FRESENIUS

Transcript
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PRESENTATION

Markus Georgi: Good morning to everyone joining us on the line today. I'm joined on the call today by Stephan and Rachel. We will start the call with some prepared remarks and then proceed to Q&A. As always, before we begin, I would like to remind you that forward-looking statements and the disclaimer are on Page 2 of today's presentation. With that, I will pass the call to Stephan. The floor's yours, Stephan.

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

Markus has pointed out the safe harbor language to you. So let's move right to **Page 3** and our Q3 highlights. We are pleased to see a continuation of healthy top-line growth across the group. Net income, currency adjusted, is flat year-over-year, in line with our expectations.

We have managed to broadly offset some negative one-time items with some positive ones. As I said at various instances, 2019 is about delivering on our commitments. And that is what we continue to do. Thus, Q3 is another solid quarter and in line with the financial performance we indicated at the beginning of our investment year. Our various investment initiatives to secure long-term sustainable growth, across all our businesses, they are proceeding according to plan. And at Helios Germany, our decisive efforts to counter regulatory headwinds are beginning to pay off.

Specifically, with regard to our growth investments at Fresenius Kabi, the plant expansions, capacity increases, and quality improvements, they are proceeding fully in line with our timing and budget expectations.

Our track record gives us confidence that those growth initiatives will pay off, as they have done, and as they do right now. Take emerging markets as a prime example, where the consistent investments into our increasingly broad local presence over the last years are now delivering nice returns. Organic investments, so into our own business, those offer an attractive low-risk, high-return profile. And they are the prerequisite for future growth. That brings me to the outstanding financial performance of Fresenius Kabi in the emerging markets in Q3 and, indeed, throughout 2019. The already strong performance of the first half even accelerated in the third quarter and offset, at least partially, the softer development in North America. Over to Helios, which showed strong organic sales growth in Q3. In Germany, we are pleased with the excellent top-line development, in Q3 now also helped by admissions growth. In Spain, we are very pleased with our efforts to drive admissions growth during the summer months. The EBIT line was, however, impacted by higher expenses for temporary staff and a few small one-timers. At Fresenius Vamed, I applaud my colleagues on the smooth integration of Helios's German post-acute business. Great execution, as those clinics continue to perform very well. And that's not a given when looking at the relative size of this project.

Over to Fresenius Medical Care, where we are very pleased to see record growth in home dialysis in North America. In light of the President's Executive Order, timing of our NxStage acquisition has been spot on. And now NxStage's products and infrastructure help us to benefit from the undoubtedly growing trend towards home-based therapies. So we continue to be at the forefront of providing patients access to superior care and outcomes in a home setting. And the advantage of that strategic head start is materializing now.

On the other hand, what I did said in the second quarter with respect to ESCOs and the need for a reliable payment model remains unchanged. We have voiced our objections to the method changes and calculation flaws at the appropriate authorities and will embrace any future comprehensive care model only to the degree we feel we're being treated fairly. Rice and Mike will give you a more detailed update in the FMC call later on.

Coming back to the Fresenius Group, where on the back of a solid financial performance in Q3 and year-to-date, we are confirming our sales and net income guidance ranges. Rachel will provide more details on guidance as part of her prepared remarks.

So onto **Page 4** with an update on Kabi, and there starting with the injectables market in North America, where we have seen a 4% year-over-year organic sales decrease in Q3 leading to a 3% decrease year-to-date. That is clearly below our earlier expectations.

The Q3 decrease is, as in H1, primarily volume-driven. Our analysis suggests that the reasons for the Q3 volume shortfall are more or less unchanged from Q2. We have seen fewer and less pronounced shortages coupled with increased competition for certain molecules. Our analysis shows that the US market for the products in our current portfolio has declined by a mid-single digit percentage since 2017, primarily driven by injectable opioids and a normalization of recent shortages. So we have not lost market share over that period. And our market has stabilized since early this year. Given population growth and aging, we continue to expect structural volume growth over time.

