FRESENIUS

Transcript
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PRESENTATION

Markus Georgi: Good morning and good afternoon to everyone, and welcome to our Q1 2018 conference call. With us today are Stephan and Rachel. Stephan will now start with the strategic business update. Rachel will cover the financials in detail, followed by a Q&A session. After the call, a replay and the transcript will be available on our Website.

The forward-looking statements and the disclaimer are on Page 2 of the presentation. With that, I would like to hand over to Stephan.

Stephan Sturm: Thank you, Markus. Good afternoon and good morning, a warm welcome. As always, we appreciate your interest in Fresenius.

Just as last quarter, I will get to the elephant in the room fairly quickly, and I will try to answer your questions on the Akorn situation as best I can. However, as we are in an ongoing legal proceeding, I am obviously limited as to what I can say. Thank you for your understanding.

But let's start with Page 3 and our Q1 highlights. We had a strong start into 2018. Healthy underlying growth is masked by the adoption of IFRS 15 and a prior-year base that includes the €100 million VA one-timer at Fresenius Medical Care and excludes biosimilars expenses. Yet we achieved healthy earnings growth of 7% including and 12% excluding biosimilars expenses, already now fully in line with our guidance ranges. I believe that bodes well for the full year as the coming quarterly comps should be at least in this regard a bit easier. We were particularly driven by an outstanding performance from Fresenius Kabi. Obviously, the additional month of consolidation from Helios Spain was also helpful. More details on our financials later from Rachel.

One word on Fresenius Medical Care. Now that we're able to perform the dosing of calcimimetic drugs in the controlled clinic environment, we have succeeded in reducing it faster than originally expected. That's good for patients. And while the effect weighs on FMC's revenue growth, hence triggering an adjustment of the company's full year sales target, FMC has confirmed its guidance related to net income growth. And so I'm happy with the underlying business. It is in good shape, both operationally and strategically. And here, I applaud Rice and team for enhancing the focus of the care coordination effort in the US with the divestment of the Sound Physicians business. While part of the group, Sound has provided important insights into efficient patient coordination and value-based programs, important for FMC while they were going about their ESCOs, their Medicare Advantage plan and various subcapitated arrangements. But given the substantial progress we made in that area, now it was time to part ways. And at the same time, FMC is strengthening its position in home dialysis now with the announced acquisition of NxStage. I'm sure Rice will give you an update on this important project in the FMC call later on.

Coming back to Fresenius Group, on the back of strong Q1 financial results and with bright prospects ahead, we feel very comfortable to confirm our group guidance.

On to Page 4 and an update on Akorn and HES, starting with Akorn. At our full year earnings call, I informed you that we had received anonymous letters alleging serious breaches of FDA data integrity requirements, including in the company's drug development process. The allegations relate to functional areas and processes not accessible, even in a detailed and thorough due diligence like ours, in the run up to a transaction between direct competitors. Indeed, misconduct and in particular fraud in those areas typically can only be detected by conducting an in-depth technical inspection. So given the nature of the allegations we had received, we evoked our rights under the merger agreement for reasonable access to relevant information.

And as I said at the last earnings calls, if the allegations had proven to be baseless or of a nonmaterial nature, we would have completed the acquisition as soon as FTC approval, which we continued to pursue in parallel to our investigation, was granted. And we would've gone about fixing the issues responsible for Akorn's operating underperformance. The evidence we have found, however, reveals that Akorn repeatedly and consciously violated the FDA CGMP and data integrity requirements and is in breach of a number of its representations and warranties and covenants provided in the merger agreement. Whilst neither our nor Akorn's own investigation is complete, we had enough information to take the conscious and rational decision that exercising our right to terminate the merger agreement is in the best interest of our shareholders. We were prepared to allow Akorn additional time to complete its own investigation and present any additional information it wanted us to consider, but Akorn rejected this offer. That refusal speaks volumes.

On April 23rd, Akorn sued us, requesting immediate closing of the transaction. Many of you will have read their complaint, as it became public last Friday. Obviously, it represents only Akorn's one-sided view. In its claim, Akorn argues that the true reason for our decision is their operating underperformance ever since we signed the agreement. Now that's a predictable argument because it deflects attention. But you know that that's not the case. I have vigorously defended the underlying business rationale of the transaction, and we have diligently pursued FTC clearance. And we have spent millions on detailed planning and preparing for the integration of Akorn's business. These activities continued unabated deep into the last quarter. We even said we wanted to accelerate completion of the transaction in order to expedite operating improvements.

But that was before we learned of the breadth and the severity of Akorn's data integrity failures and misconduct. Think about it. We have a more than 100-year corporate history and take a very long-term view. Patients rely on us. We have built a reputation as a trustworthy, high-quality healthcare provider, not only in the US, but worldwide.

We take pride in what we do. Hence, there is zero tolerance when it comes to the very heart of our generics business, integrity of products, and their development. And let me be clear. Akorn's problems aren't just simple operating issues that can be fixed in a matter of months or quarters. These violations affect the core of Akorn's franchise, and they require a complete remediation of systems and data, and that will take years.

By now, a statement of our claims is also publicly available. It discusses our case in some detail, and we believe our statement demonstrates very clearly that we acted in the best interest of our shareholders when terminating the merger agreement. As the case is now in the hands of the Delaware court, I'm asking for your understanding that I will not comment on it in detail. Last night, the court has set a trial commencing on July 9th.

Over to HES. And as you may recall, on the basis of the results of drug utilization studies which seemed to indicate a surprisingly high level of so-called off-label use, two committees of the European Medicines Agency, EMA, recommended suspending the market authorization for HES in Europe. This recommendation was issued against the majority opinion of a medical expert group consulted by EMA as part of its evaluation. However, since, and citing a lack of full consideration of all medical and technical arguments, several EU member states have raised concerns over the Commission's draft positions. And against that backdrop, the EU Commission has suspended its procedure towards a decision to withdraw HES from the market. So the case is now referred back to an expert committee at EMA for further consideration. Even though this is for now a small positive development for us, the outcome of this process remains highly uncertain. Accordingly, we remain cautious and are still considering a meaningful risk adjustment in Kabi's full year outlook. More on that by Rachel later.

