FRESENIUS

Transcript
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PRESENTATION

Markus Georgi: Good morning and good afternoon to everyone, and welcome to our Q2 conference call. With us today are Stephan and Rachel. Stephan will start with a strategic business update, and Rachel will cover the financials in detail, followed by a Q&A session. After today's 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. And with that, let me 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 in the last quarters, I will get to what we can say on Akorn fairly quickly. And we will also try to answer your questions as best we can. However, as we are in an ongoing legal proceeding, there are obviously limitations. Thank you in advance for your understanding.

But let's start with Page 3 and our Q2 highlights. All in all, a strong Q2 on the back of an excellent Q1. And hence, we're looking at a very strong first half. We're very pleased to see ongoing healthy sales and earnings growth across all our business segments, unfortunately masked by some currency headwinds.

But exchange rate adjusted, we achieved 7% earnings growth, both in Q2 and in the first half, including biosimilars expenses. Here, from September, we'll be comparing apples with apples. And hence, the coming quarterly comps will be getting a bit easier. So our confidence in achieving our full year guidance has a very solid foundation.

Whilst we see pretty consistent growth across the Group, Fresenius Kabi stands out. A very positive development across all regions, but especially in North America. And in combination with the reversal of some HES-associated risk, that puts us in a position to raise our EBIT guidance for Kabi by 4 percentage points. Rachel will give you more details in a few minutes.

Whilst we're very pleased with Kabi's performance in the first six months, we are facing some headwinds at Helios in Germany. As Rachel and I already flagged during our full year and Q1 calls, Helios has taken and will continue to take preparatory measures regarding expected structural and regulatory requirements in patient care. Those initiatives have weighed on Helios' EBIT in the first half. And we expect those burdens also to be a factor in the second.

The good news is that Helios Spain compensates for the softer development in Germany, at least to a certain extent. And we anticipate the underlying growth in Spain even to accelerate in the second half. And in addition, as discussed at our Capital Markets Day, we expect more cross-border synergies to be realized in the second half of this year.

One word on Fresenius Medical Care. The company has successfully sharpened its US Care Coordination portfolio with a stronger focus on what is truly needed to support our core business. At the same time, more progress has been made towards closing the NxStage acquisition. And so already now in the US and soon elsewhere, in health care systems rapidly evolving towards value-based care, Fresenius Medical Care is very well positioned to ensure high-quality outcomes for dialysis patients. I'm sure Rice and Mike will give you a more detailed update in the FMC call later on.

Last but not least among our Q2 highlights, we have reorganized Fresenius' inpatient post-acute care business by transferring our respective German facilities from Helios to Vamed. That transaction successfully closed on July 1st. And by bundling our great expertise in post-acute care within Vamed, we are building a platform to achieve larger synergy benefits and potentially for further international growth. At the same time, we are focusing Fresenius Helios even more clearly on acute care, whilst fostering the cooperation between those business segments continues, and we do that for the benefit of our patients. So all in all, a very busy and satisfactory second quarter, operationally just as much as strategically.

On to Page 4 and an update on Akorn and HES. Starting with Akorn, as you know, the trial took place from July 9 to 13. And as I said in court, I am convinced that we have not only the right, we have the obligation to terminate this merger agreement. We have a fiduciary duty vis-à-vis our shareholders to do this, primarily for two reasons.

Number one is Akorn's financial performance, which is nowhere near what we let alone Akorn management themselves thought it would be, and is in stark contrast to the performance of Akorn's peers, and in particular of our own business in North America. The evidence we submitted demonstrates that Akorn has suffered disproportionately. And that's a valid reason to terminate the merger agreement.

Reason number two, Akorn's data integrity issues, uncovered by our and Akorn's forensic investigations. Whoever looked, wherever they looked, they found serious misconduct, evidence of fraud, actual fraud. No doubt about it, this is systemic and obviously materially different from what was warranted and represented to us when we signed the merger agreement.

Over and above that, Akorn violated its obligation to investigate and remediate its issues, yet another valid reason to terminate the merger agreement.

So we are convinced of the merits of our case. But even if the court did not follow our view, it was the right decision to terminate the merger agreement because this is also about protecting Fresenius' reputation, protecting our credibility as a management team, and last but certainly not least, protecting patients from known risks.

So what are the next steps? So-called post-trial briefs are scheduled to be exchanged between the parties and the court until August 20th. The oral closing argument is scheduled for August 23rd. And judgment is then expected within 90 days thereafter. But the Delaware Chancery Court is known for its efficiency. For good order, the losing party may appeal to the Delaware Supreme Court. But in any case, we'd expect this matter to be finally resolved by early next year.

I can't comment on Akorn's Q2 results today, as it's my understanding that their 10-Q is only going to be published in the coming days.

So over to HES, where you will recall that, at the start of this year, two committees of the European Medicines Agency, EMA, recommended suspending the market authorization for HES-containing products in Europe. Several EU member states, however, raised concerns over the commission's draft decision. They were citing a lack of full consideration of all medical and technical arguments. And so the case was referred back to an expert committee at EMA for further consideration.

Now recently, this expert commission had a majority vote in favor of maintaining the marketing authorization for HES-containing products. That committee concluded that further risk minimization measures should be implemented to increase the in-label use of HES products, and thus ensuring their safe usage. The European Commission has adopted this position. And the necessary measures will now be implemented. Obviously, Fresenius Kabi will closely coordinate with the EMA and with the national authorities.

As you would expect, the entire debate hasn't done the product and its growth prospects a lot of good. However, it is also clear now that the meaningful risk adjustment in Kabi's full year outlook is too conservative. Also here, more on that later from Rachel.

