Company Name: Shire
Company Ticker: SHP LN
Date: 2018-04-26
Event Description: Q1 2018 Earnings Call

Market Cap: 34960.6854465
Current PX: 3827
YTD Change($): -65
YTD Change(%): -100.0

Bloomberg Estimates - EPS
Current Quarter: 1.218
Current Year: 5.07
Bloomberg Estimates - Sales
Current Quarter: 3820.286
Current Year: 15550

Q1 2018 Earnings Call

Company Participants

- Christoph Brackmann, Unknown
- Flemming Ornskov, CEO, MD & Executive Director
- Thomas J. W. Dittrich, CFO & Director

Other Participants

- Andrew Jay Finkelstein, Research Analyst
- Annabel Eva Samimy, MD
- David A. Amsellem, MD and Senior Research Analyst
- Graham Glyn Charles Parry, MD and Head of Healthcare Equity Research
- Jo Walton, MD
- Kenneth Charles Cacciatore, MD and Senior Research Analyst
- Kerry Ann Holford, Analyst
- Louise Alesandra Chen, Senior Research Analyst & MD

Presentation

Operator

Hello. Welcome to Shire's First Quarter 2018 Results Call. (Operator Instructions)

Please note this conference is being recorded.

Today, I'm pleased to present Christoph Brackmann. Please begin your meeting.

Christoph Brackmann, Unknown

Hello. Welcome, everyone. Thank you for joining us to discuss our 2018 First Quarter results, which were issued earlier today. You should have received our press release and can view this presentation on Shire's website. For those not able to view the webcast, you can find the relevant slides from the Presentations and Webcasts page of shire.com.

Our speakers today are Chief Executive Officer, Dr. Flemming Ornskov; and Thomas Dittrich, Shire's Chief Financial Officer. Please note that we're also joined by our financial adviser, David Kitterick, from Morgan Stanley today.

Before we begin, please refer to Slide two of our presentation, which provides information about certain statements we make today that are forward-looking statements within the meaning of the securities laws, including those regarding our strategic plans, development programs and future financial results. Statements made during this call that are not historical statements will be forward-looking statements and, as such, will be subject to risks and uncertainties, which, if they materialize, could materially affect our results. The forward-looking statements in this presentation speak only as of today. And we undertake no obligation to update or revise any of these statements. Additional information regarding these factors appears in our SEC filing. Following our presentation, we will also open up the call to Q&A. (Operator Instructions)

As you are aware, Shire is currently in an offer period, as defined under the U.K. Takeover Code. Due to restrictions under the Takeover Code, you will understand that we are limited in what additional information we can provide. And

consequently, we will not be able to address any questions regarding Takeda or other strategic alternatives during the following earnings call.

I will now hand the presentation over to Flemming. Please turn to Slide 3.

Flemming Ornskov, CEO, MD & Executive Director

Thank you, Christoph. And hello, everyone. We're pleased to share with you our First Quarter results that once again demonstrate Shire's strong execution against our key priorities. I would also like to take the opportunity to welcome Thomas, our new CFO. Thomas joined us from Sulzer last month and had previously spent many years in finance leadership roles at Amgen. Thomas is an excellent addition to our leadership team and brings the right experience to this role.

I'd also like to thank John Miller for serving as our interim CFO before Thomas could join us.

Now turning to the results. I'll share an overall business update. And then Thomas will take you through the financials. So can I kindly ask you to turn to Page 4.

Our presentation today will focus on 3 key areas. First, we will discuss the solid execution in the First Quarter with 7% product sales growth. Second, we continue to advance our strong late-stage pipeline, including lanadelumab. Finally, we will take a closer look at the progress we are making on our portfolio optimization and the recent agreements to sell our Oncology business.

With that, now please turn to Page 5.

In the First Quarter, we delivered 7% year-over-year growth with product sales reaching $3.6 billion. Product sales growth was 3% at constant exchange rates. Including royalties and other revenues, our total revenue was $3.8 billion for the quarter, reflecting a 5% growth. It is a good performance considering the headwinds of generic competition to LIALDA.

Non-GAAP earnings per share grew 6% versus last year. And non-GAAP free cash flow grew to $900 million. Thomas will provide further details on our financial performance.

Please turn to Slide 6.

I would like to focus your attention on 3 key growth drivers: Immunology, recently launched products and our international business.

Within the Immunology franchise, immunoglobulin and biotherapeutic products continued to outgrow the market, delivering double-digit growth. Our recently launched products contributed $464 million in product sales in the quarter and remain important drivers of our growth. Finally, we continue to deliver solid growth in international markets. While we benefited from foreign exchange rate movements, we also saw an increase in underlying demand.

Let's now turn to Slide 7.

Shire's late-stage pipeline is strong with 15 programs in Phase III and 7 programs now in registration. We achieved all of our pipeline milestones during the First Quarter. Lanadelumab was filed in the U.S., Europe and Canada, with accelerated review ongoing. In addition, the FDA accepted our filing for prucalopride for chronic idiopathic constipation with a PDUFA date in December of this year.

