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Novartis' (NVS) CEO Vas Narasimhan on Q2 2019 Results - Earnings Call Transcript

Jul. 18, 2019 4:57 PM ET | 3 Likes

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Q2: 07-18-19 Earnings Summary

Slides

EPS of $1.34 beats by $0.10 | Revenue of $11.76B (-10.59% Y/Y) beats by $310.22M

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Novartis AG (NYSE:NVS) Q2 2019 Earnings Conference Call July 18, 2019 8:00 AM ET

Company Participants

Samir Shah – Global Head-Investor Relations

Vas Narasimhan – Chief Executive Officer

Harry Kirsch – Chief Financial Officer

Shannon Klinger – Chief Legal Officer

John Tsai – Global Head-Drug Development

Susanne Schaffert – President-Novartis Oncology

Marie-France Tschudin – President

Conference Call Participants

Graham Parry – Bank of America

Tim Anderson – Wolfe Research

Keyur Parekh – Goldman Sachs

Andrew Baum – Citi

Peter Welford – Jefferies

Steve Scala – Cowen

Florent Cespedes – Societe Generale

Jo Walton – Credit Suisse

Seamus Fernandez – Guggenheim

Richard Parkes – Deutsche Bank

Michael Leacock – MainFirst

Naresh Chouhan – Intron Health

Kerry Holford – Exane BNP Paribas

Laura Sutcliffe – UBS

Mani Foroohar – SVB Leerink

David Maris – Wells Fargo

Emmanuel Papadakis – Barclays

Operator

Good morning, good afternoon, and welcome to the Novartis Q2 2019 Results Release Conference Call and Live Audio Webcast. Please note that during the presentation all participants will be in listen-only mode 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. Thank you everybody for taking the time to listen and participate in our quarter two investor call. Before we start, I'll just read 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.

Vas Narasimhan

Thank you, Samir, and thanks, everyone, for joining today's conference call. In the room with me today I have Harry Kirsch, our CFO; Shannon Klinger, our Chief Legal Officer; Susanne Schaffert, our President of Novartis Oncology; Marie-France Tschudin, our President of Novartis Pharmaceuticals; John Tsai, our Global Head of Drug Development; and Richard Saynor, our new Head of Sandoz.

So as you saw today in this morning's results, we really had an exceptional Q2 and a strong first half of the year, which we're very pleased with and very pleased to give you further details on over the course of this presentation. If we turn to Slide 4, we delivered a strong Q2 with margin expansion and continue to progress our agenda on transformative innovation. When you look at the operational performance, we had plus 8% on sales, plus 20% on core operating income with margin expansion of 3.2% and Harry will go through in a bit more detail the numbers as well as some of the pushes and pulls that we see for the first half as well as for the second half.

But based on the strong momentum that we've seen, we are increasing our sales and core operating income guidance for the full year. And Harry will go through the specifics of that in a few slides. Importantly, we also advanced our transformative innovation agenda with our pipeline with Zolgensma, Piqray and Mayzent all launched, Xiidra acquired in July is now fully integrated and we're getting prepared to re-energize that brand; SEG101 filed with a priority review. And we also had the positive overall survival data with Kisqali and premenopausal women presented at ASCO, so very strong progress on our innovation agenda as well.

So moving to Slide 5, the sales performance was primarily driven by a very strong performance in innovative medicines. In particular, we were pleased with the performance in our growth drivers. So of course Entresto and Cosentyx continue their strong momentum as you can see with the growth rates in Q2 and in the first half across our oncology brands as well very strong growth Lutathera continuing to perform well, Kisqali beginning to accelerate, Kymriah also with very solid performance. So we saw a broad-based growth across our innovative medicines portfolio, which gives us confidence as well for the remainder of this year and going into future years.

So moving to Slide 6, when you look at Cosentyx specifically and particularly focusing on the U.S., we were pleased we could continue to grow the brand in a what is increasingly competitive environment. Looking at the U.S. dermatology segment, you can see that for an NBRx percent gains Q2 2019 versus Q2 2018. Cosentyx gained 1.5 share points in a very competitive space. So we were very pleased by that strong performance by our U.S. team. When you look at TRxs, we're growing ahead of market at 28% versus a market growth of 10% and with 17% overall growth in NBRx.

When you go to rheumatology were again Cosentyx has truly unique data in psoriatic arthritis and ankylosing spondylitis. You can see our weekly TRxs are now approaching or exceeding Enbrel and Humira. When you think in terms of market growth, we're growing 38% versus the market growth of 14% on TRxs and also have solid NBRx share growth. So when you look across the U.S. business, we are very pleased with how Cosentyx is performing in this competitive environment and we'll look to continue that momentum in the back half.

Turning to Slide 7, I also wanted to highlight that we continue to generate additional data on Cosentyx in the existing indications in psoriasis and rheumatology as we prepare for data, we plan to release later this year and in the coming years on new indications. In particular when you look at psoriatic arthritis, most of these patients have so called axial manifestations. And Cosentyx has demonstrated in our recent maximized study that we could impact these axial manifestations in a significant way and you can see the data here that we recently presented. This further bolsters the case for Cosentyx use in these rheumatology patients. And I think it was just one example of many as we continue to build out the dataset to support Cosentyx broad use.

So moving to Slide 8, when you look at Entresto, we are seeing a really strong performance from Entresto, continued acceleration for this important medicine for heart failure patients. You saw the revenue growth of 81% with solid growth both in the U.S. and in the ex-U.S. But importantly, we continue to get strong recommendations from key groups. So on the right hand side you can see the European Society of Cardiology Heart Failure expert consensus, now supports Entresto's use as first-line therapy for patients with HFrEF. This will allow us to continue to accelerate the use of Entresto in the first-line setting in ambulatory and in the hospital setting.

I'll talk a little bit more about the PARAGON dataset in a few slides. So moving to Slide 9, I'd like to spend a few slides giving you an update on Zolgensma. So we're very pleased with the launch of Zolgensma today. We've seen a very strong demand. We're pleased with the launch and access, progress we're making and I want to give you a few details as

proof points. First, when you look at the launch, we had an approval on May 24th within three days we were promoting in the market within roughly a week we had our first commercial policy and product ready to ship. We had our first U.S. patient treated within approximately two weeks and we already have had patients treated through the French ATU mechanism outside the United States. In some instances, we've even had patients approved for therapy from the time of receiving the Rx within 24 hours.

So that kind of shows you the enthusiasm there is in the SMA community for this medicine. Now for some of the details, the first thing I want to highlight is even in the absence of medical policies or specific approvals, we are able to use medical exceptions to manage many of these patients getting through the process. And that's the primary route right now we're doing when we don't have a policy in place, but we're having best-in-class, we believe, progress on getting medical policies in place. Over 20 commercial plans representing 40% of commercial lives and four Medicaid plans have policies on coverage already, not all of these have been posted on external websites. The majority of these policies are in line or close to the label. The common limitations we're seeing are with patients with four SMN2 copies, which is about 10% of the overall SMN2 prevalent population in this age group and some limitations with combination use with nusinersen.

When you look at the approval rates we're seeing so far, patients going through the Novartis hub, almost all patients going through our hub have been approved thus far when appropriate steps – after appropriate steps have been taken. We have very high approval rates for the on-label patients either via policy or medical exception as I said. And I think the other important thing to note is we've had a wide range of the patients already approved, including patients from age 1 to 23 months, weights up to 12 kilograms, two and three SMN2 copy numbers, treatment-naïve as well as those previously treated by the currently approved product. In terms of contracting to get any of the special contract terms that we've been promoting, we have 17 commercial plans representing 40% of commercial lives having already signed the Letter of Intent on contracting terms. And we continue to try to progress across the relevant insurance community, so strong progress already and just with the first few weeks after launching this medicine.

So if you go to Slide 10 and you look at the newsflow we have for the second half, we are planning to initiate discussions with the U.S. FDA on intrathecal dosing for the older populations based on our strong study. We're on track to have EU and Japan approval by Q4 2019. And we plan to have other country filings initiated in Q3 for our broad global

rollout of the medicine. Later on this year, we'll show the data from – updates on data from SPR1NT, STRONG and STR1VE at various medical congresses as you can see over the course of the fall.