On to Slide 5. And there, let's start with an update on the pricing development in North America. Another quarter with a very strong financial performance from Fresenius Kabi in North America, another quarter where we have experienced only low single-digit price declines for our base portfolio of injectable generics, and another quarter where we see no current catalyst for more pronounced price pressure. Injectable generics will continue to be a demanding, yet rewarding market segment in which we have continuously grown our position organically now for about a decade. And we have every intention of continuing to do so going forward. And if we stay focused on the consistent quality of our products and processes and on the breadth of our pipeline, I have little doubt we'll succeed in strengthening our position further.

Besides Fresenius Kabi's financial performance, which basically speaks for itself, but Rachel will comment on it anyway, let me make a few observations on other topics which seem to be front of mind for many of our shareholders. It is correct that the number of FDA ANDA approvals increased significantly in 2017 compared to the prior year. However, it is also true that, by the end of last year, only about one-third of these approvals had resulted in launches. We can only speculate as to the reason for this, but it is worth noting that many of last year's approvals were for already mature generic molecules. So it is likely that, in many instances, a late launch just does not make economic sense. And the approval file stays on the shelf. And the number of approvals in the first quarter of this year, that has declined significantly year over year. And so has the backlog of applications over the last year.

Shortages. Counterintuitively, as the number of ANDA approvals has increased, so has the number of products on drug shortage. Fresenius Kabi works closely with the FDA's Office of Drug Shortage to help mitigate these shortages. But at the end of the first quarter, 32 Kabi IV drugs were designated in shortage, up from 24 at yearend 2017. Rachel will give more background on that in her section.
As we talk about competitive approvals, I'm also happy to report that Fresenius Kabi USA is well on track to launch 15-plus new products this year, well above our recent average of 6 to 10. And we expect this higher run rate to persist through 2019 and 2020. So our R&D engine continues to run very smoothly, an engine for growth.

One word on Bortezomib. On our last call, I was expressing caution about some of the expectations surrounding that particular launch, and I'd like to remind you again that the adoption of Fresenius Kabi IV administered Bortezomib is limited to those patients who do not respond well to subcutaneous administration. Please bear that in mind when making your assumptions for that particular drug.

In conclusion of my prepared remarks for our US injectables business, Fresenius Kabi is offering one of if not the broadest drug portfolio in the market at competitive prices. And despite what you may read about high drug prices in the US, the average price of a Fresenius Kabi sterile injectable remains below $5. We are proud of the fact that we continue to make healthcare more affordable. And we expect to benefit from the political and social backlash against high brand drug pricing.

With our reputation for quality, reliability, flexibility, and fairness, we have strength which will continue to underpin our success in the future. And as the latest tangible evidence, I'm proud to report that Fresenius Kabi last night received Vizient's Supplier of the Year Award.

On to a quick update on our biosimilars business, where we are encouraged by the steadily improving political environment. Take France, for example. The national health strategy, which was announced earlier this year, aims to have 80% biosimilars penetration by 2022. And now the regions in France need to propose ways how they can achieve this target. That's clearly positive for us. In the US, all biosimilars of a reference product will now be eligible for the pass-through status as part of the 340b program. Previously, only the first biosimilar of the reference product was granted this status. This means that, for the first 2 to 3 years of being on the market, the biosimilar will be reimbursed at a higher rate compared to the reference product. Thus, this should encourage uptake of biosimilars over reference products, another positive development for us. And with regard to our pipeline, all clinical studies remain well on track. Indeed, we expect the first, albeit small, milestone payment already this year. As you know, these milestone payments are strictly linked to the achievement of agreed-upon development targets. And hence, we are making very good progress. Some details on the accounting of those payments later by Rachel.

Last but not least, an update on the German hospital market. As I said during our full year earnings call, requirements for specific minimum nurse staffing levels in the hospitals have found their way into the coalition contract. And at the risk of being repetitive, our firm opinion is that hospital operators that made significant investments in efficiency over the past are penalized by such regulatory measures. In our hospitals, nurses can focus on their core responsibility, taking care of the patient. Hence, minimum staffing levels in our minds risk setting wrong incentives. Regardless, Helios can't just watch that development from the sidelines. Much rather, the company has taken and will continue to take preparatory measures regarding these potential future regulatory structural requirements. Those measures have weighed on Helios's EBIT development in Q1. And to be clear, we expect that to be a recurring theme for 2018 and potentially also beyond. As already flagged on various occasions, Helios Germany is further increasing its efficiency via digitalization and is also further intensifying its clustering strategy. Those measures are geared towards becoming truly paperless, raising the quality of care. And facilitating focused CapEx will have a midterm positive effect.

With that, let me hand over to Rachel.

Rachel Empey: Thank you, Stephan. Good afternoon, good morning, or good evening, depending on your time zone. A warm welcome to everyone. As you heard from Stephan, we are very pleased with the strong start to the year.

Let's go straight to Page 7 on our key financials. Growth rates on this slide are on a constant currency basis, and sales growth is adjusted for the adoption of IFRS 15. I'd like to start by explaining how the results are shown throughout my presentation. The figures are before special items, namely transaction-related effects with respect to Akorn and Sound Physicians. They include R&D expenses for Fresenius Kabi's biosimilars business. Obviously, since Kabi's biosimilars business was only consolidated since the 1st of September 2017, the prior-year quarter included no biosimilars-related R&D expenses. Hence, to give greater transparency, we are also showing group net income growth and EBIT growth, excluding those biosimilars expenses.

For clarity, Q1 figures last year included €100 million of sales and €99 million of EBIT from Fresenius Medical Care's settlement with the United States Department of Veterans' Affairs and Justice, the so-called VA agreement. This contributed 1.4 percentage points to sales growth, 10 percentage points to EBIT growth, and €18 million, or 5 percentage points, to net income growth in Q1 2017. These effects were not treated as special items on group level in Q1 2017 and, obviously, weigh significantly on growth rates this quarter.

