyx in non-radiographic axial SpA but also SEG101 in sickle cell disease. A range of key submissions. We've already talked about AveXis and fevipiprant, but we also will have the readout and hopeful submission of the data are positive of Lu-PSMA, one of our radioligand therapies for prostate cancer as well as the submission of our triplet combo with PDR001 in Mekinist + Tafinlar.

And lastly, a range of key readouts, we're excited to tell you more about our -- depth of our portfolio in our R&D Day in early December. But a few to highlight, ABL001 in CML, which we also now are planning to use in other lines of therapy. We also will have readouts in Beovu and DME.

A range of Phase II readouts: I'll note LNP023, which is our Factor B inhibitor, we'll have data presented at ASH and I think can eventually be a cornerstone therapy for PNH and renal diseases. So a range of things going on, and we'll provide more depth on those milestones in early December.

So with that, I'll hand it over to Harry.

Harry Kirsch

Thank you, Vas. Good morning, good afternoon, everyone. As always, my comments refer to the results of the continuing operations and growth rates in constant currencies, unless I note otherwise.

So on Slide 23, you see the summary of our quarter 3 and first 9 months continuing operations performance. As Vas said, our quarter 3 performance was excellent with double-digit sales growth driving core operating income and strong cash flow of $4 billion. Sales grew 13%, mainly driven by continued momentum of key growth drivers, as Vas laid out.

We also benefited from the first full quarter of the strong launch of Zolgensma and Piqray as well as the acquisition of Xiidra. Core operating income grew 18%, mainly driven by sales and also productivity program impact. You see a similar pattern on year-to-date results. Year-to-date sales growth of 9% drove core operating income growth of 18% and resulting in free cash flow of $9.4 billion in the first 9 months.

On Slide 24, we have laid out the first 9 months and quarter 3 core margin by division. Continuing operations margin improved by 1.4 percentage points in the quarter and 2.4 percentage points year-to-date. In Innovative Medicines, strong quarter 3 sales growth of 15% enabled core margin improvement to 34% of sales. Sandoz had a particularly strong quarter with 5% sales growth and 18% core operating income growth, resulting in a core margin of almost 25%.

The growth in Sandoz was mainly driven by Biopharmaceuticals growing 27% as well as productivity from the ongoing transformation programs falling through to the bottom line. Additionally, quarter 3 at Sandoz was hedged by, first, 3 first-to-file retail launches in the U.S. and a favorable onetime Medicaid revenue deduction adjustment in the quarter. Overall, year-to-date, you see very strong margin expansions in both divisions, with Sandoz margin of 22% almost and Innovative Medicines margin of 34%.

On the next slide, Slide 25, just to the guidance. So in light of our really strong performance, we are revising upwards our 2019 full year guidance once more. This is clearly driven by the very good performance of our growth drivers and launches. In addition, we saw less generic impacts on our onco mature products than expected in quarter 3, which we discussed as a scenario at the quarter 2 call.

So for the new focused medicines company, net sales are revised upwards, expected to grow high single digits and core operating income for the company revised upwards expected to grow mid- to high teens. From a divisional perspective, we revised Innovative Medicines' sales guidance upwards to grow high single to low double-digit and Sandoz sales guidance is revised upwards to grow low single-digit.

On Slide 26, I want to walk you through some of the dynamics for the fourth quarter versus the 9 months. Now we are having a very strong 2019 with core operating income growth of 18% year-to-date. As you can see, this is mainly driven by excellent sales momentum of our growth drivers and launches and also the productivity programs we have put in place. But we had also a very moderate generic impact on some of our older Innovative Medicines brands and upside on valsartan from competitor supply shortages.

So as we move into quarter four, we continue to expect our growth drivers and launches to be very successful. We also expect continued benefits from our ongoing productivity programs. However, we also plan to further increase investments in launches and pre-launches, such as Beovu, Mayzent, Piqray, Xiidra and ofatumumab. As of quarter 3, we do lap the valsartan upside in the base and valsartan generics are starting to return to several markets.

In addition, we expect increased generic competition on Afinitor, Exjade, Jadenu and some mature ophtha brands. However, as always in these cases, we do not know exactly when the generics will enter the market. So if generic entries would come again later or would continue to have minimal impact on our results in quarter 4, we would expect to be at the higher end of the full year guidance. As you know, the above-mentioned mature onco and mature ophtha generic entries are a matter of time and you need to consider that also in your modeling for 2020.

On Slide 27, quickly, let's look at how the currencies would impact our results if mid-October rates would prevail for quarter 4 and for 2020.

So you see the effect of the strength -- mainly strengthening dollar to diminish over time in quarter 4 already, but the full year 2019 would be a negative 3% on sales and a negative 5% FX impact on core operating income. In 2020, the currency impact would diminish down to a minus 1% for both sales and core operating income. And as you know, currency fluctuates a lot. We update this on our website every month, so you have hopefully a very transparent picture on currency impact on our results on a monthly basis.

And with that, I hand back to Vas.

Vasant Narasimhan

Thank you, Harry. So just in summary, when you look at the last slide, we continue to see tremendous momentum overall in the company; whether you look at the sales and operating

[Technical Difficulty]

… very good about where we are. And I think we look forward to taking your questions. So with that, I will hand it back to Samir.

Samir Shah

Operator, we'll be open for Q&A. [Operator Instructions]

Question-and-Answer Session

Operator

Our first question comes from the line of Graham Parry from Bank of America.

Graham Parry

So firstly, on Zolgensma, you talked through some of the moving parts and the potential drivers into next year, but I was wondering if you could express any level of comfort with the consensus number of $1.2 billion at the moment, which would seem to assume either very high penetration into the incident patient population or quite a lot of prevalent patients being accessed through the course of the year. So is there enough prevalent penetration left after your bolus to get you to that number?

And then secondly on Gilenya, it looks like you've settled that with Mylan looking at the court dockets and the stay there. Could you give us any kind of feel for what sort of time frame that would be coming into the market and whether you would expect to be seeking similar settlements with the other generic filers given the rather positive comments in the preliminary injunction from the judge?

Vasant Narasimhan

Thanks, Graham. First, on Zolgensma, as I explained on the dynamics, I think the key drivers here are going to be the continued penetration in the incident population where our goal will be, in the United States, to achieve very high coverage of incident patients, both in newborn screening or those identified later on after newborn screening to continue to drive switches. And it's important to note that while we have covered a portion of the

prevalent patients to date, because we haven't reached the highest levels of coverage within the incident population, there will continue to be opportunities for switches for Zolgensma, we expect, in the coming year. And that's the second source of the business.