As you can see on this slide, we have several important pipeline milestones coming up in 2018.

Now please turn to Slide eight for a closer look at one of our key pipeline assets, lanadelumab.

Lanadelumab, if approved, has the potential to be the first monoclonal antibody to prevent hereditary angioedema attacks and change the treatment paradigm for this rare disease. Data that we have shared before showed that with a subcutaneous injection every 2 weeks, nearly 8 out of 10 patients had 0 attacks, once steady state was reached, from

day 70 to day 182 based on a post hoc analysis. Further analyses after pivotal trial data that were presented in March showed efficacy across patients with different baseline attack rates. The data also demonstrated efficacy in both patients with and without previous prophylaxis treatment. These results are particularly relevant because they show that lanadelumab was effective in treating patients with a high burden of disease.

May I now kindly ask you to go to Page 9.

With the continued growth of our Immunology products, we are investing to ensure we have sufficient plasma manufacturing capacity to meet the increasing market demand. Our new Covington site is a state-of-the-art, fully integrated plasma manufacturing facility that, if approved, will significantly expand our capacity going forward and drive cost efficiency. We expect to receive FDA approval later this year.

Please turn to Page 10.

We announced last week that we reached an agreement to sell our Oncology business to Servier for $2.4 billion, a multiple of over 9x versus 2017 sales. While the business delivered high growth and profitability, we decided that it's not core to Shire's long-term strategy. This is an excellent example of how we can optimize our portfolio by unlocking embedded value and sharpening our focus on rare disease leadership.

I'll now turn the call over to Thomas, who'll review our financial results in greater details.

Thomas J. W. Dittrich, CFO & Director

Thank you, Flemming. First, let me say how pleased I am to have joined Shire at such an exciting point. My short time at the company has confirmed a few things I saw from the outside. Shire has a strong portfolio of marketed products, innovative assets in the pipeline that are expected to drive future growth and an experienced and talented team. I look forward to working with our colleagues to support the company's mission of improving the lives of patients with rare diseases and, in doing so, to drive shareholder value.

Turning to Slide 12.

Now product sales grew 7% year-over-year, with 3% growth in the U.S., 4% international growth at constant exchange rates and a 3percentage point benefit from foreign exchange. This is very good performance as we absorbed the impact from U.S. generic competition to LIALDA, which entered the market in mid-2017. Excluding the LIALDA impact, product sales growth was 10%, or 7% at constant exchange rates, almost all of it driven by an increase in underlying volume demand.

Moving on to Slide 13.

Our Rare Disease division grew 10% on a reported basis and 6% at constant exchange rates on the back of strong demand growth. Our largest Rare Disease franchise, Immunology, grew 8%, driven by continued and strong performance of our subcutaneous immunoglobulin brands and biotherapeutics.

HAE product sales were relatively flat year-over-year as the impact of competition and inventory stocking in Q1 2017 for CINRYZE was offset by inventory stocking and pricing benefits for FIRAZYR.

Hematology grew 9%, primarily driven by demand growth for ADYNOVATE and the benefit of favorable exchange rates. This was partially offset by a decline in FEIBA sales due to timing of large international orders and the impact of U.S. competition in the inhibitors.

The Genetic Diseases franchise was up 1% with a large benefit from foreign exchange given its heavy international weighting, offset by the timing of large orders in international markets. Our newly launched products, including GATTEX, NATPARA and XIIDRA, are driving healthy growth in our Internal Medicine and Ophthalmics franchises, primarily driven by higher demand.

As Flemming discussed, we have agreed to the sale of our Oncology franchise to Servier. As you can see, we're selling our Oncology business from a position of strength, as evidenced by the 15% growth in the First Quarter.

Turning now to Page 14 and the Neuroscience division.

You will recall that this division includes our ADHD franchise and other non-promoted products, which we call established brands. You will also recall that the established brands include products like LIALDA and PENTASA that share the same route to market as the ADHD franchise.

LIALDA declined by $113 million or 65% year-over-year due to U.S. generic competition to LIALDA. Excluding LIALDA and other established brands, Neuroscience grew 14%. This growth was primarily driven by VYVANSE price and stocking in the U.S. and continued growth in our international markets.

Please turn now to Slide 15.

Gross margin declined versus the prior year. However, it is in line with our expectations. And we remain on track for our full year gross margin guidance.

I want to provide a bit more color on our gross margin development in order to put the First Quarter into context of our full year guidance. And I will do that in 2 steps.

First, you may recall, last year we discussed that 2017 benefited from the saving of certain manufacturing costs related to Baxalta products. And we indicated those benefits would reverse. These benefits were not quantified for you at that time. Adjusted for this impact, our gross margin in the First Quarter of 2017 would have been around 74%.

Furthermore, in Q1 this year compared to last year, we had incremental costs for Covington and some margin headwinds from mix. So that is the impact year-over-year.

Second, let me now talk you through margins quarter-over-quarter.

In Q1 2018, we saw improvement in gross margins from the Fourth Quarter 2017, driven by productivity gains in our manufacturing network. And we expect to see these productivity gains continue.