On to Slide 5 and some topics that I believe are of current interest. Let's start with an update on the pricing development in North America, where we had another strong quarter, EBIT margin even ahead of Q1, another quarter where we haven't experienced anything out of the ordinary on the pricing front, low single-digit price erosion for our base portfolio of injectable generics, as has been the norm.

We obviously watch the pricing development very closely, especially given the increased number of competitive approvals last year. But as we said earlier, many of those did not turn into market launches. And many others related to molecules where competition was already intense before. And by the way, the number of approvals in the first half this year has come down pretty significantly year-over-year. But of course, we will keep on tracking market developments very closely.

A word on shortages. At the end of Q2, 35 KABI IV drugs were designated in shortage, up from 32 at the end of Q1. Do we feel a tailwind as a result of the increased number of shortage products? Yes, we do. Does this situation mask the underlying pricing dynamic? No, we don't think so.

The additional sales we generate out of this current shortage situation are primarily volume driven and thus do not meaningfully distort the overall pricing situation. And whilst in the interest of patients and the overall healthcare system, we hope that drug shortages will ease, recent developments suggest that shortages in injectables will not disappear all of a sudden, at least not completely.

As I said at various instances, we are deeply convinced of the long-term growth opportunities in the North American injectable generics market and of Fresenius Kabi's leading position to capture them. So if we stay focused on the consistent quality of our products and processes and on the breadth of our pipeline, I am convinced that we can further strengthen our already excellent position in the US market.

On to some of Kabi's further growth initiatives. To sustain and extend our position, we're investing massively in the expansion and in the quality upgrade of our US manufacturing facilities, particularly in a higher level of automation. We do that to constantly improve quality and the reliability of supply for our hospital customers.

Fresenius Kabi has substantial capital investment projects ongoing in Melrose Park, in Grand Island, and in Wilson. So we're making excellent progress on our $250 million project in Melrose Park just outside Chicago, in line with our in-the-US-for-the-US manufacturing strategy. We are expanding, but more importantly upgrading our capabilities by installing state-of-the-art sterile pharmaceutical production, packaging technologies, and warehousing management. Progress is very much according to plan. And as you can see from the photograph, we held a topping-out ceremony there in June.

In Grand Island, Upstate New York, as part of a more than $100 million investment project, we are installing new production lines and other infrastructure enhancements. Also there, the aim is to improve technology while increasing capacity.

In Wilson, North Carolina, at the pre-filled syringe plant we acquired from Becton Dickinson, we are investing more than $300 million into another manufacturing facility on our existing site. And that will help us to further broaden our product offering and will employ hundreds of new employees.

I already announced during our full year call another initiative to further strengthen our position in North America, a completely new type of compounding center that we're building with the Partners Healthcare System in Canton, Massachusetts. We believe that, with our deep experience in aseptic manufacturing, we are ideally placed to support hospitals by compounding ready-to-administer doses in a reliable and safe manner.

Construction is now complete, and production is expected to begin soon. We believe that this is a model that could be expanded to other North American cities in the future. And so we're already running a parallel project in Canada in the Toronto area, which is also expected to come online later this year.

An important growth driver of Kabi has been enteral nutrition. And as I said during our full year call, we have intensified our retail strategy in Europe over the last couple of years. And now we can start to reap the rewards. So we're gaining market share in major European markets and in China, where we also see very dynamic growth. There, we are traditionally very strong in supplying hospitals, and that obviously gives us a strong starting position for our enteral nutrition business. And on the back of the significant growth rates, we have started now to invest into a local manufacturing facility for enteral nutrition products. Start of production in China is planned for 2019.

We're also making great progress in parenteral nutrition in the US and Canada. The response from clinicians to our most modern lipid emulsion, SMOFlipid, is very positive, and sales are developing in line with our expectations. We are still expanding the market for parenteral feed whilst taking market share. We also remain convinced that our safe and convenient three-chamber bag concept will find further acceptance in the US. And so we're currently working on additional new formulations that will fit better to the practices of US clinicians.

We're also very pleased with the steady progress of our medical device business in North America. The adoption of our pumps continues to grow in the US and Canada in the value segment. That's the one we're targeting. In the first quarter, Fresenius Kabi completed an Agilia -- that's our brand name -- implementation at a network of oncology clinics, placing more than a 1,000 new Agilia devices with more than 175 new US customer sites. And in Q2, we secured a major hospital account in Nova Scotia in Canada. Great job by our colleagues over there.

On to an update of our biosimilars business, where our three late stage molecules are making progress according to plan. All clinical studies remain well on track. And testament to that is the first €10 million milestone payment to Merck. As you know, these milestone payments are strictly linked to the achievement of development targets. And the conditions for the payment were met in the second quarter. And it will become a cash-relevant item in Q3. But we will see no P&L effect out of this payment.

Last but not least, an update on the German hospital market. And as I said during our full year and Q1 earnings calls and as you have heard during our Capital Markets Day, Helios Germany is facing some specific headwinds. First, some additional DRG catalog effects. Those are related to negative price adjustments within the DRG catalog that drive negative mix effects for Helios Germany this year, especially in cardiology.

And secondly, our preparatory structural activities for anticipated regulatory measures. Obviously, Helios can't just watch the regulatory development from the sidelines. Thus, we are proactively preparing ourselves for those upcoming changes. Take clustering as an example. Clustering means that complex treatments are performed only in those hospitals which have the relevant scale, the best equipment, the expertise, and the routine. This will save costs, whilst improving the medical quality. But in a first step, clustering requires investments, and most of them are P&L relevant. The efficiency gains will have more of a midterm positive effect.