So if we eventually turn to the numbers, we delivered sales growth of 7% in Q1, nicely within our guidance range. The main driver for the strong growth was Kabi's excellent start to the year. EBIT declined by 5% including and by 2% excluding the biosimilars expenses. That's mainly due to the effects of the VA settlement payment at Fresenius Medical Care in the prior year. Fresenius Medical Care is fully consolidated into the Fresenius Group down to the EBIT line. Before the VA agreement effects, EBIT growth was at 3% including and 6% excluding biosimilars expenses.

With €146 million, net interest was, as expected, more or less flat sequentially. The Q1 net interest result reflects 3 months of Quirónsalud financing costs versus 2 months in 2017. So why is there a year-on-year decrease of €11 million? Well, that's primarily due to currency effects and successful refinancing activities annualizing. The underlying Q1 run rate is a pretty good proxy for the quarterly run rate for the rest of the year. However, it is too early to revise the targeted range of €590 million to €610 million for the full year.

Group tax rate was at 21%. The significant year-on-year decrease is obviously driven by the US tax reform which went into effect on the 1st of January. With that 21%, we are below our expectations, which is mainly due to a one-time effect at Fresenius Medical Care, but is also linked to the tax reform. There are still uncertainties overall with regards to this reform as the final implementation guidelines and interpretations are not yet available. Hence, we will stick with our projections for the full year and expect a tax rate between 23% and 24%.

So moving on to net income, earnings growth was at 7%, including biosimilars expenses. Earnings growth excluding those biosimilars expenses was at 12%. So both earnings metrics are nicely in our guidance ranges. The VA settlement effects and the additional month of consolidation of Helios Spain broadly offset each other on the earnings line.

So moving on to Page 8, which illustrates the momentum of our four business segments. For ease of comparison to our individual outlook ranges, sales growth rates on the left are organic and adjusted for the adoption of IFRS 15. EBIT before on the right is at constant currency and before transaction-related effects.

So let's start with Kabi. The company showed strong 9% organic growth. As I will show you later, this was fueled by great growth across all regions, especially from North America and the emerging markets. EBIT declined by 2%, including the biosimilars expenses. That is 1 percentage point above the upper end of our outlook range of minus 3% to minus 6% and a strong start to the year, considering that we had no biosimilars expenses in the first quarter of 2017. If we strip out those biosimilars expenses, that looked even better with an excellent 10% EBIT growth, clearly well above our outlook range of 2% to 5%. More details later in the Kabi section.

Helios was at 3% organic sales growth, but the lower end of our outlook range. That was expected, given that Q1 2018 included an Easter effect, and in 2017, this was in Q2. The Easter effect is particularly pronounced in Spain, a bit like a short version of the typical summer slowdown that we see in Q3. EBIT growth of 9% was nicely in line with the outlook range. This figure obviously includes one additional month of consolidation of Quirónsalud.

Vamed had a good Q1, in line with our expectations.

With that, let's turn to Page 9 for a review of Fresenius Kabi's organic sales growth by region. In a nutshell, Europe in line with expectations, North America and the emerging markets each with an excellent Q1. Starting in North America, we are very pleased with 10% organic growth, which is clearly above our expectation of mid-single-digit growth for the full year and testament to our continuing strength of momentum in the North American injectables market. The stronger-than-expected financial performance was particularly influenced by an increase in drug shortages. At the end of Q1, 32 Kabi IV drugs were designated in shortage, up from 24 at the end of 2017. Since our model and outlook assumes a gradual easing of drug shortages, this is a significant tailwind for us. However, we are well aware of the focus by the FDA on accelerating generic approvals to ease shortages and ensure strong generic competition. Therefore, we do not assume that the current situation will persist.

The launches. So far, we have launched three new products this year. This is in line with our expectation to end the year with more than 15 new drug launches. While the launches had some positive influence on our financials, the overall effects should not be overestimated.

We can't be sure that the drug shortage situation will continue, at least not in the same magnitude for the rest of the year. And going forward, we may see more competition on some key molecules. Hence, for now, we'll stick to our outlook of mid-single-digit organic sales growth for the full year 2018.

So on to Europe, we've seen organic growth of 3%, driven by an ongoing good sentiment in enteral nutrition. We feel comfortable to confirm our low to mid-single-digit organic growth guidance for Europe.

And continuing with the emerging markets on Slide 10, where we are pleased to report yet again an excellent financial performance with 13% organic growth. China is growing at 16% organically. We still expect that the introduction of the new tender policy will be completed by mid-2018. Due to the new tender process, we continue to expect low to mid-single-digit price reductions as a full year 2018 impact. At the same time, we anticipate continued double-digit volume growth. And that will translate into sustainable, very significant organic growth in this key market. Asia-Pacific, excluding China, showed nice organic growth of 13%, very positive sentiments here, and we expect that momentum to continue. Latin America and Africa, yet again strong with 10% organic sales growth. So on the back of the very strong financial performance in the first quarter, we feel comfortable to confirm the outlook of likely double-digit organic sales growth for the full year for the emerging markets.

So let's turn to Slide 11 and Kabi's regional EBIT development. Total EBIT came in at €268 million, a decline of 2% constant currency. EBIT growth excluding the biosimilars expenses is quite impressive: With 10%, we are 5 percentage points above the upper end of our guidance range of 2% to 5% growth. Let's take a more detailed look at the regions. With 8% growth North America is off to an excellent start to the year. We feel comfortable to confirm our expectation for the full year that EBIT should be growing at least at the same rate as sales, where we guided mid-single-digit growth. Moving on to Europe, with strong 8% growth driven mainly by an ongoing excellent enteral nutrition business. The emerging markets, with a nice growth rate of 12%, the growth rate here is mainly driven by clinical nutrition. Overall, we are pleased by the robustness of Kabi's emerging markets business, and we don't expect that to change going forward.