The second driver for positive margin trend comes from the expected favorable sales mix driven by the recently launched products, which have high margins.

With these drivers, we are on track to hit our full year non-GAAP gross margin guidance of 73.5% to 75.5%.

Moving on to the P&L on Slide 16.

Reported total revenues grew 5% based on 7% product sales growth and the decline in royalties. Royalties and other revenues decreased primarily due to the reclassification of ADDERALL XR from royalty revenue through product sales and other accounting changes as required under the new revenue accounting standard, ASC 606. And lower SENSIPAR royalties.

Non-GAAP gross margin declined versus the prior year, as we've just discussed.

Non-GAAP R&D expenses increased 5%, mostly driven by increased spend on late-stage programs, including SHP647.

Non-GAAP SG&A expenses declined by 13% as the year-ago period included significant initial launch costs for XIIDRA. And we have since transitioned to a more focused marketing approach. In addition, we remain keenly focused on operating efficiencies.

Non-GAAP EBITDA grew 2% as the benefit of higher product sales and lower OpEx was partially offset by a lower gross margin compared to a year ago.

Our non-GAAP tax rate was 13.7% in the quarter due to a net tax benefit for income tax reserves. This is a discrete item for Q1. And we still expect our non-GAAP tax rate to be in the range of 16% to 18% for the full year.

Non-GAAP net income and EPS both grew 6% in the quarter.

We have also begun reporting divisional profitability, which you will find in our earnings release and in our 10-Q.

Now please turn to Slide 17.

We generated over $900 million of free cash flow in the First Quarter, a year-over-year increase of about $700 million. This was driven by improvements in working capital and higher operating profitability and a favorable comparison period as Q1 2017 included a $350 million legal settlement payment.

CapEx was relatively flat year-over-year at about $200 million.

Our strong (free) cash flows have enabled us to pay down net debt of $900 million during Q1 and approximately $4 billion over the last 12 months. We ended this quarter with $18.2 billion of non-GAAP net debt and a non-GAAP net debt-to-EBITDA ratio of 2.8. We're on track with our previously stated deleveraging plans.

Moving to Slide 18 on 2018 full year guidance.

We are on track with our 2018 guidance. Please note, we will be updating our guidance for the impact of the sale of our Oncology business only after the closing of that transaction later that year. Also, you should note that we are now providing guidance for total revenue, which is comprised of total product sales and royalties and other revenues. As I previously discussed, certain revenue items formerly classified as royalties are now recorded as product sales due to a change in accounting standards.

Lastly, please turn to Slide 19.

After my first month at Shire, I'm pleased with our performance in the quarter. We are on track to deliver our 2018 guidance. And I see no changes to our 2020 guidance at this time, excluding the impact of the Oncology sale. I look forward to sharing our plans for a disciplined and balanced capital allocation program in due course.

With that, I turn the call black -- back to Flemming.

Flemming Ornskov, CEO, MD & Executive Director

Thank you, Thomas. And please now turn your attention to Slide 21.

In the First Quarter, we delivered solid results with 7% product sales growth and good earnings while overcoming the impact of generic LIALDA in the U.S. We also continued to progress our pipeline, including global filings of lanadelumab. These results reflect our continued progress in transforming Shire into the leading global biotech company focused on rare diseases. Approximately 70% of our revenue now comes from products to treat rare diseases. And these products are mainly biologics.

Our R&D pipeline is very strong, with approximately 40 programs in clinical development. Approximately 70% of these programs are in rare diseases. And several programs have been granted Breakthrough Therapy and Orphan Drug designations.

Now let's turn to Slide 22. As we look forward, I would like to highlight a few key regulatory milestones.

As mentioned earlier, we expect to gain FDA approval of our Covington manufacturing facility this year. Lanadelumab has a U.S. PDUFA date in late August, with a potential for approvals also in Europe and Canada. We anticipate potential approvals for VYVANSE in Japan, for XIIDRA in Europe and for prucalopride in the U.S. All of these events are, of course, subject to regulatory approval.

Shire is, as you can see, off to a good start in 2018, delivering against our key priorities and advancing our late-stage pipeline. I'm extremely proud of the entire Shire team and would like to thank all of our Shire employees for their focus and dedication to the patients we serve.

With that, I'd now like to turn the call over to the operator for the Q&A portion of our call. But please keep in mind Christoph's opening comments that we will not be able to address any questions pertaining to Takeda or any other strategic alternatives.

Questions And Answers

Operator

(Operator Instructions)

Question comes from Annabel Samimy from Stifel.

Annabel Eva Samimy, MD

So you've now had about a quarter to understand some of the dynamics with Hemlibra, which, I guess, at this point, all hemophilia specialists generally know pretty well. But the inhibitor franchise appears to be holding up nicely. So what have you observed on the ground? And is there anything that suggests that this will play out differently than your expectations? I know that you mentioned there was some stocking this quarter. But maybe you can characterize what you've seen on the ground and how this might play out.