More specifically, what has happened in Q3? A, as discussed in July, destocking already concluded in the second quarter, but has not reversed into meaningful volume growth in Q3. Hospitals have reverted to the historical levels of buying that preceded the shortages of the last couple of years. B, we expected an acceleration of new product launches. And that materialized, but only towards the end of Q3. So, the incremental sales were insufficient to offset reduced demand from shortages ending. With 12 product launches year-to-date, we expect to see, as guided, 15+ for the full year. And although Q4 should be our strongest quarter for new product sales this year, we continue to expect small- and medium-sized launch opportunities. C, at the end of Q2, we expected some recovery in the injectable opioid market, but this has not materialized. Much rather, the prescribing trend towards nonopioid pain management continued through Q3. So, the total market for injectable opioids appears to have stabilized significantly below historical levels.

Now a little more color on shortages. At the end of Q3, 31 Kabi IV drugs were designated in shortage. That is a sequential decrease of five products. And as I already said in Q2, we have seen that several key shortage situations have resolved. So, in reality, we currently have virtually no benefit from shortages left. We obviously cannot exclude that we will experience a return of shortage tailwinds. For now, however, they are essentially over.

A word on pricing in the US market. In the third quarter, we have seen low to mid-single-digit price erosion, a notch higher than in the first half, but consistent with historical trends and also in line with our Q2 assumption. We do not expect that this pricing trend will meaningfully change going forward.

Onto EBIT margin, where despite a significant easing of drug shortages and intensifying competition in certain molecules, we ended the quarter at 36.3%. That leaves our IV drug business in the US well within our expectation of a sustainable mid-30s-plus EBIT margin. Given the extra inventories we have built year-to-date, we are planning for a longer-than-usual production shutdown at both our Grand Island and Melrose Park facilities over the holiday period. We do this now, not only because we are facing softer volume demand, but also because quality has been, is, and remains key to us. Thus, we're taking the opportunity to accelerate our investment programs at these US facilities, with the aim to further modernize and automate both sites. That will ensure sustained high-quality production of our critical sterile injectable portfolio long into the future. Obviously, that extended shutdown will have some impact on our Q4 margin. You may recall the effect of that in the fourth quarter of 2016. And frankly, historically, Q4 has always been a softer quarter from a margin perspective.

Considering the current headwinds, we are facing in the US market, we have initiated decisive measures with respect to 2020 and beyond. A, we want to enhance our cost position. As I just said, we are investing significantly in the modernization and automation of our US manufacturing facilities. We do that primarily to further improve the quality and reliability of supply for our customers, including to enhance our ability to respond to any future potential shortage situation. But we also do that to enhance our cost position. Given the softer market environment, we have decided to adjust production and staffing levels at our US manufacturing sites to a larger degree and earlier than originally planned. The majority of this adjustment will be achieved by canceling open positions and reducing temporary staff. In total, a low triple-digit number of positions will be affected. B, further broadening of our product offering. The continued investments in local manufacturing infrastructure will enable us to enter new product categories. In addition, further strengthening our R&D capabilities will allow us to at least maintain our current run rate of new product launches. Both initiatives are meant to give us larger scale, enabling a more efficient and effective utilization of our expanded manufacturing capacities, and hence, increasing our cost competitiveness, at the same time, making us an ever more attractive one-stop-shop partner for our customers. And C, insourcing. Due to capacity constraints in the past we have some products that contract partners are manufacturing for us. With our expanded high-quality and cost-efficient manufacturing capacity, we will insource several of those products in the course of 2020 and beyond.

To wrap up on Kabi North America, we are continuing with investments at our US plants to support our strategy of sustainable, profitable growth in the US market.

Over to biosimilars, where the rollout of Idacio is well on track. We have entered four additional countries during Q3 and are now active in nine European countries in total. Sales ramp up and pricing of the products are broadly in line with our expectations.