But at the same time, Helios Spain is firing on all cylinders, and the company will continue to seize growth opportunities, be they organic or nonorganic. We are optimistic that we will see first successes in the not-too-distant future.

Thank you for now. And with that, let me hand you 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 pleased that the excellent start to 2018 has led into a strong first half year.

I would 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 divestitures of Care Coordination activities at Fresenius Medical Care, mainly Sound Physicians. They include R&D expenses for Fresenius Kabi's biosimilars business. Obviously, in the first half year 2017, there were no biosimilars-related R&D expenses, as the business has only been consolidated since the 1st of September last year. Hence, to give greater transparency, we are showing group net income growth and EBIT growth both including and excluding those biosimilars expenses.

As a truly one-time effect, FMC's divestiture of Sound has been treated as a special item. In the first half year 2018, the transaction generated a positive effect on group net income of around €207 million.

As far as Fresenius Medical Care's settlement with the United States Department of Veterans Affairs and Justice, the so-called VA agreement, is concerned, half one figures last year included €98 million of sales and €91 million of EBIT. This contributed 1 percentage point to sales growth, 4 percentage points to EBIT growth, and €17 million or 2 percentage points to net income growth. These effects were not treated as special items on group level and obviously weigh on our half one 2018 growth rates. The impact on Q2 2018 growth rates is, however, negligible.

So let's switch to Page 7 and 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. So finally, let's turn to the numbers. We delivered sales growth of 5% in Q2. The sequential slowdown was anticipated, given the one additional month of consolidation of Helios Spain in Q1 versus last year. For the first half of 2018 we are now at 6% growth and hence in line with our 5% to 8% constant currency sales growth guidance.

EBIT increased by 2% including and by 5% excluding biosimilars expenses, a clear sequential acceleration of growth, mainly due to the aforementioned effect of the VA settlement payment at Fresenius Medical Care in the prior year.

With €151 million, net interest was sequentially slightly up, mainly due to currency effects. Year-on-year, we've seen a decrease in half one 2018, despite the fact that this year's net interest result reflects six months of Quirónsalud financing costs versus five months in 2017. This is primarily due to currency effects and successful refinancing activities.

Given the proceeds from the divestiture of Sound, our net interest expenditures in half two 2018 will decrease. At the same time, we expect minor interest rates and currency risks. Overall, we've reduced our targeted range from €590 million to €610 million to a range of €580 million to €600 million for the full year. For good order, do remember that we have adjusted the 2017 base for Sound, including interest effects.

Group tax rate before special items was at 23.4% in Q2 2018, in line with our expectation. The significant year-on-year decrease is obviously driven by the US tax reform which went into effect on the 1st of January this year. The half one 2018 tax rate is at 22.3%, a touch below our full year expectation. This is mainly due to a one-time effect at Fresenius Medical Care in Q1. For the full year, we continue to expect a tax rate between 23% and 24%.

Moving on to net income, where the growth rates for Q2 and half one are consistent, earnings growth at 7% including and at 12% excluding biosimilars expenses. So both earnings metrics are nicely in our guidance ranges.

Onto Page 8, which illustrates the momentum at our four business segments in Q2 2018. 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 growth on the right is at constant currency and before transaction-related effects and the divestitures of Care Coordination activities at Fresenius Medical Care. All of the businesses have made a positive contribution to organic growth, We're very pleased with that.

Let's start with Kabi. The company showed strong 6% organic growth. EBIT declined by 1% including the biosimilars expenses, indeed a strong Q2, considering that we had no biosimilars expenses in the first half year 2017. If we strip out those biosimilars expenses, that looks even better with excellent 11% EBIT growth. More details in a minute in the Kabi section.

Helios was at 4% organic sales growth, in line with our full year outlook range. EBIT growth of 4% in Q2 and 6% in the first half year, this is in line with the full year outlook range of 5% to 8% and a touch below the original full year outlook of 7% to 10%. This was the outlook prior to the transfer of the post-acute care business to Vamed. The transfer became effective on the 1st of July and is thus not reflected in the actual Helios growth figures yet. Vamed contributed nicely to our top line and EBIT growth, in line with our expectations.

So let's turn to Page 9 for a review of Fresenius Kabi's organic sales growth by region. In a nutshell, North America and Europe in line with expectations and the emerging markets with an excellent Q2.

Starting with North America, given a very strong 9% organic growth in the prior year quarter and some phasing within our operating business, we are very pleased with the 4% organic growth rate in Q2. This takes us to 7% growth in half year one 2018, very strong against our expectation of mid-single-digit growth for the full year.

As you heard from Stephan, the strong financial performance was again positively influenced by drug shortages. We do not get tired of saying that our model and outlook assume a gradual easing of drug shortages. Given the FDA's focus on easing shortages and ensuring strong generic competition, we do not assume that the current situation will persist.

On to launches, where we see good momentum, three more launches since the end of Q1 brings us to six new market entries this year. This is in line with our expectation to end the year with more than 15 new drug launches. So you can see the launch schedule is, as expected, rather backend loaded. Here, we'll stick to our outlook of mid-single-digit organic sales growth for full year 2018.

So moving on to Europe, we've seen organic growth of 3%. The diminishing HES risk for 2018 had some positive influence. But of course, HES has a more material effect on EBIT than on sales, and it also plays to some degree outside of Europe. We are also pleased with the performance of all our products across our portfolio. In particular, we saw strong growth in enteral nutrition, with 3% growth in the first half year 2018, we feel comfortable to confirm our low to mid-single-digit organic growth outlook for Europe for the full year.