Flemming Ornskov, CEO, MD & Executive Director

Thanks very much, Annabel. That's excellent questions that I can only partly address, I think. So the first question is whether we have any changes to our previously stated outlook about potential erosion that we will see to the inhibitor business and to the non-inhibitor business. And we do not see any change to that. We expect, in percentage terms, a faster erosion of the inhibitor versus the non-inhibitor. It's way too early to say anything about Hemlibra. I have, of course, noted both what Roche says and observe what we say and what we see in the marketplace. As we've seen recently with a lot of products in the U.S.. And I think you've also had spotlights on some of our launches, the reimbursement environment in the U.S. has changed significantly. So I think it will take some time before you really see the full impact of a trajectory of newly launched products. We hear the same thing for Hemlibra that we've also seen with some of our products that -- getting coverage, sorting out which plans, stocking and destocking and all of these things initially. So it's, I would say, not a clear picture. What I can say is. And as you will see with FEIBA, FEIBA continues to do very strongly. And I think it's also important to realize that since we merged with Baxalta, we have consistently upgraded our efforts in hematology. You have seen that ADYNOVATE does really well in the U.S. You will see ADYNOVI, which is in the name outside the U.S., has been approved and is, I'm sure, off to a good start. You will see myPKFiT being approved for ADVATE. Now also -- and you've seen a lot of things happening that have strengthened our hemophilia franchise. We've also changed the team. We've put a lot of experienced marketeers on the team. And I'm incredibly proud of both the U.S. and international team. And I think you're starting to see the beginnings of some of their excellent efforts. And I, of course, also with great pride, noticed that FEIBA had a very good start to the year. In all due respect, also to ourselves, it is just the First Quarter. So I'm absolutely sure we will not be delayed on the year.

Operator

Your next question comes from the line of Jo Walton from CrÃ©dit Suisse.

Jo Walton, MD

I have 2 questions. Firstly, I wonder if you could confirm for us whether you think you're going to need an Adcom for lanadelumab and RESOLOR in the U.S. And secondly, again on the HAE scene, I wonder if you could break out for us or give us some more data behind the CINRYZE and FIRAZYR breakdown. And in particular, we're obviously interested in the CINRYZE supply situation and also the impact of HAEGARDA in the U.S.

Flemming Ornskov, CEO, MD & Executive Director

Yes. Thanks very much, Jo. I will -- not to monopolize the conversation. But I just want to give you a little bit of interim remarks. So we have not publicly confirmed anything about -- or I don't think that the regulatory agency, the FDA, has regarding Advisory Committees for either those products. If I had to guess, I would say the likelihood is probably higher for prucalopride than it is for the other. But I do not know just because of the filing. But we have no confirmation yes or no publicly about (all of those). If it should happen for either or both, I can assure you my team is totally prepared to address any questions in both cases. We see both of these products currently on track to the timing we've laid out with their PDUFA dates. But again, it's early in their filings. And note with lanadelumab, I think it's -- I have to say on behalf of my team, I think they've done an outstanding job because not only have they accelerated reviews in the U.S.. But you've seen the same for EU and Canada. So I feel very strongly about this. And I think both products would be future good growth drivers for Shire. As pertains to CINRYZE, hereditary angioedema. And FIRAZYR, as you can imagine. And a new competitive entry with HAEGARDA, some of the same things we've said before, that the supply patterns for CINRYZE has been a bit erratic at the end of last year. It is starting to get better. We have moved our U.S. production to Vienna. We still have international production coming out of Sanquin. And I think that is starting to be more normal and more normalized. And the other thing we're seeing is that in the marketplace, having a very strong patient service organization to support the patients as they roll on to the products is very important. And I think we have a very strong leg to stand on in the U.S. with our OnePath service organization. So I feel very good about both of those situations. Thomas, anything you want to say about (hereditary) FIRAZYR? I think we don't break it down. We feel very confident. And I would not take small ups and downs in the quarters with stocking, destocking, filling supply, given that you come out of an out-of-stock situation in the second half of last year. It's going to take a little bit longer before that is normalized. What we do see is that anecdotally, that patients continue to be very pleased with the treatment of CINRYZE. And I've also anecdotally heard about patients that had switched that are coming back.

Jo Walton, MD

I think we would have preferred a bit more granularity. But I understand that you may not be able to give it.

Flemming Ornskov, CEO, MD & Executive Director

Yes. That is true. Well we don't typically break it down to that level.

Operator

Our next question comes from the line of Louise Chen from Cantor Fitzgerald.

Louise Alesandra Chen, Senior Research Analyst & MD

So first one I had was on lanadelumab. Just curious how this product will impact your entire franchise here, how we should think about the pricing and margins when compared to CINRYZE and FIRAZYR. And how do you think about the entire franchise growth over time? Second question I had was with respect to gene therapy in hemophilia. How do you think about that within your portfolio as well as competitors'? And do you have any way to break out the

percentage contribution in EBITDA for hemophilia business? Is that in line with your corporate average, greater than? If you can give us some color, that will be great.