The third will be the global launch, which we hope to achieve in -- to enable us to go into Europe and other markets. You'll, I think, likely note from the competitor sales as well, there are substantial sales opportunities outside the United States. We continue to prepare and develop those markets. I think our ability to launch in Europe, the Middle East, eventually in Latin America and Asia, will provide an important opportunity for Zolgensma IV.

And then lastly, of course, once we clarify the final filing and time lines, we'll provide further guidance on the intrathecal formulation and when we would expect that launched. So overall, I think a lot of catalysts coming for Zolgensma, a lot of positive momentum and energy around the data, a lot of interest from the physician and patient communities around the world. So we are confident in our longer-term outlook for this medicine.

Now with respect to Gilenya. With respect to the recent court injunction, which now covers all generic manufacturers, I think that's what you're referring to, when you look at any potential settlements, we're not disclosing any detail of those settlements. Those discussions, of course, are ongoing. But just to remind everyone, we would expect at some point next year a ruling from the District Court -- or the start of a trial with the District Court, which will be important as well as the ruling on the appeal of the IPR ruling. Those are the next milestones with respect to Gilenya, but we feel very confident with our position, given the language used in the initial IPR ruling, the strength of our recent restraining order that was put in place. And so I think overall, we feel good about where we are in this process.

Operator

Our next question comes from the line of Peter Welford from Jefferies.

Peter Welford

Firstly, just with regards to Zolgensma, I guess, following up in terms of the commentary that 4Q will be broadly in line, I guess given that you've seen a roughly similar split of incident versus prevalent patients, if I understand right, in the third quarter, presumably, with still quite a large prevalent population of less than 2 years old left to be treated in the U.S. So I guess I'm just curious what is it at the moment that's the main factor to getting

those patients on drug, given the broad access that you seem to have secured? And can you help us think about perhaps how we should think about that access improving during the course of 2020?

And then just moving on to Piqray. Obviously, a pretty impressive second quarter sales number there. I wonder if you can just talk about the testing rates that you're seeing at the moment and give us some sort of idea in terms of, I guess, the coverage and the type of patients you're getting on Piqray at the moment, whether those patients are sort of last line or whether you're seeing earlier use driven by positive companion diagnostic tests?

Vasant Narasimhan

Thanks for the question, Peter. So on Zolgensma, in terms of the -- you're correct. We continue to have a prevalent population available to us. And because again, we are still climbing in our coverage of the incident population, every time we don't capture an incident patient, they become part of a prevalent pool that remains available to us for a period of time. So that dynamic, we think, will continue for some period until we achieve our goals of having very high coverage of the incident population.

Now in terms of the dynamics on the prevalent population in switches, there's a combination of factors. I think, one, it's just continuing to work on the access environment, particularly in Medicaid. We're at 30%. Our goal is to increase that now over the course of next year, and that should enable us hopefully to be even more successful in the prevalent population.

Second is to continue the journey on patient and physician education, particularly around our long-term data. I think the only reasons we hear any reluctance to make the switch is because typically right now insurers are not covering both medicines. So if you make the switch, you are making the switch on to the gene therapy. And so continuing to educate physicians and patients on it, but we're seeing, I think, very strong uptake with respect to that as well. I think those are the 2 key dynamics, access and the continuing patient advocacy and education.

And now in terms of the access dynamics, as I think I've already described, we have very good coverage in the private. Public should climb, and our focus right now is to continue to push the uptake of newborn screening.

Piqray, I'll hand it over to Susanne.

Susanne Schaffert

Thank you, Vas. Thank you, Peter, for the questions. Actually, we're very excited about our launch in Piqray. As you know, these patients that have a PIK3CA mutation usually have a very poor prognosis. So we see very high interest, a very positive feedback from physicians. We have reached 49 million year-to-date and have more than 1,000 patients that receive Piqray now. In terms of coverage, we see very broad coverage for the treatment but also for the testing. As you know, Piqray as treatment but also PIK3CA testing is covered in the NCNN (sic) [NCCN] guidelines. And we are very pleased also with the uptake of the testing rates.

Specific to your question, what patients are currently treated on Piqray? Well, there might be a few patients that are in later line. But as you know, this is metastatic breast cancer patients with poor prognosis, so we expect that the majority of patients come really from second-line treatment. And we expect continued demand and are very pleased with the performance so far.

Vasant Narasimhan

Thank you, Susanne. And we're very excited about taking Piqray into additional indications over time as well.

Operator

Our next question comes from the line of Keyur Parekh from Goldman Sachs.

Keyur Parekh

Two questions, please. One, Vas, as you talk about the momentum for the business into the 9 months of this year, can you help us think about how do you see that momentum developing into 2020? What might be things that might accelerate versus what might be things that might pull you back into next year? That's question number one.

A - Vasant Narasimhan

Thank you, Keyur. So on 2019 versus 2020 dynamics, as Harry described some of the dynamics for Q4, I think you'll have a similar set of factors that will impact us in 2020. On the one hand, you're going to see our launches, we'll continue to drive with great energy and as well as our growth drivers. We'll continue the strong productivity programs, where our goal has been to deliver $2 billion in absolute savings across NTO, our manufacturing as well as procurement as well as Business Services. But at the same time, we have in oncology a set of potential generics or generics that have already of course launched,

primarily Afinitor, Exjade -- Exjade, Jadenu, I think are the ones highest on our mind. So I think we'll just have to see how those dynamics play out, but we think we'll set up well for a strong 2020 as well and we look forward to providing full year guidance in January.

Thank you, Keyur. So on 2019 versus 2020 dynamics, as Harry described some of the dynamics for Q4, I think you'll have a similar set of factors that will impact us in 2020. On the one hand, you're going to see our launches, we'll continue to drive with great energy and as well as our growth drivers. We'll continue the strong productivity programs, where our goal has been to deliver $2 billion in absolute savings across NTO, our manufacturing as well as procurement as well as Business Services. But at the same time, we have in oncology a set of potential generics or generics that have already of course launched, primarily Afinitor, Exjade -- Exjade, Jadenu, I think are the ones highest on our mind. So I think we'll just have to see how those dynamics play out, but we think we'll set up well for a strong 2020 as well and we look forward to providing full year guidance in January.

Operator

Our next question comes from the line of Andrew Baum from Citigroup.