Corporate and R&D costs were at €126 million in the first quarter. Adjusted for the biosimilars expenses, we are broadly flat year on year. For the full year, we are expecting a ramp up of R&D costs as we are reinforcing the further diversification of our product portfolio. As Stephan said, we expect the first milestone payments from our biosimilars business to occur in 2018, which is a very positive sign for the progress we are making. According to IFRS rules, the liability on our balance sheet is not allowed to cover 100% of the future payments. So we will also see some P&L effects going forward when the milestone payments occur. In 2018, the expected P&L effect will be rather small. We are talking about likely single-digit million figures. For good order, as deferred acquisition costs, they will be treated as special items at group level. Therefore, they will neither impact Kabi's outlook nor the group guidance.

Let's turn to Fresenius Helios on Slide 12. Total sales came in at €2.3 billion, up 16% year over year. The additional month of consolidation of Quirónsalud contributed nicely to sales growth. Organic growth was at 3%. With also 3%, Helios Germany showed solid organic sales growth in Q1. As Stephan and I already flagged during the full year call, there are some specific headwinds for Helios Germany. Those topics have already impacted our business in Q1, and we expect them to be recurring themes for 2018 and beyond, namely the additional DRG catalog effects, where downgrades within the classification of case severity have led to negative mix effects, and also the lack of privatization opportunities.

Over to Helios Spain, where the outstanding sales growth of 54% is mainly driven by the additional month of consolidation in Q1 2018. Excluding this effect, the company showed a rather soft quarter due to the very pronounced Easter effect. As I said, Easter was in Q2 last year and is a Q1 event this year. The Easter effect is in Spain a bit like a short version of the typical summer slowdown. We expect that organic growth will thus accelerate in Q2.

On to Slide 13, with an overview of the EBIT development at Fresenius Helios. Total EBIT came in at €278 million, up 9% year over year. That is in line with our guidance range of 7% to 10% growth. With €177 million, EBIT for Helios Germany decreased by 2%. Here, we see the themes from the top line recurring, the lack of privatization opportunities, those additional DRG catalog effects, and in addition, cost headwinds as we are preparing ourselves for specific minimum nursing staff levels. In parallel, Helios is intensifying its clustering and digitalization strategy. However, efficiencies from those measures will have a more midterm positive financial effect. Helios Spain with an EBIT of €103 million and a growth rate of 39%. Obviously, as discussed, the additional month of consolidation contributed significantly to growth in Q1 2018. Mainly due to operating leverage effects, the light top line impacted also the EBIT line significantly. Consequently, we also we expect an acceleration of EBIT growth in Q2.

Moving on to Fresenius Vamed, which we see on Slide number 14, which showed a good first quarter. Organic sales growth was strong with 9%, at the upper end of the outlook range. EBIT was flat year over year. Here, we are very optimistic that, over the course of the year, EBIT growth will accelerate. Our expectation is underpinned yet again by excellent order intake in the first quarter, which has taken Vamed's order book to a new all-time high.

Let's move on to cash flow on Slide 15. On the face of it, a rather soft Q1, but underlying Q1 is better than it looks, €236 million operating cash flow for the group. As usual, we expect a meaningful acceleration of cash flow generation during the year. Kabi posted a Q1 cash flow of €226 million, top left. A strong Q1 margin of 14.1% took the last 12-months margin to an excellent 16.4%. As usual in Q1, there were some transitional timing issues at Fresenius Medical Care, where, no doubt, we will see the corresponding catch up in the coming quarters. To remind you, the prior-year quarter was positively influenced by around €200 million from the VA settlement. At Helios, we see some phasing issues, including new DRG catalog prices. Nothing to worry about here. We expect a significantly stronger development as we move through the year. So for the Group, the Q1 performance took the last 12-months margin to 11%. Deducting group CapEx of 5.3% in the middle column, and you'll arrive at a free cash flow last 12-months margin, bottom right, of 5.7%.

We finished Q1 at 2.98x net debt to EBITDA, sequentially a touch higher, mainly due to the free cash flow development in Q1. As I said, the cash flow generation will significantly accelerate during the year. Hence, we confirm our target to further delever this year. Of course, the outlook is excluding pending transactions and under current IFRS rules.

With that, let's turn to Slide 16 for the 2018 outlook by business segment. Let's start with Kabi. On the back of a good first quarter, we confirm our outlook range of 4% to 7% organic sales growth. That's the blend of the regional contributions I mentioned, low to mid-single digits for Europe, likely double-digit growth for the emerging markets, coupled with mid-single-digit growth for North America. On to EBIT, where we also confirm our outlook range, including biosimilars expenses of minus 3% to minus 6%. Excluding those biosimilars expenses, we are still aiming for around 2% to 5% EBIT growth. The excellent growth in Q1 was mainly driven by North America. For this region, as I said a couple of minutes ago, there are some uncertainties, especially as to how the drug shortages will evolve throughout the year. Moreover, Kabi's outlook still reflects a meaningful risk adjustment, including truly one-time noncash items for HES. We acknowledge the recent developments. However, there is still significant uncertainty in how the process will proceed. Our assumptions for potential operating downsides were mostly backend loaded, and the one-off items related to HES remain at risk. We are, of course, closely monitoring the situation. However, we feel it is too early to significantly revise our assumptions at this stage.

For Helios, in terms of organic sales growth, 3% growth year to date. As I said, we expect an acceleration of growth for Helios Spain in Q2 and feel confident to confirm the outlook range of 3% to 6% for the full year. For EBIT, we are confident to confirm our outlook range of 7% to 10% growth this year. Also here, we expect an underlying acceleration for Helios Spain in Q2.

And on to Vamed. The company's huge and well-diversified order book as well as the good first quarter gives us confidence to confirm the outlook ranges of 5% to 10% for both sales and EBIT growth.

So taken all together for the group, and that's now on Slide number 17, so starting with sales, 7% sales growth year to date means we feel comfortable to confirm our guidance range of 5% to 8% constant currency growth. The adjusted sales growth target of Fresenius Medical Care of 5% to 7% from previously the around 8% growth has not altered our Fresenius Group guidance.