Flemming Ornskov, CEO, MD & Executive Director

Okay. Thanks a lot, Louise. So a few answers first. Well we believe, of course, in having the best possible products for the patients that suffer from the rare diseases where we have product offerings. So if lanadelumab is approved in the U.S. and outside the U.S., that's, of course, going to be the key product for us with this franchise. I think anyone that's looked at the efficacy data, the convenience of this product, whether you look at attack-free. And we mentioned some of the data here, the very convenient monthly or bimonthly injection of a very small volume. We've also disclosed quality of life data that shows significant improvement there. So we feel very confident that this will be a potential paradigm shift in the way hereditary angioedema patients are being treated and their attacks are being prevented. So we're going to do everything possible to make sure that patients have available to this product in the U.S. and outside the U.S. We don't comment on pricing assumptions at this stage. But I will say that lanadelumab, which is a monoclonal antibody, will have a higher margin, without giving you the specific %. And will be a plasma-derived product. And I'm sure we will have more discussions about this. As pertains to 654, that continues to progress. We are enrolling patients. I'm feeling very confident about that and our new Head of Research & Development and our CSO. I also feel that we have an incredibly talented group. We have a great production setup in Vienna. So I feel very confident in that. I think. And I've said that before, that gene therapy -- and I know there's other companies like Spark and BioMarin that potentially are ahead of us -- that I don't think the majority of patients will be on gene therapy if approved. But I think it's a very nice opportunity for certain patients that prefer that as a treatment either alone or as a supplement over time. And I think the data in this field also from our competitors are quite encouraging. Hemophilia is a very profitable business. Anything else you want to add to that, Thomas?

Thomas J. W. Dittrich, CFO & Director

I think you covered it very well.

Operator

Question comes from the line of Ken Cacciatore from Cowen and Company.

Kenneth Charles Cacciatore, MD and Senior Research Analyst

Flemming, I'm not trying to break any rules of this call. But just wanted to ask one question then I'll ask an operational question. So first question, how are you able to gauge what Shire shareholders want you to do? I don't know if you can just talk technically about conversations you can have or how do you engage with them and if you can give any perspective of the feedback you're getting. Then operationally, if you could just be a little bit more specific on 643. Obviously, CINRYZE is doing about 90% of sales in the U.S. With 643, it looks like you could be able to finally expand both capacity of CINRYZE into the ex U.S. markets and maybe 643 obviously into those ex U.S. markets. So is it possible that 643 could equal what you do right now in ex U.S. markets if you're able to supply?

Flemming Ornskov, CEO, MD & Executive Director

Yes. So as you can hear, I'm being chaperoned today. And I know that you would never want us be known to break any rules on questions, Ken. But I can only say to you that, as you know, we have a U.K. listing. We have 2 brokers. And that's a very good entry for myself and also the board to get into what our -- what shareholders think about any particular situation. And of course, I think both myself and most of our board members and many members of my

executive team have lots of exposures to our shareholders. And we make it an absolute priority to do the very best for our shareholders and hear their feedback whenever we can. But I'm not going to comment specifically on any feedback on this situation. I think a lot of that feedback has also siphoned into the public domain through analyst reports and other people that had commented. So I'm not going to comment more on that. But getting the right feedback, hearing that feedback, making sure that's an important part of any decision making, I can assure you I have a Board of Directors that puts significant emphasis on that and have an independent channel through our brokers to get that information. I think, again, a very good, broad and, I would say, unbiased, unfiltered feedback from our investors. And also, several members of our board, including our Chairman, has a lot of interactions with investors. So -- Susan also has a very good insight into the investors. And there's also been engagement in the U.K. by our board with Investor Forum and others. So they have a very good idea about what investors in general think should be the right thing in this and other situations. So you hit a very good point on CINRYZE. And that's a good and a sad point. The sad point is, of course, that CINRYZE, I will say, ever since we acquired it, ViroPharma. But I think even before that, were suboptimally supplied outside the U.S. We have -- over the last several years up till we shifted the U.S. production to Vienna, our in-house facility that we acquired with the Baxalta acquisition, one of the many benefits from that acquisition, that we now are in a much better situation of supplying the U.S. It takes a bit of time. But we have approval for that site to supply the U.S. So I feel good about the opportunity to supply the U.S. We're still dependent on Sanquin for ex U.S. supply. And for U.S., we're still dependent on Sanquin for some of the raw materials here. So we're not totally out of the woods, I would say, in that situation. But as we work it through, we will include more countries because there's only a few right now where CINRYZE is available. So that will be an expansion opportunity for CINRYZE. But I would not, Ken, differentiate between U.S. and non-U. S. positions. One other thing that I can tell you, my channels of feedback on lanadelumab is equally strong from patients and particularly physicians in the U.S. as it is outside the U.S. There's a very high interest in this product. And I think you can also see that through the regulatory situation with accelerated review times. So I think that there will be significant interest outside of the U.S., of course, if pricing and reimbursement allows this. So this can be broadly available. But we will simultaneously shift also production of CINRYZE into higher gear so we can supply more markets and there's more choice available for patients around the world.

Christoph Brackmann, Unknown

Any other questions?