And let me remind you that we have always been crystal clear that we expect a very limited financial contribution from biosimilars this year. At the same time, we have always said that 2019 is a very important year for this new Kabi business, and our first market entries in Europe will provide us with some real-life experience and further insights that'll shape our operational approach for 2020 and beyond. In parallel, we are making good progress for planned market entries outside Europe and the US, which could be sizable opportunities for us. And with all our molecules, we are making consistent progress in terms of preparation and documentation, all in line with our expectations.

Let me briefly cover our transfusion medicine and cell therapies business. The TCT division was created earlier this year to better reflect the requirements of an ever-more agile business environment and to serve this unique and increasingly global customer base end-to-end. We're very pleased with the financial performance of this new division and are convinced that it has many opportunities for sustainable growth. By now, we have concluded our strategic review and have decided that the TCT business will remain an important part of Fresenius Kabi. We are determined to continue to invest in the division's development. And so we will rigorously drive the expansion of the business organically, but also with opportunistic bolt-on acquisitions and cooperations.

On a more general note, Kabi has grown significantly across the globe over the last years. We have not only increased our market shares, but also expanded our product portfolio. As part of our global production strategy, we constantly assess all our production sites and take measures to address their long-term competitiveness. As in the past, this may lead to adjustments of our worldwide production network going forward.

With that, onto **Slide 5** and an update on Helios, starting with Helios Germany, where our investment initiatives are making great progress. Nurses: we are very pleased that we have continued to attract a meaningful number of nurses also in the third quarter, quite an accomplishment after achieving our full year target to hire around 1,000 nurses at the end of the second quarter already. Against the backdrop of nurse shortages all over Europe, this is clearly testament to our strong reputation as an employer and, at the same time, endorses our improved and streamlined recruitment process. So we are reasonably happy with the overall number of nurses in our German hospitals now. But obviously, we will continue to hire nurses to fill positions opening due to normal fluctuation. And that brings me to our nursing academies. We will continue to invest into these academies with the clear target to cover future staffing requirements predominantly via our own training capacities. We are convinced that this will increase employee loyalty and hence retention and also decrease costs of hiring. And it will also further improve medical quality. We view our network of nursing academies as a key competitive advantage in the German marketplace.

Coming to chief doctor vacancies, we are pleased to have refilled those vacancies responsible for the weakness in admissions since summer of last year, tick in the box. Of course, in a large hospital network like ours, there will always be some fluctuation. But this is now back to a level we would view as normal. Obviously, the new hires have to properly establish themselves locally in order to gradually recapture the patient volumes lost. But we're happy with the progress we've made.

Coming to the general trend from in- to outpatient services, the gradual transformation of our outpatient centers is proceeding according to plan. We are investing into those centers with a focus on advanced medical-technical equipment and on ambulatory surgery. Low-severity cases can then be treated in our ambulatory surgery centers, freeing up capacity for more severe cases at our acute care hospitals.

The 3.66% DRG inflator for hospital services in 2020, that underpins the favorable reimbursement environment in Germany. That level is a record high. However, as in the past, whilst this is a good starting position, the final price increase materializing for us will be lower, as it is subject to negotiations at the state level.

Over to Helios Spain on **Page 6**. As I said at various instances, Helios Spain is rigorously leveraging organic and inorganic growth opportunities. So in Spain, we have opened two outpatient centers in Toledo and Algeciras to further complement our already strong network. Quirónsalud has also acquired a plot in the metropolitan area of Barcelona where a new mid-sized hospital will be developed. We plan to open that new hospital by 2022. And this will clearly strengthen our hospital network in an important and attractive region. But we're not only leveraging our growth opportunities in Spain, also in Latin America, where we are very pleased with the progress of our more opportunistic expansion strategy. We have strengthened our presence in this region with two further acquisitions in the attractive private hospital market in Colombia. Clínica Las Vegas and Clínica del Prado are two centrally located hospitals expanding our presence in Medellín, a major city of 2.5 million inhabitants. Those two facilities have a total of about 300 beds and generate annual sales of approximately €50 million. And on this occasion, I would also like to confirm that all our Latin American hospitals are performing well in line with our expectations.