So moving to Slide 11, one piece of data I wanted to highlight from our recent presentations at AAN is Zolgensma's performance in pre-symptomatic patients where patients are achieving age-appropriate motor milestones. Just to remind you, SPR1NT is our pre-symptomatic study. It's a study that has patients with both two copies and three copies of the SMN1 gene patients where pre-symptomatic. And what you can see on the right hand side is the progress these patients are making versus the WHO windows of normal achievement.

So you can see the patients in green boxes are patients who are sitting without support and have two copies of the SMN2 gene. You can see a patient standing with assistance. And you can see how these patients are now progressing and we're looking forward to providing you an update to show we hope that we can get these patients to progress normally after treatment early in their life after being identified by newborn screening or in the early months of their life, so very exciting data presented at AAN already on pre-symptomatic patients and more updates to come in the fall.

So now I'm moving to Piqray on Slide 12. Piqray received FDA approval on May 24. CHMP opinion is expected in the second half of this year. We're pleased with the progress we're already making with payers covering over 80% of the target population in terms of the engagement we have already had. We're also seeing good uptake of the PIK3CA mutation testing, which is really our focus for this year to really ensure high testing rates, so that we can drive the launch for the years to come. The NCCN guidelines currently recommend PIK3CA mutation testing and we've also entered into an agreement with Foundation Medicine to develop plasma and tissue testing. We're also pleased that we're now able to confirm we'll be exploring Piqray and other tumor types in the second half of 2019 while a trial starts for HER2 positive advanced breast cancer as well as triple negative breast cancer. And then based on data we already have in house, we will be moving to a late stage studies in first half of 2020 in head and neck and ovarian cancers.

So on Slide 13, we moved to Mayzent. Now in Mayzent, we're also pleased with the progress we've made. This was a year where we wanted to focus on educating the patient community – physician community, making sure we had strong access in place so that we could drive this brand's use in the SPMS setting for the long-term. Just to remind you, we had unique clinical data and a supportive label to start with, with the full range of RMS

indications, but the only medicine that has SPMS data specifically and its label and some of the interesting profile elements of the drug, high efficacy, reduces disease progression, no first dose observation for 70% of the patients.

Thus far our priorities for Mayzent are progressing well. We believe we're the first choice now for active SPMS for healthcare providers in the United States. We have 90% of neurologists willing to prescribe Mayzent based on the survey data that we see. We currently have 70 million lives with preferred access to Mayzent to date and we continue to try to grow that access over time. And we're also working to use digital tools to help identify patients who truly are active SPMS patients that would benefit from Mayzent in the long-term.

So we'll look forward to providing detailed sales data in Q3 for both Zolgensma and Mayzent, but I hope that gives you a sense of where we are in building the foundational building blocks for both of these launches. Now turning to ophthalmology with Beovu, or RTH258, we have as you know developed a differentiated medicine that now is on track for the launch upon approval later this year. Mind you that HAWK and HARRIER clinical programs demonstrated uncompromised vision, less retinal fluid and fewer injections versus the comparative medicine.

We've also launched a pretty expanded clinical program including a study called TALON, which is a head-to-head study of brolucizumab versus aflibercept in a treat-to-control regimen in kind of apples to apples setting. So we look to continue to provide the data needed to support Beovu's use in a broad range of patients for the long-term. We're prepared for the launch approval expected in Q4 2019; CHMP Q1 2020. We've already seen strong awareness of the clinical data. Both our U.S. and EU operations are preparing and we plan to be ready for a strong day one launch of this medicine.

Also in ophthalmology when you go to Slide 15, our plan is to accelerate Xiidra, now that we've brought it fully in-house while laying the foundation to maximize its long-term potential. Now just to remind you, dry eye is a significant patient unmet need. It's generally under diagnosed and undertreated; 34 million patients with dry eye in the U.S. alone. It's estimated only 50% are accurately diagnosed and really only a fraction of that 10% is treated with an appropriate medicine. We're well aware that when you look at the TRx data for Xiidra over recent quarters, it has been very flat.

We believe this is because of the uncertainty involved as Xiidra's ultimate ownership was not clear. Now that we brought uncertainty to the sales organization and the marketing organization, our plan is to reinvest in the medicine. We'll reengage the sales force, focus

on share of voice. We have a plan to optimize our medical education with a plan to promote including a DTC campaign starting in Q4 of 2019. Longer term, our plan to maximize Xiidra will depend on our ability to expand access for Part D patients beginning in 2021. So we'll continue to track, continue to push and we'll look forward to keeping you up to date on our progress with Xiidra.

Now lastly on our near-term portfolio, I wanted to give an update on SEG101, crizanlizumab, which has been submitted in both the U.S. and EU. Now just as a reminder, in the world of sickle cell disease, we have therapies which are to treat a sickle cell pain crisis. There are therapies to prevent a crisis from happening in the first place such as the SEG101. And then there are of course cell and gene therapies that are looking in certain patients to try to definitively treat the underlying genetic cause of the disease. In the case of SEG101, we're really focused on preventing vaso-occlusive crisis, which are the primary reason for hospitalization, the primary cause of pain and long-term sequelae for these patients, including some of the mortality outcomes, and the long-term cause of cost to the system.

So as I think you may have seen, we've been granted priority review for SEG101 in the U.S., and we continue to advance our filings around the world. We're also gearing up for a successful launch in the U.S. with a commercial organization in place, access plan in place. And on innovative disease awareness campaign, we've launched using digital technology, which we hope will truly mobilize the patient community behind this medicine. As a reminder, there's about 60% of the patients we would expect within the sickle cell disease population who have two or more vaso-occlusive crises and would be eligible for SEG101.

So moving to Slide 17, and just to say a word – a few words about upcoming readouts, we have a number of upcoming readouts in Q3, Q4 and Q1. I wanted to highlight a few of these in my closing comments.

So if you move to Slide 18, I think as many of you are aware, the PARAGON heart failure study is the first confirmatory trial that's been trying to be conducted in preserved ejection fraction, large-scale study to be conducted in preserved ejection fraction heart failure using a novel endpoint of the recurring heart failure hospitalization.

Our next expected milestones for this are results and filing in second half of 2019. And we also have a shell that's been posted for the ESC Late-Breaker. I would note we have not seen the data yet for this study. This is really a shell for the Late-Breaker presentation. The study was intentionally designed to assess Entresto's impact on the burden of

disease with repeat hospitalizations. We believe the study design looking at that primary endpoint, as well as other elements, we've learned from past failures and preserved ejection heart fraction heart failure, will give us the best possible chance of succeeding in a patient population that never had an approved medicine. So we'll look forward to giving you update as soon as we can. And hopefully, we'll have positive results to share later this year.

So moving to Slide 19, I also wanted to say a world about ofatumumab, which is our subcutaneous B-cell depletion agent targeting the CD20 target to provide – we have the potential to provide access to higher efficacy B-cell therapy for a broad RMS patient population. We believe taking a medicine that is highly efficacious, moving it subcutaneous to give patients full flexibility, the potential to avoid having to go regularly in for a lengthy intravenous infusion process, will be welcomed by providers and by patients and could potentially allow the more broad use of B-cell depleting agents in RMS.

I also wanted to remind the group of the data profile that we have for ofatumumab, where we know that with the loading dose we've taken into the Phase 3 program, 60 milligrams Q12 dosing to start, we see very rapid B-cell depletion, and you can see that in the attached graph. Then what we expect is with monthly dosing, we can maintain that B-cell depletion and hopefully avoid some of the rebound that you might see in drugs that are dosed less frequently, especially towards the end of the therapy timing. So we wouldn't want to see that rebound, so we will do monthly dosing. We'll hopefully keep those B cells down.

On the flip side, we know that when we stop therapy, the B-cell repletion will happen in case safety signals are seen. So we think it could be a positive both from an efficacy and a safety standpoint. And ultimately, of course, the data will tell us. We look forward to providing that data to you later this year and hopefully bring something to patients that's flexible, self-administered and provide an approved overall profile.