So let's continue with emerging markets on Slide number 10, where we are pleased to report strong organic growth of 11%. China is growing at 10% organically. The introduction of the tender policy is now completed. As a result, we continue to expect low to mid-single-digit price reductions as a full year 2018 impact. At the same time, we still expect continued double-digit volume growth, which will lead to very significant organic growth in China.

Great momentum outside of China with Asia-Pac ex-China and Latin America and Africa growing organically with 14% and 10%, respectively. Taking that all together for the emerging markets as a whole on the back of the very strong financial performance in the first half year 2018, we've strengthened our outlook and firmly believe in double-digit organic sales growth for the full year.

Let's turn to Slide 11 and Kabi's regional EBIT development. The total EBIT came in at €289 million. That's a decline of 1% at constant currency. Total EBIT in the half year was €557 million, also here a decline of 1% at constant currency, which is 2 percentage points above our outlook range. EBIT growth excluding the biosimilars expenses is quite impressive, with 10% growth in the first half year. We are 5 percentage points above our guidance range of 2% to 5% growth.

So let's take a more detailed look at the regions. With 7% growth in Q2 and in the first half year 2018, North America showed an excellent first half. The EBIT margin of 40.1% in Q2 was outstanding. Also here, obviously, we had some tailwind from shortages and some phasing within our operating business.

So on the back of the already strong growth and a strong margin in half one 2018 in North America, we feel comfortable to strengthen our outlook for the full year and now expect EBIT to grow faster than sales, where we guided mid-single-digit growth.

So moving on to Europe, with strong 8% growth, driven mainly by an ongoing excellent enteral nutrition business and the HES effect.

And in the emerging markets, here, an outstanding growth rate of 20%. The growth is particularly 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 €116 million. Adjusted for the biosimilars expenses, we are slightly up year-on-year. With just over €70 million of biosimilars expenses in the first half year this year, we are on track with our expectation of around €160 million for the full year. In addition to biosimilars, we are also investing in the future. And we are broadening our portfolio. Thus, we continue to expect an increase of R&D expenses, excluding those on biosimilars.

As Stephan said, the first small milestone payment from our biosimilars business has materialized. It has no P&L effect, and the cash outflow will occur in Q3. However, future milestone payments can lead to a P&L effect. As a reminder, these are deferred acquisition costs, and they will be treated as special items. Therefore, they will have no impact either on Kabi's outlook, nor on the group guidance.

So let's turn to Fresenius Helios on Slide number 12. Total sales came in at €2.3 billion, up 5% year-over-year. Organic growth was at 4%. In half one 2018, the additional month of consolidation of Helios Spain nicely contributed to the healthy sales growth of 10%.

With 3%, Helios Germany showed solid organic sales growth in Q2. The headwinds that Stephan and I already flagged on various occasions continue to weigh on our business. As a reminder, the additional DRG catalog effects, the lack of privatization opportunities, and the preparatory structural activities for anticipated regulatory measures will continue to impact our financials this year.

Over to Helios Spain, where we've seen great sales growth of 9% in Q2. The particularly outstanding sales growth of 28% in the first half year is significantly influenced by the additional month of consolidation in Q1 2018.

Primarily due to the Easter effect, organic sales growth accelerated sequentially significantly to 8%. With 5% organic sales growth in half one 2018, Helios Spain is now at the midpoint of its historical organic sales growth range of 4% to 6%.

On to Slide 13 now, with an overview of the EBIT development at Fresenius Helios. Total EBIT came in at €293 million, up 4% year-over-year. As I said already at the beginning, this is a bit soft. The driver here is obviously Helios Germany. With €168 million in Q2, EBIT for Helios Germany decreased by 6%. We've given you the reasons for the softer development already.

The good news is that Helios Spain compensates the softer development at Helios Germany to a certain extent. In Q2, Helios Spain showed an EBIT of €124 million and a great growth rate of 19%. The additional month of consolidation contributed to the outstanding growth rate of 28% in the first half year 2018.

We do, of course, expect due to the hot summer months in Spain the usual softer Q3. But it is likely going to be stronger than last year's. We are positive about the possibility of very strong underlying growth in the second half year 2018.

Over to Fresenius Vamed on Slide 14. We were pleased with Vamed's second quarter. Organic sales growth was 1% in Q2 and 5% in the first half year, reflecting the lumpy nature of the project business. As expected, the EBIT growth accelerated sequentially. 9% growth in Q2 brings the H1/18 figure to 6%.

Strong order intake of €195 million in Q2 brings the half one 2018 figure to €455 million, a healthy 10% year-on-year increase. This bodes well for the project business, and we are very optimistic for the second half year 2018.

Vamed further strengthened its unique value chain and existing value proposition with a small but attractive acquisition which will complement the company's high-end medical-technical services portfolio in the UK.

Let's move on to cash flow now, which is on Slide number 15. A reasonable Q2 with €1.02 billion of operating cash flow for the group. We saw some phasing of working capital for Fresenius Medical Care in North America and expect an acceleration of cash flow generation in the second half year.

Kabi posted an excellent Q2 cash flow of €228 million, top left, a strong Q2 margin of 14.2% took the last 12-month margin to an excellent 16.8%. With a cash flow of €162 million, we've seen a sequential acceleration at Helios. So for the group, the Q2 performance took the last 12-month margin to 10.5%. If you deduct group CapEx of 5.5% in the middle column, you'll arrive at a free cash flow last 12-month margin, bottom right, of 5.0%.