Q - Andrew Baum

I'm not sure if John Tsai is on the line, but I'd be curious as to his view both yourselves with Entresto and Biogen with aducanumab are filing date on subgroups from 2 trials which failed to hit their primary endpoint; in the context of some recent comments from Bob Temple. Should we be thinking of this as the beginning of a new paradigm in willingness of the FDA to go further with subgroup analysis that they may have done previously in terms of trials which failed to meet?

And then second, on Cosentyx, looking at the IQVIA data, the drug seems to have stalled in terms of both NRx and TRx approximately since launch the launch of Skyrizi. Is it some issue with sampling here? Or is there something else going on which should explain the paradoxical outlook?

A - Vasant Narasimhan

Yes. Thank you, Andrew. So on Entresto, John?

A - John Tsai

Yes. Thanks for the question, Andrew. I think it's very insightful you picked up some of the deliberations from Bob Temple. I think, one, when we look at Entresto and the results, obviously, we talked about the heart failure with preserved ejection fraction population that currently has no treatment. So given that's the underlying basis, we are having discussions with the agency, and they have expressed interest in seeing the results. So we'll have continued dialogue with them in terms of the best way to move forward. And we'll submit those before the end of the year. That's the approach we'll take for Entresto.

A - Vasant Narasimhan

And if I could just add, I think one important element -- I can't comment on the other filing you mentioned, but I think on Entresto, one important element is this is an approved medicine in reduced ejection fraction heart failure with a sizable safety database and a patient population that we studied that's adjacent to the original patient population. And I would say also with unclear boundaries, the 40% ejection fraction versus 60% ejection fraction, where do we cross the line from reduced ejection fraction to preserved ejection fraction? It's notable, 35% used to be the cutoff, and we've moved to 40% for reduced ejection fraction. So we're in a gray zone here. And I think that's part of the reason we believe the regulators encouraged us to file the data and then take the next steps because there may be ways to look at this to enable patients to benefit, particularly building off an approved medicine with a long track record.

Now with respect to Cosentyx NRx, Marie-France?

A - Marie-France Tschudin

So actually, we're delighted with our performance with Cosentyx. It's growing strongly, actually faster than the market in dermatology and rheumatology. It's normal for us to see some of these fluctuations in NBRx, but if we look across the year, the NBRx is very solid. In the U.S., we're actually growing twice the market in both derm and rheum. Skyrizi is expanding the market, as other launches have done, but it's taking share from older agents, namely the anti-TNF. Cosentyx is actually more than just a great dermatology drug, it's a complete treatment. 2/3 of the patients have additional manifestations beyond skin, and given the complete treatment or a strong first-line access, we're confident in the potential of this product going forward.

Vasant Narasimhan

Yes. And if I could just highlight again, we've looked -- I think tried to look as carefully as we can about the dynamics. And when we look at the NBRx data and the TRx data across -- in dermatology, we feel very good about the trends that we're seeing. And we'll look forward to continuing to demonstrate that in quarter 4 and then into 2020.

Operator

Our next question comes from the line of Eric Le Berrigaud from Bryan Garnier.

Eric Le Berrigaud

First question is about amortizations of intangible in pharma. There are some significant swings here. In the third quarter, it was significantly up. Going forward, what should we expect? Is it the first sign of AveXis of a full quarter being fully amortized? And so should we expect $700 million to $750 million per quarter to persist over the coming quarters?

And the second question is about Entresto. My understanding is that in the U.S., you suffered from some negative inventory movements. Could you quantify that for the second quarter and Maybe give some explanation whether it corresponds to any price increase or some rebate discounts in anticipation for that or these kind of things?

Vasant Narasimhan

Thank you, Eric. On amortization of intangibles, Harry?

Harry Kirsch

Yes. Eric, so amortization of intangibles, of course, what you see is the acquired medicines, so to say, to increase the amortization piece according to the expected [remaining] patent life that we assume in the accounting according to IFRS. So we have AveXis and we have Xiidra coming in which added, of course, then to the amortization. So that's the level of amortization I would expect going forward. Of course, always pending potential M&A actions, all right, which then would add to it. And of course, over time some of the older assets would come off, but that's right now roughly the level that we see also going forward.

Vasant Narasimhan

Thanks, Harry. And then on Entresto dynamics, Marie-France?

A - Marie-France Tschudin

So we have seen some seasonal effect in Q3, but this is completely in line with previous years. We'll always see some stock and trade fluctuations and we have seen some revenue reduction true-ups in Q3. However, if we look at demand, it's really strong. Our TRxs are up 50% year-over-year. We are expecting a really strong Q4 and we're comfortable with our full year consensus.

A - Vasant Narasimhan

And maybe, Harry, you want to just dimensionalize -- I know this a question on inventory risk revenue deduction?

A - Harry Kirsch

Yes. It's roughly half-half. Also, in the inventory, I just want to reassure you, this is sometimes 1 or 2 days of inventory to talk here. Overall, there's hardly any fluctuation on the company or the key brands that would be any cause of concern as one of our key control as you know, each quarter, each month to ensure that we see overall sales in line with demand. So when a couple of sites come together with a bit of revenue reduction and maybe 1 or 2 days less stock in trade, that month you have a bit of an effect, especially as we also have in quarter 3 always a bit lower new script on Entresto. So nothing to be concerned about. Very strong underlying demand.

Operator

Our next question comes from the line of Matthew Weston from Credit Suisse.

Q - Matthew Weston

Two questions, if I can. The first is on Zolgensma and the strong data. Vas, I think you said that after we'd seen the second dose you would discuss with FDA whether that was sufficient for filing or whether or not we had to wait for the highest-dose data. I wonder whether those conversations have now been had post-World Muscle and what the decision was between waiting for that third dose?

And then secondly, a question around share buybacks. Clearly, the cash flow remains extraordinarily strong with a very strong earnings growth at the business. Obviously, the outcome -- or the program associated with limiting the dilution of Alcon is now complete. But I wondered philosophically how you felt about further additional share buybacks.

And then if I can cheat a quick third one, Harry. A feature of Q2 was writing back prelaunch inventory and had a very meaningful impact on margins. I wondered if we were going to see something similar with Beovu in 4Q?

A - Vasant Narasimhan

Thank you, Matthew. So first on Zolgensma, we submitted the data to FDA with respect to the first 2 doses that we presented at WMS. And we still have not had the conversation yet with the FDA. As soon as we have that conversation and can clarify the filing approach, we'll provide that. And I would say as well, we are making progress as well on the high-dose if it is in fact, needed. But our position is that we have data needed and we'll hopefully have that conversation with FDA in a positive way. With respect to share buybacks, Harry?