So moving to Slide 20. Now I just want to say a word as well about Fevipiprant, our oral DP2 agent to tackle severe asthma. Just as a reminder, on the left-hand side, our goal here is to address the so-called treatment gap in severe asthma. We know that there are 3.4 million patients in GINA 3 moderate patients in inhaled therapies. But these patients – many of these patients progress and need something beyond their inhaled therapeutics. But we know there's only 120,000 patients on biologics, which leaves a significant gap of 3 million patients either with high EOs or all-comers. They need a better option to enable them to be in control of their asthma before potentially needing a biological or perhaps in lieu of a biologic.

We have a sizable Phase 3 program, five separate studies; LUSTER 1 and 2 look at exacerbations. We have endpoint there that tries to puts us in line with the exacerbation reduction seen with biologics. We have ZEAL 1 and 2 that target lung function. And then we have the SPIRIT trial that's looking at safety. So we look for forward to providing you additional data. ZEAL 1 and 2, we would expect the data release in Q4 and LUSTER 1 and 2 in Q1 of 2020.

So lastly, I wanted to just introduce, we have here in the room Marie-France Tschudin, who's been appointed President of Novartis Pharmaceuticals. She's, of course, a member of our Executive Committee. We are thrilled to have her. She has 25 years of experience in pharma and biotech, including a lengthy period at Celgene. And most importantly, for us, she's a purpose-driven leader who lived the culture we're trying to build at the company every day are unboxed, inspired, curious culture. She joined us in 2017, has held a few different roles, and we look forward to supporting her with great success here at Novartis Pharmaceuticals.

So thank you very much, and I'll hand it over to Harry for some more details on the financials.

Harry Kirsch

Yes. Thank you, Vas. Good morning, and good afternoon, everyone. My comments refer to the continued operations results, and growth rates are in constant currencies, unless otherwise noted.

So Slide 23 shows the summary of our quarter two and first half continuing operations performance. In quarter two, sales grew 8%, mainly driven by continued momentum of Cosentyx and Entresto and our Oncology growth drivers, including Lutathera, Taf/Mek, Promacta, Kisqali and Kymriah.

Core operating income and core EPS both grew 20%, mainly driven by higher sales and productivity, partially offset by growth investments. On free cash flow, we had $3.6 billion, up 11% in U.S. dollars, mainly driven by the strong operating performance and the divestment proceeds from the sale of our Klybeck site here in Basel. These positive cash flows were partly offset by OTC joint venture dividends, which we received for the last time in quarter two 2018.

Net income in the quarter for continuing operations was $2.1 billion and $4 billion in the first half. The decline you see here on this reported net income numbers versus prior year is due to the $5.7 billion OTC joint venture divestment gain we recorded in quarter two of

last year.

On Slide 24, you see the quarter two core margin by division. Continuing operations, margin improved by about 3% points in the quarter and the first half, driven by Innovative Medicines division. The Innovative Medicines strong sales leverage and productivity were the key drivers of the margin expansion, while with sales growing 9%, we are expanding margins while still increasing investments in our key growth drivers and pre-launches.

There were also a couple of favorable one-time items this quarter in the IM core margin. Pre-launch inventory provision releases after the regulatory approvals of Zolgensma and Piqray contributed about 1 margin point. The continued Diovan and Exforge growth due to generics valsartan supply shortages contributed about 0.5 margin point. So the total Innovative Medicines margin improved 370 basis points to 35.4% of sales. If we exclude the one-time effects described earlier, the Innovative Medicines margin would have been around 34% of sales.

Sandoz improved by 140 basis points to margin, and this was driven by sales growth, positive product, geographic mix, productivity and cost discipline as we continue the Sandoz transformation.

On to Slide 25. So in light of this very strong first-half performance, we are revising upwards our 2019 full year guidance. For the new Focus Medicines company, net sales are revised upwards, expected to grow mid to high single-digit, core operating income revised upwards expected to grow low double-digit to mid-teens. And from a divisional perspective, we revised Innovative Medicines sales guide upwards to grow mid to high single-digit. And the Sandoz sales guidance is also revised upwards to broadly in line to a low single-digit growth.

We now also expect, just a word on the tax rate, our full year core tax rate to be in line with what you see on half one core tax rate of 16.4%. The increase both verse the previous year as well as versus our original 16% is driven by some profit mix changes.

On Slide 26, I want to talk through some of the dynamics for the first and expected dynamics for the second half of 2019. Clearly, half one performance was very strong with core operating income growing 19%. This was mainly driven by the continued sales momentum of our growth drivers as well as ongoing productivity programs. We, of course, expect these to continue in the second half.

In the first half, we also benefited, as mentioned earlier, from valsartan competitor supply shortages, which resulted in double-digit growth for Diovan and Exforge. Recall that this supply issue at Diovan and Exforge growth started in quarter three of 2018 and may stop at any time. Hence, also in quarter three, we begin to lap the growth in the base from this valsartan situation.

As we look at the second half, we are expecting potential increased generics headwinds, particularly on Afinitor, Exjade and some older ofa brands. Furthermore, we continue to monitor generic activities on Sandostatin LAR. Now as discussed on the quarter one call, we were expecting these generic headwinds earlier in the year, basically in quarter two. There is, of course, a potential that we continue to see less generic headwinds than expected also in quarter three. In that case, if that situation would come up, I would assume that we end the year 2019 at the higher end of our full year core operating income guidance, but it's a bit too early to tell, and I'm sure we'll discuss this topic again at the quarter three call.

On Slide 27, you see how currencies would impact our results. If mid-July rates prevail for the remainder of 2019, the full year impact on sales would be negative 3%, and on core operating income would be a negative 4%. And as you know, every month we update the expected currency impact on our website.

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

Vas Narasimhan

Thank you, Harry. So in conclusion, a very strong first half to 2019. And when you take a step back over the last 18 months of the company, we've been able to do over $60 billion of transactions to transform the company. We've set five priorities in place to truly drive performance, starting with culture and innovation and it's starting to pay off, we believe strong sales and margin expansion, double-digit core operating income growth, the innovation pipeline is really kicking in, catalyst-rich second half, and we'll look forward to continue to keep you updated in the second half of the year.

So with that, I'll open it up for questions.

Question-and-Answer Session

Operator

[Operator Instructions] Your first question comes from the line of Graham Parry of Bank of America. Please ask your question. Your line is open.

Graham Parry

Great. Thanks for taking my question. So, the first one's on Zolgensma and the $100 million inventory provision. Is that indicative of your expectations for a quarter or perhaps the second half of the year? Just trying to get a feel for what sort of inventory you would have built prior to launch.

Secondly, on label expansion, with the SPR1NT data, could you just give us some timelines when you expect to meet with FDA and whether you think a 2H filing on the back of that still remains possible? And, similar for the STRONG data on the intrathecal filing as well.

And then, thirdly, on both PARAGON and the ofatumumab data, you submitted both for medical conferences. You flagged that you don't have the data in-house yet on PARAGON, but would you issue a headline press release on the data when it comes, or do we have to wait for ESC? And a similar question for ofatumumab; I see ASCLEPIOS is submitted for ECTRIMS. Do you have data in-house there, or should we expect a headline press release somewhat imminently?

And then finally, on Gilenya, can you just give us an update on where you are with your Mylan declaratory judgment and preliminary injunction, and whether the EPI win that you had strengthens your hand in settlement negotiations with generics now. Thank you.

Vas Narasimhan

Thanks, Graham. So on the Zolgensma $100 million provision, Harry?

Harry Kirsch

Yes. Thank you, Graham, for the question. So we basically – from an IFRS standpoint, we basically expense the write-down immediately any production of product that is not yet approved. It happens on every product. And then once approval is there, the inventory basically gets written up, and there's inventory provision release. Now in this quarter, we got two products approved, Zolgensma and Piqray and therefore had roughly $100 million in our inventory provision release in OIE, where you see it.

That happened last time I think, usually this happens and you don't even notice as much, it's smaller numbers. Last time, this large number was seven years back with Entresto approval, but it's normal practice. And basically, it represents on these products what has

been produced over the – since – on AveXis since we acquired, and is of course, also showing that production is going extremely well and we are ready to supply many, many patients with it.

Vas Narasimhan

And that does not necessarily indicate anything about sales expectations I think that's…

Harry Kirsch

No, I mean, I would not – first of all, this is, of course, this is a product that has long shelf life. And production, of course, is important. And we want to make sure that we are ready to supply any sales scenario.