That brings me back to the German hospital market, where we are currently seeing some consolidation tendencies gaining momentum. We are closely monitoring this development and will take a closer look at any suitable opportunity. Those acquisitions, in Latin America as well as potentially in Spain and Germany, are nice bolt-on deals which deliver attractive risk-adjusted ROIs. But they should not be seen as a replacement for our plan to enter a third or maybe even a fourth European country.

Summing up, we have seen a solid financial performance to date in our investment year 2019. We have delivered on our commitments, and that is also what we will do in Q4.

With that, let me hand you over to Rachel. Thank you for now.

Rachel Empey: Thank you, Stephan. A warm welcome to everyone. Overall, Q3 was another solid quarter in our investment year 2019.

The results are shown in our usual fashion, so before special items, including the operating result of NxStage, and prior-year figures are adjusted for the divestitures of Care Coordination activities at Fresenius Medical Care. They also exclude IFRS 16 effects. A comprehensive overview of all special items and adjustments is in the appendix of this presentation. And the effects from IFRS 16 are shown on Slide 8 and in detail on slides 48 and 49.

So let's switch to **Page 8** and our key financials. Growth rates on this slide are on a constant currency basis. We delivered strong and consistent sales growth of 6% in Q3 and year-to-date. Particularly pleasing is the consistent organic growth across the group.

EBIT showed a decline of 1% in Q3, mainly driven by three factors. Fresenius Medical Care had, as in Q2, a negative impact of the decreasing savings rate for ESCOs paired with adjustments for accounts receivable in legal dispute. Those effects were only partially offset by a gain on a remeasurement of FMC's investment in Humacyte. Secondly, at Kabi, the softer development in North America impacted the EBIT line and was only partially offset by an excellent development in the emerging markets. And thirdly, at Helios, investments to counter the regulatory headwinds continued to weigh on the profitability in Germany.

For good order, group EBIT was slightly positively influenced by a low double-digit million euro foreign exchange transaction gain. That effect is shown in the corporate/other line of our segment reporting. So overall, we've managed to offset some negative one-timers with some positive ones in delivering our overall results.

So with €124 million, interest decreased year-on-year by 15% in constant currency. Main drivers of the year-on-year decrease are favorable market conditions, refinancing activities, and foreign exchange effects. We now expect the interest result to be in the range of €510 million to €530 million for the full year, excluding the effect of IFRS 16. That's €30 million less than we had expected back in Q2, primarily because of effects at Fresenius Medical Care and some currency effects. Therefore, the effect on the group's net income growth at constant currency is only minor.

The guidance relevant group tax rate before special items reached 23.1% in both Q3 and year-to-date. That was in line with our expectations. For the full year, we confirm our expectation of a tax rate between 23% and 24%.

Moving onto net income, which came in at €453 million in Q3, that's flat year-on-year and brings us to a net income year-to-date which is also at prior-year level. Hence, we are fully in line with our full year expectation and, as I said, all in all, a solid Q3 performance.

Page 9 illustrates the Q3 2019 momentum at our four business segments. The results are presented in the guidance relevant fashion. Let's start with Kabi. The company showed healthy 5% organic sales growth, but a soft 1% EBIT growth. The outstanding emerging markets development offset the weakness in North America entirely as far as sales were concerned. At EBIT level, the emerging markets only partially offset the weakness in both Europe and North America. Helios with very strong 6% organic sales growth. We've seen that the hospital business in Germany continues to show stability, and for the first time in quite a while, we've seen positive admissions growth. In Spain, our marketing activities resulted in higher admission growth than expected, and therefore, our EBIT development was impacted. So don't be concerned by the fairly high percentage rates. We are talking about small absolute figures. Vamed is plowing ahead again, excellent growth rates.