As to the currency translation effect, if current exchange rates prevailed until the end of the year, we would see a headwind of 4 to 5 percentage points, most notably from the US dollar. This compares to a headwind of 8 percentage points in Q1.

And on to net income. With 7% net income growth, we feel confident to confirm our guidance range of 6% to 9% growth. Excluding the biosimilar expenses, which account for around 4 percentage points, we confirm the original range of around 10% to 13% growth.

With regard to currencies here, we also expect a headwind of 4 to 5 percentage points. So at 7.5% growth, the midpoint of the guidance range, our simulations result in group earnings of approximately €1.870 billion.

Many thanks for your interest today. And with that, Stephan and I are happy to take your questions.

Q&A

Operator: Ladies and gentlemen, we are now starting the question-and-answer session. (Operator Instructions) And the first question comes from the line of Michael Jüngling with Morgan Stanley. Please go ahead.

Michael Jüngling: Great. Thank you, and good afternoon. I have three questions. And the first one is in relation to Akorn. When I go through the Akorn court documentation and also your reply, I'm still not quite sure what it actually means in relation to the Akorn's pipeline that initially I think was quoted around 85 or so products in pipeline. Can you clarify of how many ANDAs may be invalid at Akorn? Because it may be one, it may be five, maybe it's more. Some clarity, please, would be excellent.

Then secondly, when it comes to Helios, the operating cash flow divided by EBITDA, so the cash conversion is quite low at 26%, one of the lowest that we've seen. Can you comment on whether we are seeing this development occur for the rest of the year or not?

And then secondly, when it comes to the organic growth in Helios Spain, can you comment whether it's just the Easter impact or also whether this is a reflection of perhaps the private insurance enrollments that we're seeing in Spain? Obviously, they go up when the economy is not so well, but if it improves, it goes the other way, as we saw in the sort of due diligence as part of the transaction. So can you comment on that, please, as well? Thank you.

Stephan Sturm: Michael, it's Stephan. I'll have to be brief on the -- on your Akorn question. And Rachel is going to take your two Helios questions. On Akorn, thank you for reading diligently through the two complaints. But you will have seen that this is a pending and fairly rapidly progressing court case, given that the trial date has been set for July 9th. So I'm asking for your understanding that I will not be able to go beyond what we have written in our counterclaim and in the response. But coming back to my prepared remarks, you will have heard that we are seeing serious misconduct and fraud in these processes. I cannot comment on individual numbers of drugs that may or may not be affected by this.

Rachel, over to Helios, please.

Rachel Empey: Thanks, Stephan. And, Michael, many thanks for the questions. For your first question on cash conversion at Helios, I wanted to reassure you here that what I said overall at the group level in terms of a phasing effect from Q1 is also true at the Helios level. In Germany, but also in Spain, we've seen some technical phasing effects, for example, associated with the new DRG catalog that mean we've seen a lower cash conversion in Q1. But we expect during the year to see an acceleration and no, let's say, material underlying effect that you should be worried about on an ongoing basis, so just a timing effect here.

Also a similar answer on your next question around the organic growth in Helios Spain. We're very pleased with how Helios Spain continues to perform. Clearly, from an organic perspective, there were only two months in the first quarter because we were not consolidating for January of 2017. So organically, we only had February and March. And that meant that that Easter effect, which was quite pronounced this year and generally is from a cultural perspective within our Spanish business, had a relatively material impact on the organic growth that you see. However, you should not see that as an underlying issue or one, as you suggest, that is associated with the strength of the private business within our Spanish hospitals business. We remain very happy with the performance and very optimistic about that acceleration that I mentioned that we expect to see in the second quarter. So again here, an Easter effect, a timing effect, and nothing that you should be fundamentally concerned about for the rest of the year. Thank you.

Michael Jüngling: Okay. Thank you. And may I also follow up on the date of the 9th of July in which I guess the court battle starts? Can you maybe expand a little bit how you see the legal process, meaning the first legal date, the right for an appeal, the timeframe for this? I think investors would be very keen to find out how long this trial could go at first instance and how long it may take with respect to an appeal if one party obviously loses. Thank you.

Stephan Sturm: Michael, this is a complex matter, as you will have seen from reading through the two documents. On the other hand, the Delaware court has a reputation for dealing very professionally with these -- with complex matters as such. I have full confidence in the court, taking into account all the relevant arguments that have been made and coming to a sound decision. I don't want to speculate about how long that is going to take between a first instance and a potential appeal. I would encourage you to work on the assumption that we will be able to resolve this matter at some point over the course of 2019.

Michael Jüngling: Great. Thank you.

Operator: The next question comes from the line of Veronika Dubajova with Goldman Sachs. Please go ahead.

Veronika Dubajova: Good afternoon, Stephan, Rachel. Thank you for taking my questions. I have two please. My first question is on the Quirónsalud margin. And I appreciate there's a lot of moving parts. We were missing January last year. There is the timing of the Easter effect. But I'm just curious to see the decline in the profitability year on year. And I was hoping, Rachel, maybe you can elaborate a little bit on, if you can, like-for-like, so looking at this full 3 months and maybe making some pro forma adjustment for Easter, what the margin development for Quirónsalud was, and maybe where you are in the synergy realization process. That would be helpful.

My second question is on the margin development at Kabi North America, a modest decrease there year on year. In light of the strong revenue growth, I don't know if you can give us a little bit of color on whether this was a specific product or nothing that we should be concerned about and just color on that. And then I have one big picture question after that, but maybe we can do these two questions first.

Stephan Sturm: I get the feeling that that big picture question may be reserved for me, Veronika. But in both instances, Quirónsalud and Kabi North America, nothing to worry about. And Rachel will give you a bit more color.