Operator

Our next question comes from the line of Kerry Holford from Exane BNP Paribas.

Kerry Ann Holford, Analyst

It's Kerry Holford from Exane. I have 2 questions, please. Firstly, on XIIDRA. I wonder if you can provide us an update on progress there in the U.S. market. Any comments you can make on the access trends would be very useful. Sales figures look slightly light. I wonder if you could just give us some more detail on the progress of that product. And indeed, when do you expect and when do you prepare for generic Restasis to enter the market? Then secondly, a quick one on tax. Thomas, I wonder if you can tell us what the underlying core tax rate was in Q1, excluding that one-off tax benefit.

Flemming Ornskov, CEO, MD & Executive Director

Thomas, I think you should start because people are getting tired of just listening to me. So may be a good time for you.

Thomas J. W. Dittrich, CFO & Director

Yes. I think we'll have to do a quick look here on the underlying rate. Maybe you go ahead and I'll come back on that.

Flemming Ornskov, CEO, MD & Executive Director

Very good. I'll be happy with that. So XIIDRA, let's just talk about XIIDRA. So I think with XIIDRA, what you need to look at, you'll need to look at the underlying prescription growth. And that's actually doing very, very well. The issue is still the same as it's been on previous calls, that we have very high share and very good penetration in the half of the market in the U.S., which is the commercial markets. And we still have barriers in the Medicare Part D. We are seeing that when we get into. And we have gotten access to some but still not the majority, that we capture a share which is not dissimilar to the share that we have in the commercial plans. So there were a few things in the First Quarter that was a bit unusual that related to price increase, changes in inventory and others. If you look at the prescription trends, that continues to be very strong and, I think, a very good trajectory. If there were an opportunity to change this trajectory, it would have to be that we will get access to Medicare Part D more than we have now and that we would be able to capture the kind of share that we have in the commercial plans. I feel very comfortable that even if there is. And I've heard various rumblings about that could be midyear a generic or multiple generic Restasis, I think that, that will give us a better opportunity to have a better situation in Medicare Part D. And I don't think it will dramatically change us even though I'm sure that there will be some generic pricing and other impacts. So I feel confident in the outlook. And what I also feel confident about is, as you can see, we have filed outside the U.S. We got approval in Canada. So a bit of patience with XIIDRA. But I think it's interesting to look at. If you compare XIIDRA's uptake to if you look at VYVANSE and other products that have been very successful, I think XIIDRA is on a very good uptake. And remember also, Restasis, if you compare the uptake of XIIDRA versus Restasis, it also has a very good uptake. So a bit of patience. But I'm fine with the trajectory. It is quite clear that a Restasis going generic will change the dynamic. And I think it could potentially be beneficial for XIIDRA because it will unlock further access, I assume, to Medicare Part D, which will be the next, I would say, growth trajectory for this brand and then, of course, Canada and U.S. markets and eventually, hopefully also, Japan. Those are less developed markets but very attractive markets.

Thomas J. W. Dittrich, CFO & Director

Kerry, now let me come back to the tax question. I just went and quickly double-checked because, as you rightfully say, it's an effective tax rate of 13.7%. Our guidance range is 16% to 18%. So what's going on? And I just quickly confirmed that our lower Q1 effective tax rate purely reflects the discrete timing of anticipated benefits. So we knew this benefit was coming. We knew that benefit was coming in Q1 as a one-off. And we have actually factored that in, in our guidance for the full year to be in line with our 16% to 18% guidance. So I hope that answers your question because it was an anticipated benefit factored into our guidance as we provided it.

Kerry Ann Holford, Analyst

So is it fair to assume that the underlying core tax rate remains around 16%?

Thomas J. W. Dittrich, CFO & Director

Exactly. The underlying core tax rate remains in that guidance range, exactly.

Operator

Our next question comes from the line of David Amsellem from Piper Jaffray.

David A. Amsellem, MD and Senior Research Analyst

I wanted to ask you a couple of questions about your GI franchise. It looks like you're making some progress towards getting that unfavorable growth trajectory with the pipeline. I wanted to get your thoughts on prucalopride and the different puts and takes regarding the competitive landscape and how you see reimbursement playing out given that you have fairly heavy contracting with LINZESS and then Trulance. So just give me a sense of how you're thinking about that product. Then secondly, for 621 and eosinophilic esophagitis. There's another question about, again, the reimbursement landscape and how you're thinking about pricing there given that steroid solutions are used off-label. Help us understand that opportunity.