Vas Narasimhan

Yes. And I would say also, on Zolgensma production, it's going well. We have in addition to our Chicago and North Carolina facilities; we have acquired a facility in Colorado. This year we'll have ample capacity up to 1,000 patients plus, and we'll plan to expand capacity there going forward.

Now, with respect to the SPR1NT and STRONG studies, SPR1NT is now technically covered by our existing label – the treatment of patients in a pre-symptomatic phase. So we would plan to present updates on that data for the slide, I think, at WMS, but it wouldn't affect our filing. Now, with respect to STRONG, our plan is to go to the FDA in Q3 and hopefully come to an agreement on a filing strategy. If there was agreement, we would aspire to file before the end of this year. Now, moving to PARAGON and ofa, John?

John Tsai

Yes, Graham. Thanks for the question. We have a very rich second half of the year with data readouts and Entresto for PARAGON, ofatumumab, as well as fevi. As Vas said earlier, we don't have any data in hand. We're obviously very excited about seeing the data in the very near future. We're going to look at these case by case and evaluate whether we will issue press releases moving forward, but what I will say is that we've had to submit some of the abstracts, for example, for Entresto and for PARAGON to the ESC so that we could hold the late-breaking session at ESC. So, moving forward, we'll be looking for and evaluating these on a case-by-case basis.

Vas Narasimhan

Lastly, on Gilenya, we do not expect any launch of a generic Gilenya in 2019, and this is in part because, as you know, Novartis was granted a motion for preliminary injunction which prohibits any generic manufacturers in that case from launching Gilenya until the decision on the patent – which, at the earliest, would be in March 2020. So we expect a potential appeal decision in early 2020, but right now, our focus is on vigorously defending the dosage patent and protecting Gilenya for as long as possible. So, thanks, Graham. Next question.

Operator

Thank you. Your next question comes from the line of Tim Anderson from Wolfe Research. Please ask your question.

Tim Anderson

Thank you. In my opinion, the two most important readouts for Novartis through the rest of the year are PARAGON-HF and the QAW trials, and there's reasons to be cautious with both of those. With PARAGON, no one's succeeded yet in getting a label for HFpEF, and in QAW, there's been lots of prior failed attempts at that class of drugs. So of those two programs, if you had to pick one with higher odds of success on delivering Phase III results that are positive, which would it be?

And then second question is on Cosentyx. About a year ago or so, you guys had kind of repriced the brand in the U.S. to try to get more first-line biologic usage in psoriasis ahead of TNFs. And I'm wondering how that has evolved and played out, and if you can just talk about the evolution of your first-line biologic usage due to that repricing strategy.

Vas Narasimhan

Thanks, Tim. Well, I'll let John go on his pick, and I'll think about my pick. Go ahead, John.

John Tsai

Thanks, Tim. If I had to pick one versus the other, I would say there's a differential of about 0.01% difference, perhaps, if I had to differentiate between the two, but this is my own personal, subjective opinion, which is – I would say PARAGON perhaps has a 0.01% chance higher likelihood of success. As you know, there's been numerous trial that have failed in heart failure with preserved ejection fraction, and currently, there is no treatment for this population of patients. We've learned from some of the trials that have been conducted in the past, and we've actually incorporated those learnings into our trial for PARAGON.

So, success in PARAGON really is based on what we have for a primary endpoint – a combination of CV mortality with hospitalizations, whether that would be first-time hospitalizations or recurrent hospitalizations. So, we're excited about it and we're looking forward to seeing those results.

Now, in terms of fevi, I wouldn't say it's a lower likelihood of success. It's just I think that asthma is such a significant unmet medical need. And currently, we have the biologics, and there's really no oral treatments beyond your current inhalers. So we have a very extensive and comprehensive clinical program that we call Vibrant with close to 5,000 patients, but if I had to pick one of the two, it might be slightly higher, but it would almost be on par. So I'll defer to Vas and see if he has any other comments.

Vas Narasimhan

The only thing I'd add on QAW and fevipiprant is just to remind that the key insight here was to shift the DP2s into more severe patient populations. So we saw a positive result in Phase 2 presented at ERS a few years ago, in patients with high eosinophils. The class has been explored in the past, but it had been explored in GINA 3 or less – so, far less severe patients. And so we believe that with the profile of the medicine, its good penetration of the relevant tissues, as well as the eosinophil reductions we saw in at least two studies, that's where it really gave us confidence. In terms of Cosentyx in first-line biologic use in the U.S., Marie-France?

Marie-France Tschudin

So, first of all, it's great to be back. It's a great time to be back in pharma. What I would say is that the performance for Cosentyx has played out as expected after last year's access wins, so we're very happy with that. We do remain confident that we will maintain our number one or number two position in our major markets. We see very strong underlying demand, and that is because of Cosentyx's unique profile that does address manifestations beyond skin. We also believe we've got the most robust data, and that will continue. We're also presenting further data later this year – for example, prevent and non-radiographic axial SpA. We're very confident in the future of Cosentyx in both derm and wound indications.

Vas Narasimhan

Maybe I would just add on the first-line – we believe it was the right strategy to get to the first-line because I think the data supported it, but also from a payer perspective, it put us in a strong position. I know, there's a lot of focus on some of the new entrants coming in,

and I think at least what Q2 showed is we were able to hold our own on formulary positioning thus far, and that's going to have to be our focus going forward to ensure we keep growing share and beating the market in the years to come, but we're on it, and we continue to believe that first-line uses and keeping in the first-line is critical. Thanks, Tim. Next question?

Operator

Your next question comes from the line of Keyur Parekh of Goldman Sachs. Please ask your question.

Keyur Parekh

Thank you. Good afternoon. Two questions, please. The first one for Vas, and then for Harry. Vas, you described the launch for Zolgensma as being very strong and good demand. Can you give us some sense for how many patients have you actually treated so far? Is it kind of single-digit? Is it double-digit? How should we think about that?

And then, secondly, Harry, kind of in your remarks about the differences between the first half and the second half, you alluded to the fact that if there was going to be lower generic impact than you expect, you would get to the higher end of the range you have just issued. Given you've delivered 19% core operating income growth in the first half, it would be difficult mathematically for you to get to anywhere other than the midpoint of the range even if you were to get a lot of generic competition, given the guidance you've given on Afinitor. So, what would it take for you to grow above the range, and why isn't that more likely? Thank you.

Vas Narasimhan

Thanks, Keyur. So, first of all, on Zolgensma, we're not going to give any specific numbers. What I would say is we're seeing strong demand in terms of Rxs coming into the hub, which I think is the first marker we were looking for, and that's steady week on week, and that's what we wanted to see, and it's in line with our plan. We're seeing good conversion of those Rxs through the system, whether it's in Medicaid or in private payers, ultimately into approvals, either through the medical exception process or getting policies in place, and then, ultimately shipping the medicine and getting the patients treated, which is when we ultimately recognize sales.

So we're looking at all three. We have a great team on it. I think I personally am involved in many elements of this, so when we say it's on plan, I think it's exactly what we mean. It's where we wanted it to be. We have a lot of work to do, but we're happy with where we

are. Now, with respect to the second half, Harry?

Harry Kirsch

Yeah, Keyur. We have great momentum, no question. So, the first half has been great, and we do expect that the key growth drivers continue to do well; productivity programs continue to grow slightly or ahead of expectations. The generic impact, we start seeing some. There is Zemplar coming in a couple of European countries. So we expect a bit higher generic impact. We see early signs. Of course, we will rigorously defend all of our products, but that started a bit.

And of course, the inventory provision release will not to this magnitude happen again. The second impact, I don't want to talk down the second half here, but we saw the acceleration of our sales momentum in the second half of last year, and also, when you compare half two margins last year versus half one, already an increase of the margins last year. So we have also a bit of a base effect, but we expect continued good performance, and just mainly for generics in addition to some of the base effects, basically, is the unknown.

Vas Narasimhan

Next question, operator. Thanks, Keyur.

Operator

Your next question comes from the line of Andrew Baum of Citi. Please ask your question.