Rachel Empey: Sure. Hi, Veronika. Thanks for the questions. So looking at Quirónsalud, I would reiterate what I said earlier to Michael. We're very happy with the continuing performance. It really is a timing effect associated with the way that the dates run and the way that the calendar runs this year. Clearly, it's a business similar to our German business that has a relatively high level of operating leverage. So you very quickly see a relatively material impact at EBIT when you see a drop off in sales due to the effects like we've seen at Easter. And I think, if you remember back to what we saw in Q3 of last year, that very marked effect on the EBIT margin was also very visible. And this is a smaller effect of that. So without doing, as you say, a detailed reconciliation, I can reassure you that the profitability of the business remains absolutely intact. And we're very comfortable with how that is running. And you should see an acceleration coming out of the reversal of that Easter effect as we go into Q2.

Specifically on your point on synergies, as we've been explaining to you during the course of 2017, we focused on those low-hanging fruit associated particularly with procurement synergies. We set up Helios Health from the 1st of March this year to facilitate the closer collaboration and the first steps towards the more fundamental intrinsic medical synergies that we hope to be able to drive. But clearly, they are in the infancy in terms of starting those activities. But nevertheless, the first signs in terms of the interaction of the teams is very positive. So we remain very optimistic as to what we may be able to drive there.

Your second question on the margin in -- at Kabi North America. I would say, firstly, very pleased with the business in Kabi in North America in the last quarter, continuing the momentum we saw at the backend of last year. I think the growth rates really do speak for themselves and show the momentum and the positioning that we have in that market. Margin remains from my perspective very healthy at around 38%. You're right. There is a slight dilution year on year. If you have a look at it, what we can see is that some of those shortages where we're benefiting, we have a slightly lower margin on some of those products. And particularly, the success we've seen at daptomycin, which comes through a contract manufacturer and with a slightly lower margin, is also one of the drivers of growth and thus has a small impact in terms of margin dilution. But nevertheless, margin remains at a healthy level, very, very good growth coming from the North American business.

Veronika Dubajova: Thank you, Rachel.

Stephan Sturm: And, Veronika, on your question on Helios cross-border synergies, we -- that's firmly on our agenda for the Capital Markets Day in early June. And we will further elaborate on that.

Veronika Dubajova: Okay. I look forward to that. And my big picture question, Stephan, I noticed in your slide deck this morning, you say that the strategic rationale for expanding the products offering in North America still is valid. And so my big picture question is, in the absence of Akorn, what kind of path do you anticipate taking towards achieving that goal, and if you can give us some insights into how you can effectively get back to speed on some of the strategic priorities now that you won't consummate the Akorn merger, assuming it all goes your way? Thank you.

Stephan Sturm: Veronika, this has always been about a combination between organic and acquired growth. And forgive me, but I need to take issue with your terminology of getting back to growth because I think last year and now in particular Q1 is a very strong organic growth track record. Acquisition growth is meant to fast forward us to the strategic goal to near complete our product offering in the injectable generics space. But

we can obviously also get there just by organic growth. And if you think back to some of our statements from end of February, we were very consciously alluding to our growth plans, in particular in North America, when it comes to upgrading, but in particular, expanding manufacturing capacities, where we have reserved very meaningful triple-digit million euro CapEx amounts. And I am very optimistic that that will be the foundation for further growth this decade, next decade, and beyond.

Veronika Dubajova: Okay. And apologies, Stephan. What I was trying to say very poorly I think is, clearly, Akorn would have given you a full and ready portfolio. If you are to build this organically, I presume there's a bit of a delay to some of the opportunities, let's say, outside of the injectable channel because you'll have to go through an ANDA -- drug development and ANDA process, or am I misunderstanding that?

Stephan Sturm: As we said before, Akorn -- closing of the Akorn transaction would've meant a faster realization towards our strategic aim. That was on the assumption that we could deal with a well-functioning unimpaired drug development engine. That from what we know today is not the case. So yes, at least for the time being, our plan is to go back to focusing on organic growth. Yes, you're right. That will take longer than with a fast-forward acquisition. On the other hand, it has a lower risk profile, and obviously, it also requires less capital spend. Is the delay that comes from focusing on organic growth something that impairs our strategic position? I would say, in particular against the backdrop of our Q1 results, I have no indication that that's the case.

Veronika Dubajova: That's very clear. Thank you, both.

Stephan Sturm: Thank you, Veronika.

Operator: Next question comes from the line of Ian Douglas-Pennant with UBS. Please go ahead.

Ian Douglas-Pennant: Thanks very much. Yes, it's Ian at UBS. So sticking with the same theme on the injectable generic space, might your expansion activities include semi-organic opportunities, such as expanding contract manufacturing or repackaging? You alluded, obviously, to daptomycin earlier. I was wondering whether that is a conscious kind of strategic move to push on that.

And a linked question, please. Roughly, what proportion of your sales or the drugs that you sell are manufactured by third parties today? And I've got one on HES, which I'll hold.

Stephan Sturm: Ian, on the first point, yes, that has been and continues to be a strategic direction that we're taking. And just in her last answer, Rachel was making reference to daptomycin as an ancillary product where we are in a partnership. And we had entered into partnerships already before. We are very open to in-licensing. We are a well-sought-after partner, given the strength of our GPO relationship. The core of our business has been and remains manufacturing for -- under our own name and using the strength of our distribution. But very obviously, if there was a partner out there who had a ready-to-launch product but didn't feel comfortable exploiting it to the max, given a rather limited scope of products vis-à-vis the GPOs, then we have been there and will continue to be there to help.

As to your second question, I can't give you a precise number. My best guess is that it is a single-digit percentage. So it isn't very meaningful.

Ian Douglas-Pennant: Yeah, sure. Thank you. And for the other question, and my apologies to everyone on the call if I missed it, did you quantify at all the potential risk around HES, or are you holding off on that for the moment?