We finished Q2 at 2.80x net debt/EBITDA, nicely down from Q1. Excluding the Sound divestiture, we ended at 3.02x net debt/EBITDA, sequentially broadly flat, mainly due to the dividend payment in Q2. As I said, the cash flow generation will accelerate in the second half year. Hence, we confirm our target to further delever this year. Of course, this outlook is excluding Akorn and Sound as well as NxStage and under current IFRS rules.

So let's turn to Slide number 16 for the 2018 outlook by business segment, starting with Kabi. On the back of 7% organic sales growth in the first half year, we confirm our outlook range of 4% to 7%. Against the backdrop of a strong performance across our portfolio and the HES effect, we expect to end the year more in the upper half of that range.

On to EBIT, where we increase our outlook range by 4 percentage points. Including biosimilars, that's from minus 6% to 3% to a new range of minus 2% to plus 1%. Excluding biosimilars expenses, we also increase our outlook range by 4 percentage points and now expect 6% to 9% EBIT growth. Here, we see the impact of our strong development across the portfolio, in particular in North America and the HES effect. As a reminder, we always said that the HES risk adjustment would have a significantly more material effect on EBIT than on sales.

For Helios, with organic sales growth at 4% year to date, we feel confident to confirm the outlook range of 3% to 6% for the full year. For EBIT, we expect more synergies to be realized in the second half year of 2018. We also do anticipate an underlying acceleration of growth for Helios Spain in the second half year. On the other hand, we expect the softness of Helios Germany to continue. Hence, we confirm our outlook range of 5% to 8% growth for the full year. However, with 6% growth in the first half year this year, you should expect rather towards the lower end of that range.

And on to Vamed. The company's huge and well-diversified order book as well as the strength of the service business gives us confidence to confirm the outlook ranges of 5% to 10% for organic sales growth and EBIT growth of 32% to 37%. The high EBIT growth range is obviously a consequence of the already announced transfer of the post-acute care business from Fresenius Helios to Fresenius Vamed.

Then if you take all of that together for the group, that's now on Slide number 17. To remind you, group guidance is always given excluding significant transactions and thus also here excluding Sound. We are convinced that this is the best way to show the underlying growth. Thus, here, we have adjusted the 2017 sales and net income base accordingly. I would like to point you to our reconciliation table on Page 27 of our presentation.

So starting with sales, we feel comfortable to confirm our guidance range of 5% to 8% growth at constant currency. However, with 6% sales growth in the first half year, the upper end is now less likely.

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

And then net income. With 7% net income growth in the first half year, we feel confident to confirm our guidance range of 6 to 9 percentage points of growth. Excluding biosimilars expenses, which account for around 4 percentage points, we confirm the original range of around 10% to 13% growth. On the back of the strong financial performance of Kabi, we expect growth more towards the upper end of those guidance ranges.

With regard to currency, we expect also here a headwind of 4 percentage points.

Many thanks for your interest. 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 Veronica Dubajova from Goldman Sachs. Please go ahead.

Veronika Dubajova: Good afternoon, Stephan and Rachel. And thank you for taking my questions. I will keep it to two, please. My first question is on Helios Germany. And, Rachel, I was hoping you could give us a bit of insight into whether the margin that you've seen there in the first half of the year as a reasonable proxy for how you think of a full year or to what extent some of the investments that you're making there are likely to dissipate as you move into the second half of the year. And related to that, maybe when do you expect to have clarity on the changes to reimbursement in Germany? That's my first question.

And my second question is on Kabi North America. If I look at the divisional disclosure, it seems like the IV growth was somewhat soft there, and this was maybe offset by some of the success in medical products and nutrition and IV solutions. Is that a fair characterization of what you saw in Kabi North America this quarter, or have I read too far into the disclosure?

Rachel Empey: Hi, Veronika. Rachel. Thank you for the questions. I'll start with Helios Germany. So you asked in terms of how the margin has developed. And you can see that, across the first half year, we were just above an 11% margin, which is a slight decline year-on-year for the reasons that both Stephan and I have described at length.

Clearly, there is always some seasonality in terms of margin. The high operating leverage that we see in the Helios Germany business clearly will dictate that. But nevertheless, you've seen a reasonable level of stability between Q1 and Q2. And I think it's not a bad proxy, notwithstanding some of the seasonality that you've heard from us very clearly that we see that the softness will continue. The measures that we're taking will continue, and so will the effects that we have seen to date. So I think your point is not a bad proxy without clearly ignoring, if you like, the seasonality that is within there.

Stephan Sturm: Hey, Veronika. It's Stephan. And as far as legislative changes in the German hospital business are concerned, it is my understanding that we're likely to see draft legislation later this week. We are eager to learn more about this. But as I believe I said on the Q1 call, I say that something is going to happen that is near certain. That is that something is going to happen with regard to minimum staffing levels is almost as certain to happen.

It'll come down to the fine print and whether it is a fairly crude measure or whether there is some room for differentiation in the different job profiles that we have invested in and whether there is also some differentiation for the CapEx levels. And that is obviously something that we would like to see happen.

My understanding is that this is going to be discussed over the summer break, that in all likelihood, it's going to be brought into Parliament later this year and that it is meant to become effective 1st of January 2019.

So bear with us. We need to take a closer look at this and also need to figure out what the consequences for us are. On the other hand, I would work on the assumption that, in the general direction, there is not going to be anything surprising and that, hence, the preparatory measures that we have launched will serve us well to mitigate any negative impact and maybe potentially even get some positive out of this.