Andrew Baum

Thank you. First question is I note that your provisions of $700 million in relation to DOJ case related to Diovan. Given your chief legal counsel is on the call, perhaps she might care to talk to any anticipated changes to your corporate integrity agreement in terms of the addition of any onerous impact for your marketing activities going forward.

Second, on Zolgensma, historically, Novartis has provided guidance for full year for the newly launched products, I'm thinking of Entresto and Cosentyx. I wonder whether you might intend to do so in this case.

And then finally, I know you're not exposed to government plans anywhere near as much as some of your peers, but I also remember that you enthusiastically embraced the proposed rebate reform as being good for patients, and by inference, for the industry. Now

that that's no longer in place, I'd be interested to hear your thoughts on how you assess the risks of U.S. reimbursement and pricing, given the pressures from both sides of the aisle. Many thanks.

Vas Narasimhan

Thanks, Andrew. So first, on the provision, I'll answer the question. We've taken the legal provision of about $700 million related to the Southern District case. We've taken the provision in the context of the ongoing settlement discussion, and I think you can understand we can't comment further, as the discussions are ongoing. Once we have a further update, we'll, of course, provide it, but I don't want to pre-speak against those negotiations.

Now, with respect to providing full-year guidance, I can't recall what we did when, but I think with Zolgensma, we're focused on getting the fundamentals in place, getting a very strong launch, and getting as many patients as possible in – let's call it the prevalent pool, patients who are not newly diagnosed, trying to get all the patients who are newly diagnosed if we can. So we're not going to give any guidance, but anyway, you'll see it all in Q3, and I can just say we feel very good with where we are and we feel very good with the trajectory that we're seeing thus far.

Lastly, with respect to U.S. government policy, certainly, the environment is very fluid. You can imagine we need to stay very close to it. It's very difficult for us to predict between the executive branch and between the various proposals between the committees in the Senate which ones will ultimately prevail or if they come in the end to a full legislative vote. So it's hard to comment on specifics. It's also hard to comment on specifics, because we haven't actually seen on paper any of the proposed legislation, proposed rules or proposed bills.

In broad strokes, we as a company remain supportive of many of the reforms, whether that's around transparency, whether that's around some of the elements addressed by the CREATES Act, enabling stronger access to biosimilars, reforming Part B, thinking about out of patient caps in Part D. I mean, all of these things are things we're open and supportive of, but until we see something concretely on paper, it's difficult to say and difficult to really determine how any of this will progress. So we look forward with you to get more updates as the year progresses.

I would want to highlight our very low exposure relative to our peer group, and we're amongst the leaders' ex-U.S. in the world in medicine. Depending on how you look at it, number one in Europe and amongst the leaders in the world. In the U.S., we're low-

exposed to these government programs relative to our peers, so that also, I think, creates a positive relative situation for us. Next question, operator?

Operator

Your next question comes from the line of Peter Welford from Jefferies. Please ask your question.

Peter Welford

Hi. Thanks for taking my questions. I've got a few quick ones. Firstly, just for Harry, on the margin, we all know the Innovative Medicines margin long-term gain is supposed to go to around mid-30%. Just curious as to whether or not we should think of that now as being conservative, or should we think of that to be likely to be hit sooner. I guess I'm asking if it's likely that is a conservative number where we can likely go ahead of that, or is it more likely that mid-30% would just be achieved before the initial 2022 guidance.

Secondly, then, on Piqray, you mentioned that the sales for Zolgensma and Mayzent could be disclosed in the third quarter, but there was no mention of Piqray. Should we be taking that, I guess, to mean that Piqray with the companion diagnostic is going to take longer for sales to build or should we also expect some further visibility on Piqray during the quarter? Thank you.

Vas Narasimhan

On the margin, Harry?

Harry Kirsch

Yes, Peter. So, as we all know, quarterly margins are always a bit volatile. So for example, last year, in quarter three, we had a 34% margin. We ended the year at 32%, and we made good progress in 2017, 31%, last year, 32%. Now if you take the one-timers out, in the first half, we are in the range of 33% to 34%, so, good progress. Now, could we achieve on a full-year basis a bit earlier? We have to see. Two or three big components, I would say that, we'll determine that, one is the Gilenya defense. That is, of course, a big piece. We are confident, but of course, from when we gave the mid-30% guidance, it was not part of it.

So that would certainly be helpful, and a potential upside if it holds longer than that, and we will do everything that it would, but too early to update our guidance. And the other element is, of course, how the launches are doing. And we have many of them. Good

progress overall. And I think what I'm highly confident about is how our productivity efforts are progressing, that's fully in our own control and was part of our over-delivery in the first half already. But of course the first two elements I described, we have to see how it develops over the next two quarters.

Vas Narasimhan

And then, on Piqray, Susanne?

Shannon Klinger

Peter, as Mayzent and Zolgensma, there's no difference in terms of disclosure for Piqray. As Vas said we are off to a very solid start. As you know, Piqray is approved together with a companion diagnostic for PIK3CA mutation testing from QIAGEN, and both of that is already included in the NCNN guidelines. We are engaging these payers covering 80% of the target population and as we emphasized last time, obviously focus is on testing because that's the condition for Piqray treating. And we have to say that testing is going up and we expect this to continue.

Vas Narasimhan

Thank you, Shannon. Thanks, Peter. Next question.

Operator

Your next question comes from the line of Steve Scala from Cowen. Please ask your question. Your line is open.

Steve Scala

Thank you. I have a few, first on Zolgensma. Based on the strong reception in the market, it would seem an average of five to 10 patients could be put on the drug per week in Q3. Would you like to take this opportunity to suggest that expectation is too aggressive, too conservative or are you unsure? All of your comments on the call so far have been plural, patients or excess, plans, contracts. So based on what you've said, it would seem like that would be a good range.

Second, if PARAGON is a clear success or clear failure, why didn't you have to issue a top line release before ESC? So no top front line release implies fuzzy data at ESC. And then lastly, what are some reasons why may Mayzent cannot duplicate, Gilenya's first year sales, which were nearly $0.5 billion given a superior profile and label. Thank you.

Vas Narasimhan

Thank you Steve. Always well, well phrased questions from Steve. On Zolgensma unfortunately I can't provide specifics on patients per week. I think what we would say is we are in the plural range on all of the things you mentioned. And so we continue to see very solid uptake and we are seeing that uptake every week and so I think it's been positive every week in terms of patients, every week in terms of plans, every week – plans, in terms of policies and every week as well in terms of contracting, so good momentum and we'll look forward to sharing the sales in quarter three.

In terms of the PARAGON top line release, John?

John Tsai

Yes, thanks Steve. As I've had a chance to look at various clinical trials, especially the large ones in cardiovascular clinicals, we've seen that results are sometimes difficult to interpret because it takes longer for us to either look at subgroups or sometimes there are secondary end points that we need to understand. So it'd be great if we're clear and it'd be great if we're clearly positive and I think that would be a very easy decision for us to move forward. But obviously it really depends on the results that we see. And we do have some secondary end points as well as some sub-studies. So we'll have to wait what those are.

Vas Narasimhan

And then lastly on Mayzent, Marie-France, you want to just take that?

Marie-France

Sure, Vas. Thanks. So the first thing I would say is that the physicians haven't identified patients so far with SPMS because there has been no medicine in the marketplace. So as we've said before, this year is all about education. I can give you some data on where we are with the launch. As you know, it is the only product proven to delay disability in active SPMS patients. The awareness is high. We've got more than 90% of neurologists willing to prescribe, even in my own personal conversations with physicians, there is a lot of appreciation for the EXPAND data. They need a treatment for this patient population. We've also seen a lot of progress in access over 70 million lives with preferred access, but we really need to focus on patient identification, creating a sense of urgency, at the end we're very confident in the long-term potential of nascent, but this year is all about education.

Vas Narasimhan

Okay, thanks. Next question?

Operator

The next question comes from the line of Florent Cespedes from Societe Generale. Please ask your question. Your line is open.

Florent Cespedes

Good afternoon and thank you for taking my questions. Three quick ones, first on ENTRESTO, what is behind the sequential acceleration of the sales mainly in Europe, the guidelines, your recommendations and I was just wondering what could be the trigger to see such acceleration on the U.S. market? A second question on Beovu, can you give us more color on your U.S. commercial operations as your competitors are quite strong and well established there. And if you have maybe some flexibility to even further expand your U.S. operations on ophthalmology. My last question is on Sandoz, the division growth is back into positive territory, do you see some improvements in some areas or is there any base effect and is this better performance sustainable? Thank you.