A - Harry Kirsch

Thank you, Matthew. And also for noting the strong free cash flow we have which is always of course a key focus area for us and we are doing quite well. Always improvement areas of course, but wonderful $9.4 billion, the first 9 months, so going well there. And overall, share buybacks, I continue -- we continue to see share buybacks as part of our capital allocation priorities, but it's also #4. So after we have completed this one, the $5 billion the we announced last year in June, we completed in quarter 3, we of course continue to look at our capital overall. And just to remind everybody on the phone, after the first priority being organic investment, the second we have strong and growing dividend and third being bolt-on up to basically 5% of our market cap before us is share buyback. And so we will continue to evaluate this as we go forward. In case, we would have specific share buyback program to lower the underlying share count, we would make an announcement publicly. We have an ongoing commitment to mitigate any diluting effects from our employee participation programs, so you will see ongoing some share buybacks as we buy back employee shares. So let's see. We'll continue to be part of the future capital allocation priorities, but it's #4. And we would always announce when we do a specifically one.

A - Vasant Narasimhan

And Harry inventory movements on Beovu?

A - Harry Kirsch

So this is the launch provision as we prior to approval write off any launch inventory according to prudent IFRS accounting rules there will be some, but I don't see this -- that this would impact as you have seen before. So usually, our prelaunch inventory, the cost of goods are quite low. And therefore, you don't see these effects and they level out over years.

A - Vasant Narasimhan

Maybe I'll take the opportunity, Marie-France, do you want to provide some color of the conversation you had Beovu at AAO and some of the excitement that you saw on the product?

Marie-France Tschudin, Novartis AG - President of Novartis Pharmaceuticals 34

So we're very thrilled about the feedback we got at AAO, we spent some time there and obviously met with some of the top retina specialists in the U.S. I mean what we're hearing from physicians is they really make their decisions on the ability of a medicine to dry better on the dosing interval, on the safety and on the cost. And what we know with Beovu is that we really believe we've got a product that can deliver on these 4 dimensions, providing greater fluid resolution, longer intervals for patients, uncompromised safety. And definitely, what we've heard from AAO is that physicians were very impressed in how we priced the product. We really got great feedback. They're excited to use Beovu and want to treat patients quickly. A lot of them described Beovu -- and I'll just use a quote as a "generational leap." So we're very excited. We believe Beovu will be a major player in the wet AMD space and beyond.

Vasant Narasimhan, Novartis AG - CEO 35

Thank you Marie-France. So we'll keep working to demonstrate that in the coming quarters.

Operator 36

And our next question comes from the line of Steve Scala from Cowen.

Stephen Michael Scala, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst 37

Two questions. First, on Zolgensma. It was launched with a paid-for-performance program. What portion of dosed patients have fully achieved the necessary milestones required by the paid-for-performance program so any clawback is now not possible?

That's the first question.

Second question is on fevipiprant. What can you say about the performance on FEV1? Was it just inconsistent? Or was it a complete miss? It would seem less likely that a drug that fails on FEV1 hits on exacerbations. [Kalyd] did that just that, but its FEV1 data was inconsistent and not a complete miss.

Vasant Narasimhan, Novartis AG - CEO 38

Thanks, Steve. On Zolgensma pay-for-performance, what I can say is we have that feature and many if not all of our contracts with private insurers. I think very few, if any, have yet met the milestones associated with those contracts. I would say as well, though, that we have now presented data with patients out beyond 5 years, maintaining all motor milestones, the average patient now from the START Study is beyond 4 years of age. And we continue not to see deterioration in the motor milestones gained in those patients treated with Zolgensma.

Harry Kirsch, Novartis AG - CFO 39

If I just add, Steve, on the revenue recognition principals, of course are a very small portion of patients that would be on that pay-for-performance. We ensure that we have appropriate revenue deductions from statistical model so to say, which initially we have from the clinical trials and which we would update every quarter, according to real-world, which we expect to be close to [clinical] trials. So revenue deductions are already taking this into account and are very prudently managed.

Vasant Narasimhan, Novartis AG - CEO 40

John, on the fevipiprant ZEAL?

John Tsai, Novartis AG - Head of Global Drug Development & Chief Medical Officer 41

Thanks for the question, Steve. I'm not going to go into the details of the fevipiprant study result. But what I will say is that we're currently in the process of really analyzing the results. And one bit of color on this, we're not surprised by the results that we received in the ZEAL 1 and 2 studies. As you know, these studies were conducted in a moderate asthma patient population and that was across a broad unselected population and it was not stratified by eosinophil count. So that was the basis.

Our original intent in terms of filing was always looking at the severe population and especially looking at the elevated eosinophil count. Given that that's our focus, we'll look forward to sharing the results in the first quarter as well as sharing the results of LUSTER 1 and 2, which will form the basis of our filing in the first quarter of next year.

Operator 42

Our next question comes from the line of Florent Cespedes from Societe Generale.

Florent Cespedes, Societe Generale Cross Asset Research - Senior Equity Analyst 43

Two quick ones. First on the respiratory. Could we have your view on the respiratory franchise strategy going forward given the fevipiprant results and the (inaudible) products approvals expected next year as you can explain [patients] in Europe versus patients and your strategic in the U.S.

Second question for Harry on Sandoz margin. How sustainable is that Sandoz operating profit margin improvement? How should we extrapolate the Q3 performance? Or in other words, what is the underlying growth or operating profit improvement for Sandoz this quarter?

Vasant Narasimhan, Novartis AG - CEO 44

Thank you, Florent. I just want to say it's ladies and gentlemen now, at least for Novartis, so we have almost 50-50 representation in the room. So on the respiratory franchise, I think when you look at it, we have positive results now for QVM, the triple in asthma as well as QMS, which would be a LABA ICS in asthma. That would be built on top of (inaudible) which is our LABA/LAMA in COPD. So we have a broad portfolio of inhaled medicines, and we are now looking at the optimal way to launch that entire respiratory portfolio. Clearly, the final results for fevipiprant will shape a lot of our thinking. Our overall strategy in respiratory was to move towards more specialty respiratory and severe respiratory, building on our strength from Xolair. And our ideal positioning would be to have Xolair, fevipiprant, then having QVM as an option for patients before they move on to the more advanced therapy. So we'll see how that evolves. We continue to have a research program looking at diseases like IPS, sarcoidosis, pulmonary arterial hypertension as well. I think we'll have a better view on our longer-term outlook in the respiratory franchise in 2020.

Now with respect to Sandoz and margins, Richard?