Rachel Empey: Ian, it's Rachel. So specifically, when we gave the guidance for Kabi at the beginning of the year and obviously then implicitly within our group guidance, we were clear that the risks associated with HES needed to be taken into account into those numbers. Those risks were always backend loaded because we knew that the procedure would be going through its processes during the first quarter. And contained within that risk, we had always some one-off items associated with a potential suspension of the drug. We were never very specific in terms of the exact size of the risk. But nevertheless, clearly, if you look at the inherent guidance ex-biosimilars for this year and compare it to the performance and guidance that we had from Kabi from last year, a significant contributing factor to that difference is coming from the HES business. And clearly, it also has an impact in terms of the margin that you would expect inherently to calculate from the guidance that we've given from Kabi. Without that HES effect, you would expect a more stable margin when you also exclude the biosimilars effect at Kabi. I hope that is helpful to give you an order of magnitude of what you might expect and what we have still considered within that risk profile for the outlook for Kabi for this year.

Stephan Sturm: And, Ian, to remind you, those are -- the overall potential burden consists of forgone profit, but it also consists of some intangible assets that, if the decision that has now been halted was still enacted, would be at risk. So we were also alluding to a pretty meaningful noncash charge that could come at any point as soon as the decision is invoked.

Ian Douglas-Pennant: Perfect. Thanks very much.

Stephan Sturm: Thank you, Ian.

Operator: The next question comes from the line of Lisa Clive with Bernstein. Please go ahead.

Lisa Clive: Hi. Stephan, I have a few questions around the staffing ratios. Firstly, how would you handicap the chances that something happens? Is it almost a certainty at this point, or is there some ability for the industry to lobby against it and stop it in its tracks? And if something does happen, I'm just trying to understand what the range of outcomes are here. Is the best-case scenario that there is a staffing ratio put in place but that the government will provide some level of compensation to cover the incremental costs so it's largely neutral at EBIT, or is that way too optimistic? Meanwhile, is the worst case a fairly draconian target with no offsetting help, which will just entirely hit your cost structure and thus essentially create a lower EBIT margin business for the foreseeable future?

And just along those lines, what exactly do your preparatory measures include? I appreciate the comments that they're more than just one time in costs. Are you actually hiring more nurses at this stage? It would just be helpful to understand that.

Stephan Sturm: Lisa, as I said, it has made its way in the coalition contract. It is a very popular topic that is very close to the hearts of the electorate. As you heard me, I would always argue that there is a lack of transparency and, in particular, a lack of differentiation. And what we are concerned about is that some crude measures are going to be implemented. Is there going to be some sort of measure implemented? I would say that is near certain. Is it going to happen over the course of this year? With a very high probability. That's the assumption that we would be working on. Is this something that sets the wrong incentives? Yes, I alluded to it. And we would very much argue that is what we're trying to make clear to the acting politicians that apples and oranges must be clearly differentiated.

And given the past investments that we've made into efficiency, into processes, our nurses typically don't have to do what nurses at other underinvested hospitals do have to do next to their core responsibility. I would still argue that, if it were implemented, it would even pronounce a certain nurse shortage in Germany. Let's take one step back. I would strongly argue, and I've done that in the past, that for the country as a whole, there is a sufficient medical staff. However, unfortunately, it is spread over too many, too small, too inefficient hospitals and that, therefore, it is rather a reallocation towards larger entities that is required. If there was really a minimum quota, then I would argue that, in particular, those smaller hospitals will find it difficult to hire more nurses and that, therefore, there is a scenario that, in the medium term, this could even facilitate and trigger more consolidation in the hospital space.

So whilst we're preparing ourselves with short-term investments, and yes, hiring initiatives is one of them, but on the other hand, clustering and focusing individual cases in certain larger departments and, therefore, also taking a very conscious look at the existence or the future existence of individual departments in hospitals. While that for the time being weighs on our EBIT and also does require a bit of CapEx, for the medium to longer term, I am absolutely convinced that this quasi-investment that we have to take through the P&L is going to yield a return.

Lisa Clive: Okay. And then a last question on Helios. Pay for performance, there was a bill passed, I think it was December 2015, that mandated the creation of some sort of reimbursement system tied to outcomes in Germany. Is this any closer to happening? And if so, what sort of opportunity do you think this is?

Stephan Sturm: This is a pretty tame regulation I would say because it really works on the basis that, if you don't deliver quality, then you're being penalized rather than, if you're delivering superior quality, you're getting something extra. And it is really only singling out the worst of the bad performers. And therefore, the effect is much rather one in public perception than in reality. I would very strongly argue that we need to see more of it, that we need to see more transparency on quality outcomes, a closer link between those quality outcomes, and reimbursement in both directions. Ideally, that would fast forward the necessary and overdo consolidation process in the German hospital landscape.

Lisa Clive: Okay. Thanks very much.

Stephan Sturm: Thank you, Lisa.

Operator: The next question comes from the line of Tom Jones with Berenberg. Please go ahead.

Tom Jones: Oh, good afternoon. Thank you for squeezing me in. I have a couple of questions. On Helios, I was just wondering if you could give us a little bit more specific detail about what exactly the measures that you are currently taking to address the staffing issue. Really, what I'm trying to understand is whether what we saw in Q1 is a kind of permanent step up in cost, or are you currently reorganizing services and things are being a bit disrupted, so there's some kind of temporary opportunity cost to what's currently going on? That would be my first question.

And then the second question was just on the shortage situation in the IV drugs in the US. You mentioned there were 32 drugs on the shortage list which Kabi makes. How many of that 32 are you also struggling to supply the market with as much volume as you would like, or are you completely unrestricted on those 32 products?

Rachel Empey: Tom, it's Rachel. On your question on Helios, to be honest, I think Stephan pretty much said it already, but let me try to answer your question a little bit more. So clearly, it's not a straightforward, simple answer. It's very specific in terms of when we look across our portfolio in terms of how we are trying to prepare and optimize ourselves. As Stephan said, that means, to some extent, yes, in some areas, hiring more nurses, physically more. In some areas, it means looking at the efficiency and the effectiveness of individual departments within wards or wards themselves in terms of how we would be able to fulfill the potential criteria of the future. And clearly, the clustering activity, where we're working on investing to cluster key types of diagnoses or treatments, and we're investing in the capability and capacity to cluster those activities geographically, but clearly, with the knock-on impact that that means that we would close certain capabilities in certain hospitals where it would be too small or ineffective or inefficient to keep that in the longer term.