Flemming Ornskov, CEO, MD & Executive Director

Yes. Those are excellent questions. Thanks very much, David. I'm very pleased that you noted that the Lumena GI business is one of our very attractive and one of our very key growth drivers. I think you were a little bit modest in your description of GATTEX. I think the kind of growth rate you see for GATTEX would speak to that the team is doing an outstanding job. I don't know if you also referred to NATPARA. But if you look at GATTEX, I would say that it took us a little bit of time. And that's fair enough, it was all of us, to figure out the complexity of short bowel syndrome, whether the underlying cause was surgical or nonsurgical, whether you were trying to be using that product as a supplement in patients to total parenteral nutrition or whether there were some patients that you could wean off. And I really think we have been much better at this. We've also gotten, I think, the service part of our organization, the patient selecting being much better at interacting through our medical colleagues with the key prescribers and the researchers. So I think you're seeing 2 things that is driving that very strong growth. I think there's an underlying very strong growth in the opportunities for patients. But also, we have been better targeting the patients that probably can benefit the best from the products. And there are clinics around the world, there's one I'm aware of in France, where they have weaned off a very impressive number of pretty seriously ill patients that had been on total parenteral nutrition for a long time. You can't achieve that with all patients. So I think we've gotten much better in terms of the targeting of the right physicians, better describing what is the ultimate profile of the patient that can benefit the best from that, of course, how -- the pricing reimbursement situation. And then also provide the support through various organizations to patients so that when they get on, they stay on the product. But they also manage this very complex transition from being only on total parenteral nutrition to being on a product and total parenteral nutrition and some of them being weaned off. So I totally share your enthusiasm. And I'm very proud of the people. I know that was a question mark that many analysts have raised. Of course, it's still a bit early days. But I think we're doing really well. So let's talk about the other aspects of the GI franchise. 621, if you're a cynic, you will say, wow, it's budesonide in a new formulation. So how exciting can that be? I'm a person -- maybe that's my physician background. I look at the data. If you look at the Phase II data, I actually think they showed significant improvement, whether you looked at overall the functional data but also if you looked at the histological data in terms of resolution of the various severe eosinophilic inflammation that there was. So this, as you know, is a condition that is frequent. It starts in adolescence. These kids are very, very severely affected, dysphagia and many other things. Steroids, whether it's given one way or the other or given as a spray is, in most patients, not sufficient. So I think both, there's a need for this product. I think it will do better than many people expect. And I think that if its efficacy is repeated and it's approved, of course I think it could be a very good product for these very severe patients. 555. So that's prucalopride. So that's a promotility agent for idiopathic constipation. It's a product that we originally -- not us but another company. And then it was acquired by Shire, got out of J&J. I think the product, if approved -- and I know the class has had a history here. But we also did additional cardiovascular studies and case control studies, the FDA has accepted the file, they're reviewing the file -- that this would be the first promotility agent on the market currently. And I think there's a significant unmet need if we do a little bit of market research. I know that the challenge we're going to be having here is a 5-year exclusivity period. We know that it's a DTC (7) promotion-sensitive product. Without going into details whether we will do it ourselves, on partnerships, we have a very good plan. So I'm, first of all, incredibly optimistic about our GI franchise. I have hope. You also mentioned 647, which is our largest clinical program for ulcerative colitis and Crohn's. But I think with 555, 621 and with GATTEX

and with 647 on the pipeline, I think we can say we have an incredibly attractive GI and very scientifically attractive GI franchise.

Operator

Next question comes from of the line of Graham Parry from Bank of America Merrill Lynch.

Graham Glyn Charles Parry, MD and Head of Healthcare Equity Research

So firstly, just a technical question. Can you just quantify the stocking in a number of products, please? So VYVANSE, the immunoglobulins, hemophilia and inhibitors? And also, the impact of shipment timing on ELAPRASE, especially given this is the second weak quarter in a row on that product. Just be useful to understand what the underlying trends are in that. Secondly, you've given the contribution margins for the divisions. But obviously, there's an awful lot of central costs that's separated out of that. If you were to look at the separation of the businesses, how should we be thinking about those central costs being allocated across the 2 businesses if they're separate entities? And what additional costs might the business incur? So any sort of dis-synergies that we should be thinking about?

Flemming Ornskov, CEO, MD & Executive Director

Yes. So thanks very much, Graham. I'll take the first part of the question. So unfortunately, if you want to follow ELAPRASE, you're going to have a lumpy ride because it's an international product that is dependent on large orders. We cannot determine the timing of these orders. So you will never see typically a smooth ride. There was 2 countries. I think, in this case, it was Russia and Brazil, where there were some order delays. And that -- if you look back at the history of ELAPRASE, that's what you typically see. I think the underlying demand and growth and the need for this product continues to be attractive. Remember, this is not a product that was launched yesterday. But I think it continues to be a good, solid driver for Shire and a good product class in our Genetic Diseases franchise. As pertains to immunoglobulin and GAMMAGARD LIQUID and some of the other products, it's important to understand that if you look at the IgG business in whole or individual parts, we are seeing a growth which significantly exceeds the planning that we had and the growth that we saw when we integrated Baxalta. You also know that there's long lead times on a lot of these products. Either it is to get a plasma collection, which we have significantly planned and are increasing the collection of. But then there's still long lead times. So we have a lot of demand for our immunoglobulin portfolio. And we have certain cases where we cannot fully meet the demand. We try to prioritize certain jurisdictions like the U.S. and others. But we could certainly fill even more demand if we were looking at filling all of the demand that is outside the U.S. The other reason for this is we're winning more and more tenders, which only speaks to the attractiveness of our portfolio. Finally, as you can see, we have -- I don't want to call it phenomenal. But we have impressive growth of our subcutaneous portfolio, which, of course, also puts strain in a positive manner on the supply situation, hence the need for Covington that we hope to have later in this year, which will increase our capacity with 30%. Thomas, any other comments?