So let's turn to **Page 10** for a review of Fresenius Kabi's organic sales growth by region. Starting with North America, here, we saw a 4% organic sales decline. This decline has to be read against a very strong prior-year comp with a tremendous 12% organic growth. However, sequentially, we have seen a nice growth of 7%. Nevertheless, we are facing a further easing of tailwinds from drug shortages and an increasingly intense competition for selected molecules. Given this development, we reduce our expectation from low single-digit growth to a slight decline for the full year. In Europe, we have seen a nice acceleration of 4% organic growth, yet again driven by dynamic growth momentum of our enteral nutrition business, but also supported by a very pleasing performance across all product groups. To be fair, the prior-year quarter was also a softer comp. With 3% organic growth year-to-date, we feel comfortable to confirm our low to mid-single-digit organic sales growth expectation for Europe for the full year.

So moving onto emerging markets, and that's on **Slide 11**, here, the emerging markets continue to shine, again with an acceleration, this time to 17% organic growth, especially fueled by an outstanding performance of our clinical nutrition business. China with a remarkable 18% organic growth in Q3. We continue to see very healthy double-digit volume growth coupled with low single-digit price declines, which leads to very significant organic growth. For emerging markets as a whole, with an outstanding 15% year-to-date organic sales growth, here again, we confirm with even more conviction our clear double-digit organic sales growth expectation for the full year.

So let's turn to **Slide 12** and Kabi's regional EBIT development. Total EBIT came in at €306 million, an increase of 1% at constant currency in Q3. Total EBIT year-to-date was €917 million, an increase of 4% at constant currency. And overall, the top-line trends are obviously also reflected on the EBIT line.

North America: we've seen a year-on-year decline of 8% over a very tough prior-year quarter, which had an outstanding 16% growth. The decline is obviously driven by a significant easing of drug shortages and that increasingly intense competition. Considering what Stephan said with respect to the longer-than-usual production shutdown, we cannot exclude that we will see a somewhat softer margin in Q4.

Moving onto Europe, which showed an 11% decrease in Q3 2019, but again, of course, on relatively small absolute numbers. Various small one-time items in our production facilities, as well as seasonal effects, had a negative impact on our EBIT line. And please keep in mind that we launched Idacio in Europe this year, which leads to a slightly higher SG&A profile compared with last year. We expect that, with the seasonal effects not recurring in Q4, the EBIT line will also improve slightly.

Emerging markets, with an outstanding growth of 34% in the third quarter this year, although over a weaker prior-year comp, that brings the year-to-date growth rate to 24%. We are very pleased by the consistent strength of Kabi's emerging markets business and the broad-based positive development across all subregions and product groups.

Corporate and R&D costs at €129 million saw a 3% increase year-on-year. Excluding biosimilars, we continue to expect an increase of R&D expenses for the full year. Year-on-year, we have seen slightly lower biosimilars expenses. Sequentially, however, those biosimilar expenses have increased significantly. And we expect a further sequential increase of those biosimilars expenses in Q4. But we will stay clearly below the prior-year level of €166 million. This is definitely no read-across for the progress that we are making in this business. Much rather, this is within the scope of the usual volatility of R&D expenses.

With that, let's turn to Helios on **Slide 13**. Organic growth at Helios accelerated to 6% in Q3, bringing the year-to-date growth to 5%, and thus at the upper end of our outlook of 2% to 5% growth for the full year. Helios Germany showed very strong 5% organic sales growth in Q3. We are pleased to see that admissions growth turned positive despite the very hot summer in Germany this year, testament that our countermeasures are materializing. For good order, sales growth was inflated by roughly 1 percentage point due to a technical reclassification of nursing staff funding from other income to sales. Over to Helios Spain, where we have seen healthy organic sales growth of 9% in Q3. As I said, our marketing activities resulted in higher admissions growth, but of course, on very low absolute figures. With 7% organic sales growth year-to-date, Helios Spain now even exceeds its historical organic sales growth range of 4% to 6%.