So it's really a mixture of activities that involves some CapEx, as Stephan said, some one-time OpEx, but some recurring OpEx. So it's really a mixture. Clearly, we started some of those activities last year. We definitely continued to invest in the -- in Q1. And you should anticipate continuing to see that during the course of 2018. And the obvious question, so when does that pay off, and how does it relate to the legislation? Well, clearly, as Stephan said, the legislation is uncertain in terms of both timing and content. And obviously, some of the measures will pay back over different periods because it is special to each hospital or to at least each region. I hope that's more helpful to give you a feeling for --

Tom Jones: No, that's very helpful. Just maybe one quick follow up. Stephan mentioned that, ultimately, this could create some financial stress for some other hospitals and open up a few M&A targets. But there are kind of two ways to address minimum staffing regulations, one to increase the staff, and two is to reduce the volume of work you do across the same staff base, which may be a way that a lot of other hospitals are forced to address this. They simply can't afford to provide more staff. Does that create the potential that there might be a little bit of a volume uplift for you in the kind of shorter to medium term before the medium-term benefit of more M&A opportunities crystalizes?

Stephan Sturm: Tom, this consolidation is something that, on the one hand, is overdue. On the other hand, it may prove to be yet again really just something that we're longing for, for a long, long time because, from where I sit today, privatizations in general and that of hospital in particular remain something that is unwanted. In theory, you're absolutely right. And also, in practice, we're working in both directions. And in the latter direction that you were referring to, that is truly -- well, I said this can also come about concentrating certain procedures at individual hospitals, where we find it easier to meet those minimum staffing requirements. So clustering is also part of an overall initiative to go about these minimum staffing levels.

And rest assured, Tom, early June, Capital Markets Day, that is going to be one of our focus areas where our colleagues from Helios will go into more detail.

Tom Jones: Perfect. And the question on --

Stephan Sturm: On your second question, end of April, it is actually 34 drugs in shortage. It is 34 that we are active in. Still, the FDA lists them as shortage drugs. And I can confirm that we are completely sold out and that we are also dealing with back orders, hence us going about very vigorously about these CapEx plans to upgrade, but in particular, to expand the manufacturing capacities. If we had more capacity at hand right now, organic growth would be even larger.

Tom Jones: Perfect. That's very clear. Thank you very much.

Stephan Sturm: Thank you, Tom.

Operator: Next question comes from the line of Gunnar Romer with Deutsche Bank. Please go ahead.

Gunnar Romer: Gunnar Romer, Deutsche Bank. Thanks for taking my questions. First question again on Helios. Just to be clear, when you look at the EBIT performance in Germany, the 2% decline, can you potentially quantify the impact of the negative mix on the one hand and then the P&L relevant investments in the preparatory work? That would be helpful.

And then the second question would be on clinical nutrition. I saw a pretty nice acceleration here to 14% organic growth, if I'm not mistaken, up from the high single digits, as seen as over the last I don't know how many quarters. Just curious what has driven that acceleration and to what extent that is sustainable.

And then the last question would be on the drug shortages again. Can you potentially quantify the impact of -- the positive impact of drug shortages on your numbers in the first quarter, i.e. is it fair to assume that, without the increase, you would've been basically in line with the 5% target or the mid-single-digit growth target for the US, or is the underlying growth still trailing a bit higher, as seen at the end of the year? Just some color around that would be very helpful. Thank you.

Rachel Empey: Gunnar, Rachel. A good mix of questions. Let me start and try to address some of them for you. So firstly, your question on Helios EBIT. Clearly, we flagged to you the key reasons in terms of the development that we see. And I would particularly stress the cost headwinds as a significant explanation for the year-on-year development. And although I stressed the Easter effect for Spain, there is, of course, still some year-on-year effect coming from Easter also in the German market. But I would underline the cost impact as the bigger driver of the negative development year on year and remind you what I said in Q4 when we announced the results back in February that I think, at least in the short term, the days of very significant EBIT growth at Helios have come to an end and that we should anticipate that, with the top line effect in combination with those cost investments that we see, that will weigh to some extent on the Helios EBIT for some time. But we are clearly very optimistic about the opportunities that remain in the German business going forward.

Your second question was around the clinical nutrition growth. You quite rightly cited the 14% organic growth in clinical nutrition. And I think, here, two or three things to really stress. We've seen very good momentum in both enteral and parenteral nutrition, particularly in Europe in enteral and in Asia in both enteral and parenteral nutrition. And those have continued to be the key drivers of that growth in the first quarter. We are clearly also having some, let's say, first steps and first shoots of activity also in the US. But finally, those main drivers of that growth to date are in Asia and in Europe. And we continue to be very happy with those businesses.

Stephan Sturm: And, Gunnar, first of all, thank you for bringing up the clinical nutrition topic, which in our minds is the most underappreciated theme in the Fresenius and Fresenius Kabi story. I do believe that the clinical nutrition growth that you're referring to coincides with the healthy ongoing growth that we're seeing in the emerging markets. So beyond Europe, there's also an emerging market story to both EN and PN.

I cannot provide you with details on the effect of the shortages. But look at it that way. Rachel said that it's early in the year and that we -- our model works on the assumption that these drug shortages are going to ease, work on the assumption that the contribution that we've seen in Q1 would've brought or has led to us exceeding our original assumptions and guidance. And given the assumption that we will see some normalization, we refrain from taking a more bullish stance on Kabi's outlook for the remainder of the year today.

We're conscious of time and that you have a pressing appointment at 3:30, i.e. in 10 minutes. So we need to bring this call to a close today. Thank you very much for your questions, for your interest in Fresenius Kabi. There is a lot going -- and Fresenius as a whole. There is, obviously, quite a lot going on. As we said on the 23rd of April, don't expect interim updates from us on the proceeding court case. But we look forward to exchanging our arguments in front of a court. And I'm certain that it's going to be well covered.

Thank you for now. And I look forward to seeing many of you at the Capital Markets Day June 7th in Berlin. Thank you.

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