Unidentified Company Representative 45

Thank you, Florent. The core (inaudible) clearly there was exceptionally strong results for the quarter, reflecting good underlying performance, but also a noticeable impact of U.S. onetimers, particularly Medicaid gross-to-net adjustment. The core growth margin, really driven by favorable product mix, strong underlying growth from the Biologics business growing at 27% and the geographic mix, plus the ongoing transformation of productivity improvements as well as the positive impact of the Medicaid gross-to-net, partly offset clearly by the continued price erosion particularly we're seeing in the U.S. Our goal is to continue to drive margin improvements as we drive the operational focus. But clearly, we don't make specific forecasts. And in 2020, we'll give you guidance for going forward.

Vasant Narasimhan, Novartis AG - CEO 46

And Richard, any early perspectives on Sandoz and how you see things progressing?

Unidentified Company Representative 47

No. I mean clearly, we're on track with the Sandoz transformation. We have seen a very engaged organization that's very growth-orientated with a lot of work going on in terms of our supply chain, our alignment. And we are noting that transformation is really much on track, but this is a multiyear journey in terms of building a generic-focused business which I look forward to talking to you about later.

Operator 48

Our next question comes from the line of Tim Anderson from Wolfe Research.

Timothy Minton Anderson, Wolfe Research, LLC - MD of Equity Research 49

Just going back to fevipiprant. Would you -- I guess you still sound quite bullish on the program. You did hit FEV1 in your Phase II trial. My question to you is, are you saying that the probability of success in hitting results in LUSTER are just as high now as they would have been before you knew the results of ZEAL? It seems to me that not showing an FEV1 benefit has to be a negative harbinger of sorts on what to expect from the next round of trials.

And then just a quick question on Zolgensma. Just the number of patients treated, do we just simply take sales in the quarter divided by 2 million? Or can you actually give us the actual number of patients?

Vasant Narasimhan, Novartis AG - CEO 50

Just on fevipiprant just to, I guess, clarify. When you go back to the Phase II studies, the (inaudible) class I think has been well studied also in our hand. When we studied mild-to-moderate patients in various context, we didn't see a -- we did see some FEV1 benefit. We didn't see a significant benefit. It was only when we studied patients in a publication we published at ERS a few years ago and it looked at high-use eosinophil patients that we saw the benefit. So I think it's important context. ZEAL 1 and 2, LUSTER 1 and 2 are very separate efforts. ZEAL 1 and 2 is looking at this mild population, moderate population, I should say, not stratifying for eosinophil. LUSTER is looking at the severe population, looking at the high, primarily hopefully looking at it with a positive result in the high-use eosinophil population, as you've seen with the various Biologics. The ZEAL results is largely in line with what we saw in Phase II. It was requested of us as has been requested of others to look at a less severe population. I don't think there's a readthrough. I can't say we're more or less bullish about LUSTER 1 and 2. LUSTER 1 and 2 is just a different patient population.

With respect to Zolgensma, you'd have to divide the total sales by the net pricing that we've achieved and also look at our U.S. EU mix. But you can think about we're in the range of 100 patients treated that currently under the paid program. We also, of course, have many patients that were previously treated in the (inaudible) program as well as the ongoing clinical trials, but I think roughly 100 patients treated to date around the world is a reasonable number, give or take.

Operator 51

Our next question comes from the line of Richard Parkes from Deutsche Bank.

Richard J. Parkes, Deutsche Bank AG, Research Division - Director 52

Firstly, I'm just trying to understand a little bit better the Mayzent onboarding issue. I'm just trying to understand why Mayzent would be any different from any other MS therapy. It sounds like reimbursement access isn't the issue here. So could you just confirm specifics whether it's a logistical issue rather than reimbursement access. So that's first question.

Then the second question, just on Cosentyx and non-radiographic axial spondyloarthritis. Obviously, penetration rates are partly low due to the lack of approved therapies in that setting. But I think biologic drugs have been a valuable for a little bit longer in Europe. Can you discuss what experience in Europe tells us about the likely barriers to uptake in that setting and what you might be able to do to go back improving on those levels of penetration?

Vasant Narasimhan, Novartis AG - CEO 53

On Mayzent uptake, Marie-France.

Marie-France Tschudin, Novartis AG - President of Novartis Pharmaceuticals 54

The NBRx that we see shows that physicians see the value in this product. We do see a 90-day lag between start forms and paid scripts and this is due to baseline testing and free drugs. However, now that we've been in the market for a couple of months, we do see opportunities to accelerate this. I think if I go back to what I said in Q2, we have always said that the first 12 months with Mayzent would be about education. Physicians recognize that these patients are progressing. The challenges that they are not diagnosing SPMS, and that is because there's been no effective therapies until now. So this means we need to change habits, and that takes time. We're very committed to Mayzent because patients need it. It's really the only DMT with proven efficacy in this population, so we just need to work, continue to work on education and continue to work to accelerate the pull-through.

Vasant Narasimhan, Novartis AG - CEO 55

I think one element that's specific to Mayzent is the need for genetic testing which we're now working to accelerate as well, that's just one component. But I think we really view this as a logistical operational challenge. We're seeing strong interest and strong demand from the patient physician community. Now on your question on non-radiographic axial spond, you are correct there are TNS that have been approved in the past in this indication in Europe. I think the key things for us are going to be making a strong access argument around the world in the U.S. and in Europe and in improving diagnosis rates. When you look at the diagnostic inclusion criteria, it does involve an MRI. And so I think one of the key things for us is going to be to work through patient -- physicians understanding how to identify patients that might be in what is really an early stage of ankylosing spondylitis, take the appropriate measures to evaluate the patient and then hopefully get them on the medicine.

Operator 56

Our next question comes from the line of Richard Vosser from JPMorgan.

Richard Vosser, JP Morgan Chase & Co, Research Division - Senior Analyst 57

So 2, please. First just going back to Sandoz. I wondered if you could give us the contribution from the all solids business in the 9 months, both on the sales and operating profit, and also give us the idea of the contribution from the lack of depreciation to the margins from that business for the 9 months.

Second bit on -- linked to that is just when do you we think the disposal to [Oravendo] will happen now? Is that going to be by the end of the year? Or should we continue to think this contributing to numbers in 2020?

And then second question, just on Sandostatin LAR. I noticed that you are not commenting about that in terms of an impact on generics. And just maybe if you could give us some flavor of the impact that you're seeing in Europe, the proportion of the rest of world sales that are from Europe and what's happening ex Europe, what sort of growth are you seeing ex Europe that may be balancing any impact from the generics in Europe?