As far as your second question is concerned, you are right. When you were looking at the different product lines, our injectables business was growing at 1% globally relative to the 4% that we were showing in North America. I would attribute that, and I believe that Rachel in her prepared remarks already alluded to that, to some phasing issues not only, but in particular in the North American market. I would also attribute it to a particularly strong comp. In the prior year Q2 from recollection, it was a 9% or even 10%, 9% -- Rachel is just nodding -- 9% organic growth in Q2 of last year.

In general, and I want to come back to what I said in my prepared remarks, we're very happy with the development of our injectables business, not only but in particular in North America. Pricing development remains as far as we can see fairly steady. And the number of new launches that Rachel made reference to and that they will provide a further support to our business performance in the second half. I hope that was helpful.

Veronika Dubajova: That was very clear, Stephan. And if I can just add a quick follow up -- well, follow up or maybe an unrelated question, but on your M&A plans for the Helios business more broadly, there's a couple of assets which are supposedly for sale. And I'm wondering if you are in a position to make a move on a potential transaction this year, or is that really something we should be expecting for 2019? And I'll leave it at that. Thank you.

Stephan Sturm: Rachel, you won't be surprised to hear from me that I'm obviously not going to comment on transactions that are happening in the market and whether we do or do not participate. I would really like to leave it at what we said at the Capital Markets Day. In an ideal world, we would continue to focus on synergy generation over the course of this year and ideally also next.

I really would like to see an even closer collaboration between our German and Spanish businesses. What we do see in the German environment is frankly just what we expected, only a bit faster. And that is that very many of the practices that we do see in Spain will undoubtedly arrive in Germany rather sooner than later. And therefore, we are well advised to foster the collaboration there. And therefore, if everything goes according to plan, I really would like to embrace a somewhat larger acquisition project only in '19 with a potential closing, again in an ideal world, only in '20.

Veronika Dubajova: Very clear. Thank you, both.

Stephan Sturm: Thanks, Veronika.

Operator: Mr. Berenberg, your question please.

Tom Jones: I wish I was Mr. Berenberg. It's Tom Jones from Berenberg here. I had two questions. One just was on the Kabi guidance upgrade. If I've done my math right, the 4 percentage point increase looks like roughly a €50 million absolute increase. How much of that is related to the H1 performance and your expectations for operational performance in H2? And how much of that really relates to the removal of the HES risk discount? That would be my first question.

And then the second question is sort of a follow up to Veronika's question. But I think, Stephan, your comments were more related to largescale M&A. On small-scale M&A, particularly within Spain, I don't know if I heard it right in the call, but were you kind of steering us to think a little bit more about a slight acceleration in inorganic opportunities in Spain in H2 on the small end of the scale, or was I perhaps reading too much into your commentary there?

Rachel Empey: Hi, Tom. Thanks for your questions. I think I can give a relatively easy answer to your first question. Clearly, we are very pleased with the development of the business overall in Kabi in the first half year. And that is always an important factor when you're thinking about what the guidance should look like for the full year. And to some extent, some of that HES upside has already been seen in the first half year because we were already expecting some of that risk, particularly in the second quarter.

But in terms of the specifics of the upgrade, I would say that a significant amount in absolute terms is coming from HES. But it is clearly also in combination with the strong performance across the portfolio, particularly in North America in the first half year.

Stephan Sturm: Tom, this is Stephan Fresenius. Congratulations to owning a bank. And I can tell that you have been tracking us for quite a while now, and you're paying attention to nuances. And yes, as a matter of fact, within -- my comments were primarily meant at a potential expansion into a third country. And the nuance that I had in my language was meant to indicate that there are a few projects that we're working on in a more Spanish environment as we speak. Obviously, too early to be more specific, but I am reasonably optimistic that, also on this end, we can show a bit of progress.

Tom Jones: Okay. And then just one quick follow-up question, if I may. You seem fairly committed to the idea that this minimum staffing thing is going to go through. But the discussions between the insurers and the hospital associations seem to have kind of broken down with not much progress, and it's been sent back to the health ministry. I wouldn't say it's been kicked into the long grass, but it feels certainly like that the board's been nudged in that direction.

Is there any possibility that this -- people see this for what it is and how disruptive and unproductive it is for the German healthcare system and see sense in the end, or I'm just intrigued as to why you seem so confident that this is going to come to pass and won't get properly kicked into the long grass.

Stephan Sturm: I'm not sure whether that's a golf or rugby analogy, but probably golf. I do believe -- as I said on earlier calls, I firmly believe that this is something where a lot of time was spent in the recent election campaign. It is a very popular topic. And no politician in their right minds will want to see whether the hospital operators and the insurance companies will come to an agreement. I would be working on the assumption that this was a good faith effort, and if a resolution cannot be obtained, then the politicians themselves will drive a proposal.

Tom Jones: Fair enough. We'll just have to wait and see I guess. Thanks for your comments. Very helpful.

Stephan Sturm: Thanks, Tom.

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

Lisa Clive: Hi, thanks. I have three questions. First, can you comment on the double-digit growth that you've seen in infusion therapy in the past two quarters? Have you made any headway in the US market yet, and is it around competitor shortages, and when might those resolve, or there are other regions that are driving this?

Second question on Helios Germany, historically, you've guided to steady and gradual margin improvement. Obviously, you're in investment mode right now ahead of any regulatory changes. But once that all settles out, is this still a business that can improve its profitability over time?