Thomas J. W. Dittrich, CFO & Director

Yes, I would just state on immunoglobulin, you see 12% growth year-on-year in the quarter. The underlying volume demand is bigger than that even because, to your point, Graham, inventory and stocking was actually negative. So the underlying volume demand is even higher than that. Then also due to some international pricing, pricing was slightly negative. So this actually backs up what Flemming just said, that the underlying core volume demand is more healthy than what you see in the 12%. Then maybe the second part of your question, maybe going towards me on the separation of costs, look, unfortunately, we made a conscious decision to say we are breaking the divisional costing down to EBITDA margin contribution. We are not guiding towards how to deal with the overhead cost bucket that we have left out because the drivers are different ones and we didn't want to lead you down the wrong path. If you chose to

get to another level of profitability and chose one of those allocation methods in the business, you can do that. But we -- from a -- from the standpoint of how we run the business and how we look at those divisions, we look at it at the contribution margin level because that is reflective of the drivers that we pull and push to make sure those businesses, those divisions grow in the best way and how we hold accountability or ensure accountability that targets are being met. So that may not be super helpful to you at this point. But hopefully I explained why and that we are having -- taking a very conscious approach to this. And I would leave it at that for now, if that's okay, Graham.

Andrew Jay Finkelstein, Research Analyst

Sorry...

Operator

Question comes from Andrew...

(technical difficulty)

Flemming Ornskov, CEO, MD & Executive Director

Sorry, I think they cut you off. So maybe you were saying a question we couldn't hear. But do you mind repeating it?

(technical difficulty)

Andrew Jay Finkelstein, Research Analyst

The question. Just following on the profitability of the 2 segments. Could you address what -- some of the opportunities to further leverage the margins in the Rare Disease business over time? We talked a bit about some of the short-term inefficiencies on the COGS and -- which should improve. But what other opportunities are there, whether it's international expansion, et cetera, that would allow the gap between the margin -- or the contribution margins of the 2 segments to narrow? And I'll leave it at that.

Flemming Ornskov, CEO, MD & Executive Director

Well I think, first of all. And I'll let Thomas supplement, we're almost looking, in my experience, at the 2 extremes of, relatively speaking, still very high-margin businesses compared to most other sectors I'm aware of. So if you have a small tablet business with no in-house manufacturing and a sales force and limited R&D investments, you get to a margin situation that is very different than when you have a rare disease business where a large part of it is driven by plasma products that require significant infrastructure, manufacturing that has acquisition costs on the raw material side. So yes, that clearly is an opportunity over time. One of those opportunities is called lanadelumab. So as you supplement products that are plasma-derived or you substitute them with monoclonal antibodies and if you look at our portfolio, an increasing number of our future products are in the Rare Disease space, be it the 647, 643 and others, are products with significantly higher margins, multiple of them biologics, several of them antibodies. So you also saw pretty impressive growth and -- of very high-margin products that are newly launched products since 2013. So we know that could be -- largely be done. And we know that if you look at Rare Disease itself, there is some opportunities on the cost side. But given that we have Thomas now coming from Sulzer, we have an expert that can help us also in this area. Not to say the team has not done an outstanding job so far. But I'm sure that's going be one of the things that Thomas will continue to look at. But don't take the artificial picture of this setup for the long-term guidance for profitability.

So with that, I think we have come to an end. I took a list of the questions that you asked. And I'm really pleased that you're focused on the right things, which is our growth drivers. I saw lots of questions about lanadelumab or 643. I saw a lot of questions about XIIDRA. I saw a lot of questions about our hemophilia business. I saw a lot of questions about our Immunology business. And of course, to my personal pleasure, I also saw a lot of questions about our strong and rapidly growing, even stronger GI business. So I'm really pleased that we're all focused on the right thing. And of course, we have to be balanced with a cost focus that you also asked about.

So in summary, I think it was a good start to the year. 7% growth, 6% EPS, $900 million in free cash flow, which I think we still should take as something we have to look very carefully at, I think, for our business, going through that. Very strong debt paydown. And I think what I would tell my R&D team, an impressive number of products progressing on regulatory filings, are being filed. And with a number of key milestones coming up. So I feel good about the year. I look at all of these upcoming events and think that the pipeline, the growth and the opportunities we have are still very attractive. But it is what it is. It's our First Quarter. And we do not see any change in any guidance or anything at this stage. And we will stay focused on continuing to give our -- the outlook for the year as we've made it out.

So with that, thank you very much. Thanks for your questions. And I really appreciate your understanding that I'm sure some of the hot topics you wanted to discuss we could not address fully. But I'm sure there'll be an opportunity in the future to address some or all of those questions. So with that, thank you very much. And have a nice day and evening.

Operator

Thank you. This now concludes our conference call. Thank you for attending. You may now disconnect your lines.