Vasant Narasimhan, Novartis AG - CEO 58

So Richard, on the Sandoz mix from oral solids versus biosimilars and other businesses.

Unidentified Company Representative 59

Thank you. Clearly, the Biologics business accounts for roughly, I guess, about 20% of the total business within Sandoz, give or take. And clearly, the biologics underlying growth about 27%. So it's accelerating quickly versus, I guess, still growing but flattish oral solids business. On your second part to that question, around [Oravendo] clearly we are working closely with the authorities and with Oravendo to close and hopefully we'll get that approved by the authorities within the next month or so.

Vasant Narasimhan, Novartis AG - CEO 60

And Harry, I think we should also add a question on lack of depreciation. Any comment?

Harry Kirsch, Novartis AG - CFO 61

Yes. That's a relatively small amount, We get back to you on that one. We had mentioned it before, but it's not very significant.

Vasant Narasimhan, Novartis AG - CEO 62

And then on (inaudible), Susanne.

Susanne Schaffert, Novartis AG - President of Novartis Oncology 63

(inaudible) were broadly in line with last year. And when you put the different markets, there is still growth in the U.S. So the product's holding very well. While in Europe, we see some first erosion from generics. To give a little bit more color, so we know there is one generic company having marketing authorization for Europe, and they are now working through the local or national ratification. We know that U.K., Spain, France, Switzerland and Germany have approvals. And we see first commercial activities in Germany, where we see first erosion of our product.

So going forward, you have to expect very focused erosion in some markets. That's what we expect. For the U.S., we have no news at this point. We continue to monitor the situation closely. But when you ask for how you would model that, we would expect there is only very limited generic entry, probably one company only, so we would see a more gradual erosion if a generic enters.

Vasant Narasimhan, Novartis AG - CEO 64

Thank you, Susanne, I just want to highlight this is a very complex manufacturing process as far as we know only one potential generic entrant, depending on the market in Europe and the U.S. and not a product that's easy to supply in large volumes as well. So these are all important factors to consider when you think about Sandostatin LAR in the formulation.

Operator 65

And our next question comes from the line of Emmanuel Papadakis from Barclays.

Emmanuel Douglas Papadakis, Barclays Bank PLC, Research Division - MD & Head of European Pharmaceuticals Research 66

(inaudible) seems to have had a somewhat slower start in Europe and it seems to be perhaps slowing somewhat in the U.S. So just your perspectives on market trajectory of development from here and if you're able to give us any update on litigation that will also be helpful. And the second should be relatively quick one, if you could give us any updates on the status (inaudible) filing in the U.S., that would also be helpful.

Vasant Narasimhan, Novartis AG - CEO 67

So on Aimovig, Marie-France?

Marie-France Tschudin, Novartis AG - President of Novartis Pharmaceuticals 68

So to answer your question in Europe, I mean where we've seen reimbursement, we've seen very strong uptake. If I take Germany as an example, we're doing extremely well in that market. Getting reimbursement in Europe has been difficult as we anticipated, given also the comparator to the product. In the U.S., actually, our performance is very good. We remain well differentiated. We've got 4.5-year data that confirm efficacy and the safety. We've got good access. And since we were first to market, it is a product that is familiar to physicians. We do expect Aimovig's performance to continue. And we will continue to pursue reimbursement outside of the U.S.

Vasant Narasimhan, Novartis AG - CEO 69

And on litigation, we have no material updates on the litigation. We'll of course keep everyone you up-to-date. On (inaudible) Richard?

Unidentified Company Representative 70

Thank you Emmanuel. Clearly, we remain very confident in the quality dossier and we expect that the FDA should complete its review very soon.

Operator 71

Next question coming from the line of Laura Sutcliffe.

Laura Sutcliffe, UBS Investment Bank, Research Division - Equity Research Analyst 72

Firstly, one on Zolgensma, please. You said that 2/3 of patients on Zolgensma -- incident patients on Zolgensma who have been given Zolgensma when newborn screening is being implemented. Do you have any sense of why it's at that level? Is that just a reflection of current Medicaid access? Or is there anything else at play there?

And then secondly, could you just remind us of your current situation with respect to a biosimilar etanercept at Sandoz? Any thoughts you have on a potential launch down the line there?

Vasant Narasimhan, Novartis AG - CEO 73

So on Zolgensma, I think when there's newborn screening in place, we see one, a high awareness of the potential of gene therapy to lead to a definitive, hopefully definitive, treatment for these patients. And so I think with gene therapy, sorry, with newborn screening, there tends to be a high correlation with high degrees of awareness. When patients are identified later on, they tend not to be at -- specialized centers or we have to then work a little bit harder to get the switches to happen. So I think that's probably why

we see that effect. Our aspiration is regardless of whether newborn screening are identified otherwise, we believe Zolgensma should be the first choice for all of those patients. And our aspiration is to be above 90% coverage of all of those early incident patients in SMA. With respect to etanercept, Richard?

Unidentified Company Representative 74

Again, thank you. So first nugget, clearly (inaudible) was approved by the FDA in 2016, but not launched due to the pending patent litigation with Amgen. The U.S. District Court of New Jersey ruled against us the patent litigation of August 9. We respectfully disagree with the ruling. And while valid intellectual property should clearly be respected, we believe patient patents in this case are invalid. We've appealed already to the U.S. Court, Federal Circuit, and the parties have agreed to an expedited appeal. And we look forward to bringing (inaudible) to U.S. patients as soon as possible. And clearly, we'll update you of any progress.

Vasant Narasimhan, Novartis AG - CEO 75

And as soon as we have more color on when a potential decision might happen, we'll, of course, update all of you.

Operator 76

Next question is coming from the line of Seamus Fernandez for Guggenheim.

Seamus Christopher Fernandez, Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals 77

So just a couple here. On fevipiprant I don't want to overread into the fevipiprant situation, but as I look at your slide deck, you specifically comment on a planned filing in 2020. And then in your appendix, it says that the LUSTER 2 trial is complete. Just a question here, do you have any data in hand from the LUSTER trials on exacerbation? Or is that review to be completed? It just seems like that there's an implication that in the eosinophil-high patient population, maybe there's an effect but you're waiting for LUSTER 1?

And then the second question, really, is to kind of focus in on the way that you see Beovu ramping. Maybe you could just help us understand the launch trajectory for Beovu and how we're going to see revenue kind of grow -- coming into the model. And maybe you can just metric that for us versus the kind of launch that we saw with Eylea.