Vas Narasimhan

Great. Thanks. First on ENTRESTO acceleration, Marie-France?

Marie-France

So we see very strong momentum overall and this is really due to underlying demand. Obviously the PIONEER data has opened up a new patient segment for us in the in-hospital initiation and we're very confident with the momentum we're seeing across geographies, not only in Europe and in the U.S., but I can also say that China's off to a good start. Obviously the ESC Heart Failure Association, consensus paper that position us in first line on new onset and de-compensated patients has been, very, very useful for us and a real endorsement of the product, we're confident ENTRESTO is becoming standard of care across the board so we will continue to see strong momentum as I said worldwide.

Vas Narasimhan

Thank you. And then lastly on Beovu, we're having a really strong commercial team. We've been able to attract some excellent talent with deep experience in retinal disease and in launching retinal medicines. We have a field force fully deployed and ready. We have an excellent MSL team that's been out now for some time educating physicians on

the data. We have good plans in place with respect to contracting, particularly given how the medicine is given in a buy-and-bill – buy-and-bill model. We've been working a lot on our patient hub to ensure that we're ready to go and make it seamless and easy for physicians to get favorite patients onto the medicine. So we've got all, I think the elements in place ready to go. Also ex-U.S. as well, we are gearing up well for the RTH, as the Beovu launch. So overall we feel like we're in a good place.

I would say that for all our launches we have an executive level review with our leadership team in deep ownership, I think the executive team level to make sure that we're doing the best we can to get all the details right on these upcoming launches. Thanks Florent, next question.

Florent Cespedes

Sandoz.

Vas Narasimhan

Sorry, Sandoz growth. So yes – of course. So Sandoz growth, we were pleased by the Q2 performance, when you look at it was primarily driven by strong performance outside the U.S. a mix of mostly strong biosimilar performance, but also I would say our core generics business with some recent launches such as fulvestrant and a few others continues to do – overall do well. So we're very – I think proud with how Sandoz is performing in ex-U.S., within the U.S. our team continues to work hard in what is a challenging environment.

If you take out onetime effects – certain onetime effects, you would see that in the U.S. the base business continues to have declines in the mid teens, consistent with what we've seen in past quarters. So we haven't seen stabilization in that core Gx business in the U.S., I think for U.S. – in the U.S. the key will be our upcoming launches which we hope will be pegfilgrastim potentially as well. Our inhaled generics as well as some of the injectable launches we have upcoming. And if those go well, we hope to also have the U.S. contribute. So going forward we feel comfortable in raising the guidance to in line to low single digit based on that momentum that we're seeing, really all outside the U.S. Thank you, next question.

Operator

Thank you. Your next question comes from the line of Jo Walton from Credit Suisse. Please ask your question. Your line is now open.

Jo Walton

Thank you. Just a few quick ones please. Harry, you said that you were looking at Sandostatin LAR generics in Europe. I wonder if you could tell us which countries, the product has been approved in and what you expect the timeline for that to be moving into perhaps bigger, more important countries and potentially into the U.S. On the Gilenya situation, could you tell us whether you're still accruing for royalties to Mitsubishi Tanabe, they're changing guidance earlier this year suggested that they're not being paid since February. So is that an extra benefit, this product is now even more profitable for you? On Zolgensma, I wonder if you could just tell us a little bit about how you're progressing ex-U.S, you said that you've treated somebody in France, when do you think we'll actually be able to see paying customers outside of the U.S. And finally for Harry, you mentioned the tax rate going up because of the mix effect to over 16%, does that mix effect keep going? Should we now be looking at something above 15% for a medium term tax rate? Many thanks.

Vas Narasimhan

Thanks Joe. So on Sandostatin, Susanne?

Susanne Schaffert

Let me share the effects that we have. So there's one generic company that has recently received marketing authorization in the EU via decentralized procedure and they are started getting national ratifications for their local marketing authorization. We know that there are several countries where they already achieved that, like UK, Denmark, Germany and we see some first limited commercial activity. On the U.S. we are closely monitoring the situation and we will keep you updated of information in case we have.

Vas Narasimhan

I think one reminder on Sandostatin, it is a unique medicine – the setting it's given in – so when and if one generic starts to come in, you would really have to model your erosion curves similar to what you see with biologics and move with very limited competition, that's what our expectation at the moment in all geographies. Next on Gilenya, Mitsubishi. Harry?

Harry Kirsch

Yes, Jo, mean all I can say and I don't know where some of those two statements come from, but we are still paying and accruing royalties for Gilenya, to Mitsubishi Tanabe and according – in accordance to the contractual terms and agreement with them. So we actually, we keep paying and we keep growing.

Vas Narasimhan

And then in terms of Zolgensma, ex-U.S., first to clarify on the patients we reference from the French ACU or from the name of the patient program are fully paid patients. So these are not, – these are paid patients by the either by self or by the relevant government in the case of France. In terms of when we would expect approval as I said in the presentation, we are targeting approval before the end of this year. I think for planning assumption you should assume Q4 in this year is when we expect to get European Commission, okay. And be able to launch the medicine. In terms of tax rates Harry?

Harry Kirsch

Yes, Thank you for the question on tax rate Jo, because often a it's a complex topic and sometimes overlooked topic, but it's also hard to forecast. So we had a slight increase from 16% to 16.4%. That's where we are quite confident tax rate will be for this year. First of all couple of developments as you know, the Swiss tax reform got approved for us here in the Basel city, cantonal level, and federal level, which is excellent because that gives us very good planning security in a very large part of our operations.

We have huge substance, as you know here in Switzerland with our 10,000 process associates, many manufacturing sites as well as R&D and our headquarters, many of them are here. So very positive development there, that takes away uncertainty, that's great. And we have overall a very attractive tax rate, of course the tax environment is getting more and more difficult, we have been able to maintain attractive tax rate and I also expect as we continue to maintain an attractive tax rate, probably mid-term in the range between 16% and 17.5% to be more precise than that, we usually do year-by-year, but I expect it over the year as we continue to have a very attractive tax rate.

Jo Walton

All right, thanks, Harry.

Vas Narasimhan

Thank you, Joe. Next question operator?

Operator

Your next question comes from Seamus Fernandez from Guggenheim. Please ask your question. Your line is now open.

Seamus Fernandez

Thanks very much for the question. So just a couple here, can you guys talk a little bit about Cosentyx and the directional performance there? Just looks like you were coming in somewhat below in the U.S. relative to script trends. Just wanting to get a better sense of how the mix impacts there were coming in, whether it be some inventory effects, price, direct price negotiations impacts relative to formulary access or perhaps just the donut hole there impact. The second question, just wanted to get a general sense of the performance of your Humira generic or biosimilar, I assume presumably most of that performance came in European markets, can you just give us a general qualitative sense, if you can't give us the, exact sales, just trying to get a sense of how the penetration is going for that product.

And then the last question in terms of the expectations for PARAGON, John, you mentioned that there are always things with regard to large clinical studies like this that we have to be careful about and think about. Maybe could you just give us a general sense of what you would characterize? You said a clean win. How would you characterize a clean win? And what are some of the aspects that you think kind of complicate an evaluation of a large study like PARAGON, whether it be the different regional dynamics that we've seen become an issue in a number of studies, or other factors? Thanks a lot.

Vas Narasimhan

Thanks, Seamus. First, on Cosentyx, I'll just quickly take that one. In terms of what we saw, there was a small difference in terms of sales versus script trends. That was primarily driven by a small bit of inventory. Mostly, it's RDs, which were just related to formulary access. But, in general, right now, we're seeing sales volume trend with Rx Scripts, and it's nothing that we would say is important to flag with respect to Cosentyx momentum in the U.S. across indications.