And then third question, which hopefully you can give some insights on, on Akorn, obviously, we need to wait for the conclusion of the legal process. But one way of looking at this is that I think the biggest concern upfront was that the FDA would hear about these data integrity problems and would come out with a warning letter or worse. And that hasn't happened yet. So in the scenario that you do have to close this transaction, might the residual value of Akorn not be that badly impaired? Obviously, I'm focused on the pipeline here. The decline in the current marketed products is what it is. But really, a lot of the value of this asset is their pipeline. And if the FDA doesn't take a particularly stern look at this, might there be some salvage value here?

Stephan Sturm: Lisa, it's Stephan. Thanks for your questions. As far as infusion therapy is concerned, on the one hand, we're very pleased with the development in the recent past. There is nothing in particular that I could point you to. And in particular, it would be wrong to guide you to an extra contribution from the North American market. There, yes, for the time being, we're playing a somewhat smaller role, as you know. We have the agreement with Becton Dickinson. We're shipping limited volumes of product over the Atlantic. It is not enormously profitable. It is also overall volume wise nothing really to write home about. It is much rather a fairly positive development around the globe.

As far as Helios Germany is concerned, on the one hand, we're looking at structural changes that we believe are likely and that at least we want to be prepared for. Clustering is a term that we have used maybe for some of you too often. But it is very much on our minds. It is also the concept of driving, just as we've seen it and living it in Spain, a growing share of ambulatory care relative to stationary. And I do believe that, over the next 2, 3 to 5 years, we're going to see fairly meaningful change in the overall regulatory environment.

At the same time, I would expect if we stay nimble, stay on our toes, watch this evolving regulatory environment, and in particular take some cues from our Spanish colleagues that we can preserve our market-leading position with quite some bigger. This is -- and also from my perspective will remain a business that has a very meaningful fixed cost block, will remain a business where we're going to see a lack of appetite for privatization and hence the necessity to drive top line reimbursement at a healthy level.

And as long as this is the case, coupled with a lack of any discrimination efforts, and I do not see anything in that regard, discrimination of private versus public operators, I would very much work on the assumption that we can take advantage of our operating leverage that undoubtedly does exist in that business. And therefore, we'll be able to drive our EBIT at at least a slightly faster pace than our top line. That to me is a structural truth of this business.

And we may see more investments. I don't want to spook you right now. We're well on track with what we had set out to do right now, and I don't see anything worsening. We stand by our guidance absolutely. But structurally, for the medium term, I would also work on the assumption that we can generate at least small margin improvements.

Your third question on Akorn, and I really do not want to and cannot speculate about the FDA's actions or the lack of it. All I want to say is -- and I want to refer you back to my prepared remarks -- we need to protect Fresenius' reputation. And even more importantly, we need to protect Fresenius' patients. And we will not cut any corners. We will not take any known risks.

And I think it is an ill-fated strategy to wait for the FDA to come down on you. You've got to be proactive in your regulatory behavior. You've got to stay ahead of the FDA. And again, if the court is not prepared to follow our view and we are forced to close this transaction, then some pretty substantial remediation effort has to go through, irrespective of whether the FDA reacts in the meantime with a warning letter or other sanctions or not.

Lisa Clive: Okay. Thanks very much for the color.

Stephan Sturm: Thank you, Lisa.

Operator: Next question comes from Gunnar Romer, Deutsche Bank. Please go ahead.

Gunnar Romer: Good morning, everyone. Gunnar Romer, Deutsche Bank. Thanks for taking my questions. The first one would be on organic growth in Spain. I think you saw 5% now in the first half. And I think you're pointing us to some acceleration in the second half. Is that right? And can you be a bit more precise on what you would expect in terms of organic growth in Spain for the year?

And then secondly, also related to Helios, EBIT was down 6% in Germany I think in the second quarter. Can you help us understand what the impact or what the growth would've been without the preparatory measures?

And then on Kabi, my question would be on the North American EBIT margin, which was obviously up quite substantially, 250 basis points quarter over quarter. I think you talked about some phasing effects here. Can you be a bit more precise on what that means? Thanks.

Rachel Empey: Gunnar, thank you very much for the questions. Let me try and rattle through them. So your first question was associated with the organic growth for Spain. You're absolutely right. We have 5% organic growth in the first half year. We did see quite a significantly different phasing between Q1 and Q2, primarily driven by the Easter effect. That 5% puts us nicely into the historic range that we've guided you to in terms of what you might expect from Helios Spain, which is 4% to 6%.

I did overall say that we expect some acceleration of underlying growth in the second half year. I wouldn't guide you outside of that historical organic growth range. And as ever, the phasing will be, say, Q4 heavy in terms of absolute terms due to the hot summer months. But we are anticipating a strong second half year. And we are, as I mentioned in my prepared remarks, also expecting that Q3 this year could be a touch stronger than it was last year.

Your second question associated with the EBIT development within Helios Germany, you rightly pointed out that we saw an EBIT decline of around 6% in the second quarter. And we were declining around 4% in the first half year. Clearly, there's a lot of moving parts within the profitability of the Helios business. There are a lot of seasonal effects. So from my perspective, it is very difficult to isolate one set of cost measures and say for sure this is what the growth would have been without it.

But clearly, the combination of those measures and those circumstances that both Stephan and I described have led us to the situation where we are today. But those proprietary cost items are clearly a significant contributor to the development that we have seen, both in the first half year, but also in the second quarter.