Vasant Narasimhan, Novartis AG - CEO 78

Yes. So on fevipiprant first, it's important to note that in order to file in the severe population, we need both studies, the LUSTER 1 and the LUSTER 2 study. So in order for us to make a determination, we also need to see the pooled analysis across the 2 programs. And we have locked -- as you rightly point out, we have locked the LUSTER 2 database. So we do have the initial readout from that study, but we're waiting now the LUSTER 1 readout to understand where the overall program in the pooled analysis as well fits all of the elements that would be required for a regulatory filing. We also have an additional study called the SPIRIT study, which is required from a safety standpoint as well. So once we have a clear perspective on all of these studies, we'll be able to provide an update in Q1. On Beovu, Marie-France?

Marie-France Tschudin, Novartis AG - President of Novartis Pharmaceuticals 79

Yes. So on Beovu, I will just really reiterate what we're hearing from the marketplace, which is that physicians are very excited to use the products. We know from clinical practice that fluid is the #1 factor for treatment and for switching decisions. We believe that Beovu will convince, given the HAWK and HARRIER data, and no doubt it will convince even more in clinical practice. We've seen a lot of positive feedback from AAO. I think what I would say is Beovu meets physician needs for greater fluid resolution in these patients' needs for greater treatment intervals. And we believe that Beovu will be a major player. I'll also say that I believe we've got a world-class team in place in the U.S. and that we'll see a really strong launch with Beovu.

Operator 80

The next question is coming from the line of Simon Baker from Redburn.

Simon P. Baker, Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research 81

Two, please. Firstly, on Zolgensma, I wonder if you could give us a little bit more color on the phrase even distribution of patients by type and age. I'm assuming it's not dead 50-50. So any more color on there will be useful. And then sticking with fevipiprant I wonder if you could give any us thoughts on any potential mechanistic reason for the ZEAL result. Is this due to different implication of Th2 cells in moderate and severe asthma? There have been a few papers suggesting maybe there could be some possible explanation there. So your thoughts on that will be much appreciated.

Vasant Narasimhan, Novartis AG - CEO 82

Thanks, Simon. For Zolgensma, we're obviously not providing that granularity of detail, but what I can say is we've seen solid uptake in both patients between the ages of 1 and 2 and patients between the ages of 6 months and 1 year and patients below 6 months. So we've seen, I think, relatively even distribution across these different age groups. And we've seen an even distribution as well between type 1, type 2 and type 3 patients. But those are the numbers -- those are the groups we're talking about when we say an even distribution. So I'd say, in large part, what we're trying to indicate is we are seeing approvals for the use of the medicine when prescribed when on label and after taking the appropriate steps with insurers.

Now with respect to this ZEAL results and the mechanism, John?

John Tsai, Novartis AG - Head of Global Drug Development & Chief Medical Officer 83

Thanks for the question. I think you guys all know that fevipiprant is a selective DP2 agent. In that case, it's not a classic bronchodilator. What we know is that DP2 activation increases with disease. So in fact, as you have more disease, you actually -- would likely get more response from DP2s. Now just one correlation that you probably know in terms of the biologics or IL-5s, in the moderate population, there is not significant improvement in FEV1. So I think, in this respect, we obviously want to see the results of LUSTER 1 and 2 and expect to see better results in the DP2 antagonists for patients with severe population, especially with high eosinophils.

Vasant Narasimhan, Novartis AG - CEO 84

Actually, Harry, you had one clarification.

Harry Kirsch, Novartis AG - CFO 85

Just for Richard. Richard Vosser, you asked about the divested Sandoz U.S. business-related stock depreciation. It is a small number, is about $10 million per quarter. So $30 million year-to-date, $10 million per quarter is the stock depreciation.

Operator 86

The next question is coming from the line of Mark Purcell from Morgan Stanley.

Mark Douglas Purcell, Morgan Stanley, Research Division - Equity Analyst 87

First, on China. Could you please help us understand the outlook for your business in China, framing the opportunities as well as the threats? Clearly very strong growth the more key growth drivers that you highlighted and launched as a (inaudible) incentive in

(inaudible) heart failure and consensus, et cetera. But from the threat perspective, obviously a number of LOEs I presume are coming up, potentially including products such as Galvus. So if you could help us understand the key approval decisions and your [L] decisions and LOE timings, that will be fantastic. There isn't a lot on LOE timings outside the U.S., Europe and Japan in your annual report.

And then secondly on canakinumab I guess this a bit of a wildcard in your pipeline. Could you comment on the -- any interim analysis planned ahead of the primary completion of CANOPY 1 and 2 in the first half of 2021? And then just more broadly, in terms of your ambitions on IL-1B (inaudible) as a mechanism following the acquisition of the [Zoma] product.

Vasant Narasimhan, Novartis AG - CEO 88

Thank you, Mark. On China broadly, we see it as a very important opportunity for the company. We publicly stated we have overall business in IM that's over $2 billion. Our goal is to at least double that business over the 5-year term. It's driven entirely by new launches, our ability to launch a new medicine. And I'll have John comment a bit more on the number of NRDL -- number of approvals and NDAs we expect and then maybe Marie-France can give more color on how we're doing on some of the launches. John?

John Tsai, Novartis AG - Head of Global Drug Development & Chief Medical Officer 89

Thanks Vas. As you know, we put a significant effort into China. Already in the last 2 years, we've had 24 NDAs approved. That's across 9 NMEs, new molecular entities. And moving forward over the next -- between now and 2023, we expect to have 50 NDA submissions. So in total, with that combination, it's over 70 NDAs. So a significant effort that we're putting in behind China over the last 2 years and over the next couple of years.

Vasant Narasimhan, Novartis AG - CEO 90

And that fits with our overall belief with the 7 plus 4 initiative to take -- expand out of older medicines and free up resources to launch new medicines. We want to be well positioned will all our portfolio available in China and ready to launch. Marie-France, want to give us some color on how we're doing on some of those products?

Marie-France Tschudin, Novartis AG - President of Novartis Pharmaceuticals 91

Yes. So first of all, I'll just comment and say that our China business is growing really well. Our growth rates are in the high 20s. The innovative portfolios is really what's driving the launch. So if we look at Entresto, Lucentis, Cosentyx, they're among the 5 growth drivers

for China. Entresto is actually the best primary launch ever. And we do expect to see NRDL listing in Q4. So that should be a big opportunity for China. Cosentyx is also off to a great start, but obviously maintaining patients on out-of-pocket setting is a challenge. So it is a priority for us to get NRDL listing also in 2020. We also expect NRDL listing for Lucentis and DME and RVO this year. So all in all, again, it's the innovative portfolio that's driving the growth. We currently have no products on the 4 plus 7 list, although that may change. And again, what we're going to focus on is really this innovative portfolio and expect to continue the strong growth.