With respect to adalimumab in Europe, I think as you know, there's a number of generic entrants who have come to market in adalimumab, which means that it's, of course a competitive marketplace. We have our experience teams, solid uptake of the adalimumab biosimilars, whether it's through tenders or in other ways. When you look at our ada penetration in Europe overall versus the originator, it's around 22%. We estimate we're ranked Number 3 among biosimilars players. That's probably the best data we can get. We're very proud of our performance, particularly in rituximab where we face less competition, as well as in etanercept, which is, I think a little more favorable situation for us relative to the competition.

With respect to PARAGON endpoints, John?

John Tsai

Yes, thanks, Seamus for the question regarding PARAGON. As you know, what I said earlier, the success would be really based on the primary endpoint, and the primary endpoint being CV mortality and hospitalization. What we know about heart failure with preserved ejection fraction is that the burden really is around hospitalizations and rehospitalizations for these patients. So, for us what we think would be success, really is dependent on hospitalizations or sometimes a subsequent readmission into the hospital. So, that's something that we're looking at very closely, and knowing that this is a significant burden for that population of patients.

Now, regarding your second part of the question, on what are some of the things we're looking at for perhaps, secondary endpoints or sub-studies, and you'd specifically mentioned are there regional differences – we have looked at some of the previous studies, looking at regional recruitment, particularly in the eastern European countries, and we think we've factored that into our study. We have less than 5% from Russia and Georgia, where in one of the previous studies, where there were some questions around that.

So, we think we've taken that into consideration, but thinking about some of the other perhaps sub-studies we're looking at; we have a cognitive sub-study looking at cognitive impacts. What I will say is that as we look at the overall adverse event reporting we have been seeing, as well as the patient experience from spontaneous reports, because Entresto is being used. We have not seen any signals in the current spontaneous adverse events, but obviously we need to see the results of the cognitive sub-study to be able to tell for sure. So, these are some of the things that we take into consideration for the trial.

Vas Narasimhan

Yes, I think overall with PARAGON, I think that the key thing to remember as we get to the final study is we looked very closely at past history. We studied very closely how the past studies were conducted. We tried to manage as best we could. We tried to also ensure we used repeat hospitalization to the composite endpoint, along with CV deaths for the composite primary endpoint. And then, we tried to also leverage our Phase II study, which showed both significant decreases in NT-proBNP as well as atrial remodeling. So, all of that taken together makes us feel like we've conducted a study in the best possible way to give us a chance of success, but then in the end, the science will ultimately tell us.

Okay, next question, operator.

Operator

Your next question comes from the line of Richard Parkes from Deutsche Bank. Please ask your question. Your line is now open.

Richard Parkes

Hi. Thanks for taking my question. This is Richard Parkes from Deutsche Bank. And first question on, gross margin within Innovative Medicines. I think you'd previously said that flat year-on-year gross margin for the full-year would be a good guide, but you had a very strong second quarter, and I just wondered how we should think about that, whether there was anything specific in Q2 gross margin, and should the new launches be a positive to gross margin offsetting maybe some of the impact from the generic launches. So, that's the first question?

The second question is on Lutathera. I think sequential quarter-on-quarter growth slowed a bit, so I just wanted to fill in any special effects there, and whether you could discuss the longer-term growth prospects for that franchise? Thanks.

Vas Narasimhan

So first on gross margin, Harry?

Harry Kirsch

Yes, gross margin is a bit hard to predict, as you know. Our gross margin started to increase quite significantly driven by the productivity programs' and favorable mix in the second half of last year. So, while I continue the good growth margin for the second half, probably improvement versus prior-year second half, where it's expected not to be as much.

Now, a lot depends on the product mix. As you know, it depends on some of the products with higher cost of goods progressing versus the ones that have either no royalty burden or very high gross margins. So, hard to predict, but I think it hopefully had split with the modeling that probably was prior-year half 2. I would not assume such a significant improvement.

Vas Narasimhan

I just want to add – overall, our transformation of our manufacturing is progressing really nicely, whether you look at our improvements in yield, improvement production performance in our facilities, the optimization of our plant footprint around the world, the

use of new technologies we had set up to really transform our manufacturing engine at the company. I think you're seeing now the impacts of all of that work in the gross margin.

Susanne, on Lutathera?

Susanne Schaffert

Yes, thank you, Richard, for the question. So, on Lutathera, we had another strong quarter, reaching $109 million, and the majority of sales are still coming from the U.S. And, you're right that growth rates in the U.S. slightly declined in Q2 and the main reason is really that major Tier 1 centers have now worked through their prevalence pool – really, patients on the waiting list that were mostly in late-line.

So, what we are focusing now on is really positioning Lutathera as the preferred second-line treatment, and we expect really further continued growth. We remain very confident in Lutathera, and we also expect now sales coming in from ex-U.S. We make nice progress in receiving reimbursement approvals, recently got approval for reimbursement in Spain and Italy; we got all the regulatory approval in Switzerland and in Israel, so we remain very, very confident with Lutathera, that it has potential for blockbuster sales, and will continue to grow strongly.

Vas Narasimhan

Great, thank you, Susanne. Next question, operator. If the remaining people in the queue could try to limit themselves with one question, and maybe not so many parts to the one question. We only have a limited amount of time left. So please, next question.

Operator

The next question comes from the line of Richard Vosser from J.P. Morgan. Please ask your question. Your line is now open.

Richard Vosser

Thanks. Thanks for taking my question. One question on China and the impact from the 4+7 tenders, please. Thinking about – I think Glivec has mentioned and there's been some tenders there, but maybe thinking about the impact on Diovan and Exforge, how should we think about that?

And, maybe if I can one second question, just on SEG101, how are you expecting that to be used? Do you see it being used primarily in patients who've had a vaso-occlusive crisis? How should we think about that? Thanks very much.

Vas Narasimhan

Thank you, Richard. So, on China in general, we are focused very much on our launch medicines. We are focused on moving out of the historical established medicines business, given the number of recent approvals we've had. We've had double-digit approvals, double-digit reimbursements, Entresto is doing well, Cosentyx is off to a strong start, our new oncology medicines are off to a strong start. So, our focus is very much on driving the new launches.

We do expect in due course these tenders to impact our legacy established medicines business, primarily Glivec and valsartan-containing medicines. To date, these tenders have not started at a significant scale on those specific medicines for a variety of reasons, so at the moment it's not a significant impact. Even when it comes, we expect that our launches should more than offset the impact of the 4+7 tenders. That's very much our focus on strategy. We also believe the government is doing the right thing in shifting resources from these older medicines and focusing on new innovation. It actually fits Novartis's strategy quite well.

With respect to SEG101, Susanne?

Susanne Schaffert

Yes, in terms of positioning, what we would expect – really, SEG101 has impressive effect on prevention reduction of VOCs. We could show in our data that we could reduce VOCs by 50%, and that's how we would expect it to position. So, patient population is probably be patients with two or more VOCs per year, which is around 60% of the total patient population.

Vas Narasimhan

Great, thank you, Susanne. And next question, operator. Thank you, Richard. Next question.

Operator

Your next question comes from the line of Michael Leacock from MainFirst. Please ask your question. Your line is now open.

Michael Leacock

Thank you. Two very quick questions. On Entresto, any update in terms of reimbursement timing in China? And, you mentioned on Xiidra that there was a lack in progress owing to uncertainty to its ownership. Could the same apply to Aimovig?

Vas Narasimhan

I'll start with Xiidra, and then come back on Entresto. So, right now, with respect to Aimovig, we think there's clarity in the field force, and we've been working together with Amgen to ensure that any of our legal disputes do not impact the focus of the field force in the United States. I would also say we're pleased – even though it's not come up yet on the call, we're pleased with the uptake of Aimovig outside the United States. It's been very positive overall, and we continue to drive that.

With respect to Entresto, we're working through now reimbursement at the regional level and are focused very much on getting an NRDL listing nationally for Entresto. We hope to achieve that in one of the upcoming cycles. We do have a number of regions where Entresto is already now on the listing at the regional level. So, but the goal very much remains to get on the national NRDL schedule in the coming cycles.

Michael Leacock

Thank you.

Vas Narasimhan

Next question, operator.

Operator

The next question comes from the line of Naresh Chouhan from Intron Health. Please ask your question. Your line is now open.