Stephan Sturm: Even though she does not need it, I will still come to Rachel's support. And I wouldn't underestimate the catalog effects that we made reference to. I would also not underestimate the remnants of fixed cost. When we're trying to build clusters and to move patients, then it is the aim at the same time to bring the cost at those hospitals down, where we're trying to transfer the cases from.

That is something that in general hasn't gone as fast as we originally expected it to be. We keep on working on that. But in general, what I'm trying to confirm is that it is very difficult to disentangle the different moving parts and their effects. Apologies for that.

Rachel Empey: Gunnar, your third question was the Kabi North America EBIT development. What you see is a margin just under 39% in the first half year and around 40% for the second quarter.

You're right. I did mention in my prepared remarks the effect of phasing. What I meant here specifically is clearly we are making shipments to the GPOs, to our customers. And we are making shipments often to those wholesalers in bulk, if you like, so in groups. So it can often be that, based on mix effects and based on timing, you can get some small differences in growth rates and in margin rates between quarters, between months, and between periods. So that is, if you like, the nature of the business. And that is the specific point that I had behind my phasing comment.

The margin does remain from my perspective strong. Here, clearly, we do have a small headwind associated -- sorry, a small tailwind associated with the shortages that we continue to see in North America. That has consistently supported our margin over the last two quarters and the preceding quarters. And we remain very happy with the ability that we have been able to keep driving such a good and profitable margin within the North American business. But there is nothing specific that you should read into the development between the first quarter and the second quarter associated with those specific numbers. I hope that's helpful for you.

Stephan Sturm: And for the avoidance of doubt, I do not think that Rachel wanted to imply with phasing that that was a supporting factor of our Q2 results. Okay? It is on the margin rather the opposite.

Gunnar Romer: That's helpful. Thank you. Just a quick follow up, hopefully an easy one. On the guidance, you're raising EBIT guidance for Kabi, while for Helios, you're pointing us towards the lower end. Would that not have warranted a small upgrade or at least an upgrade of the lower end of the group guidance? Any comments around that why you've left the group guidance range unchanged at the net income level?

Rachel Empey: Thanks for the question, Gunnar. Finally, one of the beauties of a diverse group is that you always have a portfolio of assets with different influencing factors and different microtrends in terms of their performance. And that's exactly what we see here. You're absolutely right. The upgrade to Kabi's EBIT outlook is, of course, a nicely positive influence on the group net income guidance. At the same time, you rightly identified that I pointed more towards the lower part of the range in terms of the Helios EBIT outlook.

I did point you more towards the upper end of the range on the group earnings guidance. And of course, there are some smaller effects when we look at the overall performance and the overall portfolio to decide where we think we stand on the net income growth. We're very pleased with the overall performance of the business. We're confident with those ranges and happy to point you more towards the upper end due to that portfolio effect that I mentioned overall.

Gunnar Romer: Thank you very much.

Operator: We have only time for one more question. Last question comes from Patrick Wood, Bank of America Merrill Lynch. Please go ahead.

Patrick Wood: Perfect. Thank you very much for squeezing me in. I have two remaining, if I can, please. One would be on the Helios Spain division and generally, obviously, growth going very well. It'd just be helpful to know up to date how that split out. I was looking roughly in terms of volumes relative to price mix. I'm presuming it's still inpatient growth and volume driven, but let me know if it's not.

The second one is on Kabi and again sort of looking at the margins. The margins in totality, not just North America, seemed quite a bit stronger than certainly I'd expected on an underlying basis. And that was despite in some ways a negative mix, i.e. lower IV sales and more EN sales. Is there something we should be looking at in terms of total Kabi? Is that just operating leverage? Is there another mix effect? Are there some more cost savings? It'd just be helpful to understand how you guys see that margin structure not necessarily for the second half of the year, but more long term. That'd be helpful. Thank you.

Rachel Empey: Hi, Patrick. Thank you very much for your questions. Helios Spain, so you're absolutely right. You took our moves correctly. We are very pleased with the overall development in Spain, the overall growth and also the organic growth that we are being able to deliver. Specifically the rates of privately insured patients and that overall penetration and development of the marketplace in Spain is supporting us here.

So your assumption is absolutely right that this is a more volume-driven effect than anything else. And we continue to be optimistic in terms of how that volume and mix effect will evolve for us over time, so very pleased with the development and the continuation of the trends and also that the growth is coming significantly from that private orientation and movement within the overall Spanish marketplace.

Stephan Sturm: Patrick, on Kabi, I'd say there is nothing structural that I would point you to. You are right at the face of it. You can suspect a somewhat negative mix effect for the margin. At the same time, we were talking about also the North American injectables business growing faster than the injectables business elsewhere. It is also not too much of a secret that our clinical nutrition products, both PN and EN, come at a fairly healthy margin, which may not be that different from the injectables business outside the US.

And maybe my last comment would be that, with a generally growing business, you have a better chance to distribute your overheads in the corporate and the R&D line of the P&L over a larger base, which from my perspective then yes should be a more structural support to the EBIT line going forward, to the EBIT margin going forward. But apart from that, as I hope we more or less convincingly brought across, we're very happy with the business development, not only but in particular at Kabi. And that applies basically to each and every business line.

Patrick Wood: Very helpful color. Thank you, both.

Stephan Sturm: Thank you.

Rachel Empey: Thank you.

Stephan Sturm: Thank you, Patrick. And thank you, all. That brings us to the end of today's conference call. Want to give you a bit of breathing space ahead of the FMC call starting in a few minutes. Thank you for your interest. Thank you for your questions. And for those of you who haven't been away yet, have a very good summer holiday, and we'll meet many of you then after the summer in September on the various conferences. Thank you very much.

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