Vasant Narasimhan, Novartis AG - CEO 92

On canakinumab, John, any interim expectations?

John Tsai, Novartis AG - Head of Global Drug Development & Chief Medical Officer 93

Yes, so specifically, obviously, we had the PARAGON results read out. One of the areas that we're looking into is the post-...

Vasant Narasimhan, Novartis AG - CEO 94

No, no, sorry John, not Entresto, canakinumab (inaudible) lung cancer, first line, second line.

John Tsai, Novartis AG - Head of Global Drug Development & Chief Medical Officer 95

What we can say about canakinumab, sorry about the confusion there, for CANOPY trials, CANOPY 1 and 2, those are moving forward and recruiting well. We continue to see good results in terms of recruitment. Now what we do see in the adjuvant population is a little bit slower population in terms of recruitment in that study. But I think, balanced what you're seeing in the marketplace, there's just last patients that are actually moving forward in the adjuvant population. For CANOPY 1 and 2, those are moving forward very well in terms of recruitment. And CANOPY A in the adjuvant population is a bit slower than we expected.

Vasant Narasimhan, Novartis AG - CEO 96

So we do expect CANOPY-2 particularly, potentially CANOPY-1 to read out in 2021. I'd say more broadly, our efforts in IL-1 [beta] and (inaudible) are -- we are quite bullish on it. Not only did we have the canakinumab program, not only did we bring in a second agent for IL-1 beta antibody but we've also acquired a company called IFM Tre, which has oral inflammasome inhibitors and we are now -- that molecule as well as internal program

we're taking across a range of autoimmune indications, oncology indications, neurological indications. So we would like to own the inflammasome space for the long term and that's what we are working towards.

Operator 97

Our next question comes from the line of Naresh Chouhan from Interim Health (sic) [Intrinsic Health].

Naresh Chouhan, Intrinsic Health Advisors - Founder 98

Firstly, on Tasigna which seems to have returned to growth, at least in the U.S. Is it fair to assume that the impact from the TFR data is now played out and we should see sustained growth in the U.S.? And similarly so, in Europe in the coming quarters? And then secondly, the gross margin (inaudible) was impacted by the cell and gene therapy investment. Should we expect that to continue well into 2020? Or is this a short-term impact given the Zolgensma uptake?

Vasant Narasimhan, Novartis AG - CEO 99

So I think both questions for Susanne. First on Tasigna, Susanne.

Susanne Schaffert, Novartis AG - President of Novartis Oncology 100

Yes, on Tasigna we saw indeed very strong growth of 11% in the quarter. So what we can say in the U.S., if you notice (inaudible) focusing our messages around efficacy and around targeting new and switch patients. So we believe this strategy is paying off and we see the situation stabilize and expect modest growth going forward. The Q3 effect is an unusual one because it is artificially high because of inventory phasing versus Q3 in the U.S. So that I would not expect to go forward like that. But overall, we are pleased Tasigna seems to be stabilized, and we'll expect modest growth going forward.

Vasant Narasimhan, Novartis AG - CEO 101

And then cell and gene manufacturing investment?

Susanne Schaffert, Novartis AG - President of Novartis Oncology 102

Yes. I say we have a lot of focus on improving our manufacturing process. And we are quite pleased that capacity has been gone up by 60% between Q1 and Q3, so making good progress there. We have started to shift out of (inaudible) and sign for clinical supply and overall making good progress on that.

Vasant Narasimhan, Novartis AG - CEO 103

Our goal is to work back up. I think you were correct we have with the cell and gene technology had to take some hit on our gross margins, particularly in oncology with CART therapy. Our aspiration is now to start to improve that and get that back up now in the coming year.

Last question I think, operator.

Operator 104

Our last question comes from Mani Foroohar from SVB Leerink.

Mani Foroohar, SVB Leerink LLC, Research Division - MD of Genetic Medicines & Senior Research Analyst 105

Quick first one on Zolgensma. Obviously, the expanded access and compassionate care dynamics in the U.S. are very different than other markets. When you think about the bolus phenomenon we're seeing in the U.S., could that phenomena actually be more pronounced in some other markets as you roll out in Japan, Europe, et cetera?

And regarding sickle-cell for SEG101, it's a little different administration profile and reimbursement profile than the oral generic that's on the market currently but has really impressive clinical data. How do you think about investment in infrastructure and operational expertise that you can bring to bear to commercialize SEG101 across a market that has historically been pretty difficult to penetrate?

Vasant Narasimhan, Novartis AG - CEO 106

Thanks for the questions, Mani. On Zolgensma ex U.S., what we have seen is in certain markets there is a high degree of interest. They've already put in access programs in place to enable use of the medicine in multiple patients. So I think in some countries in Europe as well in the Middle East, there could be very strong demand coming very quickly after approval. Difficult to dimensionalize precisely, given that obviously the rarity of the disease, but we do expect there to be similar, let's call it, pent-up demand effects in overseas markets. Now on SEG101, Susanne?

Susanne Schaffert, Novartis AG - President of Novartis Oncology 107

Yes. We are quite diligently preparing for the launch of SEG101, looking forward to getting approval Q1 of next year. And when you asked about our commercial model, there's obviously big focus on access to get access approval very quickly. I'm very confident

about the product because it has an impressive impact on patients. As you know, SEG101 is targeting VOCs, which is the hallmark of the disease. And when you talk to patients how devastating pain crisis is and seeing that SEG101 could help episodes of VOCs, I think that's impressive. That's also the feedback we get from physicians. So our focus is to work on access, but we're very confident and looking forward to be ready for launch.

Vasant Narasimhan, Novartis AG - CEO 108

Thank you, Susanne. So thank you all for joining today's call. We look forward to seeing you at our R&D day in early December. For those of you who can make it, we'll be focusing on profiling our next wave of innovation coming out of our early Phase III and late Phase II programs, so you'll get a sense of the next wave of important medicines we'll be bringing forward as a company as well as providing more detail on the depth of the programs we have on many of our products, including Cosentyx, Piqray and others that we've profiled over the course of today's call. Thank you for your interest in Novartis, and we'll look forward to speaking with you soon. Thank you.

Thank you. That does conclude our conference for today. Thank you for participating. You may all disconnect.+