Naresh Chouhan

Hi, there. Thanks for taking my questions. Just on Mayzent, can you update us how you're doing with setting up and implementing the CYP screening, and is that adding to the inertia among doctors to – you've mentioned trying to instill some urgency in doctors. Is this kind of adding to the inertia in prescribing or switching patients to Mayzent? Just quickly, if I can, Entresto ex-U.S. was very strong. Some insights would be helpful. Thank you.

Vas Narasimhan

So, on Mayzent, Marie-France?

Marie-France Tschudin

So, with Mayzent, we are using a hub system that does manage the start forms, benefits verification, and genotyping, as well as the other lab data, and then ultimately, the delivery of the product. What we do see is that the numbers in the hub are encouraging, but it is a 60-day onboarding, plus one-month free, so it's about 90 days. So, we are now working to try and accelerate that, but our initial feedback is very positive on how that's looking.

Vas Narasimhan

And then, with respect to Entresto ex-U.S. acceleration, Marie-France would be the right person to ask. She oversaw Entresto.

Marie-France Tschudin

Yes, as I mentioned before in the call, I think just the momentum is really strong all over, and the PIONEER data has really boosted the in-hospital initiation, which has really changed the dynamics. And so, overall we've seen great performance in Europe, we've seen great performance in the U.S., we're starting to see very encouraging performance in China, and I just believe that momentum will continue as we go forward and we establish Entresto as standard of care.

Vas Narasimhan

Thank you, Marie-France. Next question, operator.

Operator

Your next question comes from the line of Kerry Holford from Exane BNP Paribas. Please ask your question. Your line is now open.

Kerry Holford

Thank you. It's Kerry Holford from Exane. One from me, please, on Xiidra. So, I noticed on the slide in your pack and you highlighted that you're not expecting significant Part D access expansion until 2021. I wonder if you can just talk through why that couldn't come earlier – beginning of next year and so, you're essentially saying that really, we should expect limited growth in Xiidra in 2020, which will be primarily dependent on that commercial plan patient only? Thank you.

Vas Narasimhan

Thank you, Kerry. Marie-France, on Xiidra?

Marie-France Tschudin

First of all, let me just say that we're excited to add Xiidra to our portfolio. We think it's a great complement to our front-of-the-eye business, and it does bridge to our pipeline. Xiidra has got a really strong clinical profile. It's really the only product proven to reduce signs and symptoms. Vas already mentioned the medical need, and how under-diagnosed dry eye disease is. Currently, we see 1.6 million prescriptions in a market that's 34 million. What I can say to you is that we've got excellent commercial coverage, and expanding to Part D will happen over 2021 because we're pretty much locked in for 2020. However, we do believe that there is a lot of room to grow. Dry eye disease is promotionally sensitive. We're starting a DTC campaign in Q4. We think it's a strong strategic fit and there's clear blockbuster potential for us in the U.S. alone.

Vas Narasimhan

Thanks, Marie-France. I think if you go back in time and you look at the early quarters, when there was a heavy focus on Xiidra, you saw the strong performance of this medicine, so we want to rekindle that fire.

Next question, operator.

Operator

Your next question comes from the line of Laura Sutcliffe from UBS. Please ask your question, your line is now open.

Laura Sutcliffe

Hello. Thank you. Just on the Zolgensma and specifically on your Medicaid book of business. We know that reimbursement in Medicaid is going to take much longer than in the commercial setting. But I was just wondering, if you could tell us whether your views on access and uptake in the Medicaid environment have evolved at all over the last few weeks since you got approval. Thank you.

Vas Narasimhan

Yes. On Zolgensma in Medicaid, we have four policies now already up on Zolgensma in Medicaid, which I think is very encouraging. I would say in terms of medical exception request thus far in Medicaid that Novartis at least are managing through our hub, we've

also seen positive responses from Medicaid states, our first patient actually was a Medicaid patient. And so when you look at those narratives in general, patients are able to navigate Medicaids with medical exception.

So that gives us encouragement that even in the time it will take up to get the medical policies fully set up, we can still work through the system and get patients treated, given the demand from the parents, the children, the providers, we feel generally optimistic. We love to accelerate getting those policies in place and our teams are working hard to do that. But as you rightly pointed out, it will be longer in Medicaid versus in the private insurance segment.

Next question, operator.

Operator

The next question comes from the line of Mani Foroohar from SVB Leerink. Please ask your question, your line is now open.

Mani Foroohar

Okay. Thanks for taking my call. A quick question on Zolgensma, you talked about the attractive launch metrics you've seen thus far. When we think about modeling in the future quarters, how should we think about time from dosage to realize reimbursement in the U.S. versus global markets where you're going to be launching? Should we expect that to be relatively swift or should we expect the payment over time dynamic you've talked in the past to come into play as you launch all U.S. across different markets.

Vas Narasimhan

So with respect to the payment over time, it's important to know we're doing this through a third-party. So actually what we do is we recognize revenue immediately and then take a provision for our estimate or whether or not we would need to have any sort of rebate at some time over the period that we ultimately contract for. So you shouldn't model any lag, as Harry guided last time, it's really revenue recognition at the time of dosing.

Today, because it's very early days, we don't have any plans currently using these kinds of models that we continue to work with plans in terms of contracting. It would be a similar situation we expect outside the United States as far as we can tell, once we get those launches moving we'll of course keep you updated if you need to shift your modeling at all for x-U.S. patients.

Thank you for the question. Next question?

Operator

The next question comes from the line of David Maris from Wells Fargo. Please ask your question, your line is now open.

David Maris

Thank you. Just a question, one of the proposals being floated is reference pricing. If you could just address in broad strokes, what's the average selling price difference of your lead products or the bulk of your pharma products are versus – U.S. versus Europe or the developed markets that they're thinking about benchmarking to? Thank you.

Vas Narasimhan

Yes. When you look at the proposals, in our experience, a very limited exposure in Part B, we don't have many Part B medicines, I can't really give you a specific answer on Part B probably a better to ask some of our competitors on Part B. With respect to Part D, our analysis suggests when you take into account, rebates, other government, subsidies and things that we give, patient assistance programs, redrug et cetera, that are net pricing for our major medicines within Part D really, at least recently launched medicines in Part D approach those will be seen in top European countries. So we at least don't see a significant gap in Part D.

I know from an industry wide perspective there's certainly a high variability within Part D and I think that's where the focus has been.

Thank you for the questions. And then I think time for one last question before we finish the call. So last question, please.

Operator

The last question comes from the line of Emmanuel Papadakis from Barclays. Please ask your question, your line is now open.

Emmanuel Papadakis

Thank you. I'll try and keep it to one semi-brief question. It was just a push Harry and perhaps you provided a little bit of margins, you talked about potentially getting a bit earlier to that mid-30s target, you didn't mention the possibility of us actually getting through that target and beyond. And in particular R&D is, I mean it's been perhaps one of the areas

where you most actively talked in the past about something you can internally control in terms of reduction. You're already at the 20% taught extent in the world of big data. Could you take it below that figure? Thank you.

Harry Kirsch

Yeah. Thanks for the question Emmanuel. In general for the company, we're trying to make the company as productive as possible. So our goal of course is not to stop at one specific number, but certainly focus on areas where we can become as efficient and as competitive with anyone in our industry and if relevant in areas like business services, our procurement competitive with anyone in any industry.

Right now our goal is to get to the mid-30s and by 2022, if we get there on a full year basis sooner then of course we'll give you an updated perspectives on where we want to head next on margins. But I certainly want to set the expectation; our aspirations are to be as productive as possible. Now with respect to R&D, we don't view R&D as the key lever to achieve this. R&D is fundamentals of the company, we always wanted to get to that 20% range, where they're now, but we don't use R&D as our driver for margin improvement.

What we want to do is ensure we fund every good program. And we do that and we assure that we are – and if we need to of course increase our R&D levels in order to fund excellent project, we'll do that.

Now in the medium and longer-term, if data science, digital technologies can help us transform not only our manufacturing and business services and sales areas, we hope that also will transform R&D. We hope that actually gives us capacity to do more programs and we can continue to be at 20% and do even more programs to grow the company.

So that's – I think that's it for today's call. Thank you again for investing in Novartis, for your interest in Novartis. We look forward to delivering a strong second half of the year. We appreciate your interest in the company, and we wish you a great summer. Thank you.

Operator

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