Moving onto **Slide 14,** where we see an overview of the EBIT development at Fresenius Helios. Total EBIT came in at €183 million in Q3, a 10% decrease year-on-year, bringing the year-to-date rate to a minus 7%. This is slightly below the outlook range of minus 5% to minus 2%, but fully in line with our expected phasing of growth. We will see a significant acceleration of growth in Q4 as the positive effects of the initiated measures to counter the regulatory headwinds at Helios Germany will start to show first positive effects. And frankly, we have some softer comps at Helios Germany from Q4 of last year. Helios Germany had an EBIT of €130 million and a decrease of 9% year-on-year in Q3. The EBIT margin contracted to 8.8% and was mainly triggered by costs for the implementation of those measures to counter regulatory headwinds, as well as ongoing investments into our outpatient centers and occupational health centers. We continue to prepare ourselves to capitalize on the trend from acute care to more outpatient care. Year-to-date, our EBIT margin is at 9.7%.

At Helios Spain, EBIT declined by 5% or €3 million to a seasonally reduced level of €56 million, affected by some smaller one-time items and higher costs due to a better than originally anticipated admission development. To handle the more-than-expected incoming patients, we had to make use of temporary workers. Year-to-date though, EBIT growth is still pleasing with an increase of 5% and a margin of 12.4%.

Over to Fresenius Vamed on **Slide 15**. We are pleased with Vamed's Q3 2019 performance. And for the first time in 2019, we are now comparing apples with apples, given that the transfer of the post-acute care business closed at the beginning of Q3 2018. Total sales showed accelerated 18% year-on-year growth in Q3, resulting in a tremendous 48% growth year-to-date. If we strip out the acquired German post-acute care business, organic growth year-to-date was still excellent with 24%. As far as sales development is concerned, both of Vamed's business lines performed very well. While the service business increased sales by 11%, the project business showed stronger phasing with an increase of 32% in Q3 this year.

EBIT growth was strong with 10% in the quarter. And the 33% year-to-date growth rate is significantly positively affected by that transfer of the post-acute care business from Helios. Order intake in Q3 more than doubled, and also, year-to-date, we see a significant growth of 30% to €738 million. That bodes well for the growth of the project business for the coming quarters.

Let's move onto cash on **Slide number 16**. Strong Q3 with €1.298 billion of operating cash flow for the group. Fresenius Medical Care's Q3 cash flow accelerated to healthy €715 million. More details later from Mike. Kabi posted an excellent Q3 cash flow of €362 million, top left. A very strong Q3 margin of 20.6% took the last 12 months margin to 13.4%. At Helios, we saw a nice 43% year-on-year increase, the good cash flow of €183 million improving the last 12 months margin to 7.0%. So for the group, the Q3 performance took the group last 12 months margin to 10.4%. Deducting group CapEx of 6.6% in the middle column, you'll arrive at a free cash flow last 12 months margin, bottom-right, of 3.8%. CapEx is obviously inflated in our investment year and therefore weighing on our free cash flow.

Including the acquisition of NxStage, we ended the quarter at 3.13x net debt to EBITDA as a ratio. Our expectation for 2019 is unchanged. We expect this leverage ratio around the upper end of our self-imposed target corridor of 2.5x to 3.0x net debt to EBITDA, of course, including the acquisition of NxStage and excluding the IFRS 16 effects. Hence, we are anticipating some deleveraging in Q4.

With that, let's turn to the 2019 outlook by business segment, which you find **on Slide number 17**. So starting with Kabi, 4% organic sales growth year-to-date for Kabi as a whole. Thus, we confirm our outlook range of 3% to 6% organic sales growth for the full year. However, we believe the top end of that range is now less likely. In Q4, the emerging markets are unlikely to reach the heights of Q3, and we do expect the softness in North America to continue. Onto EBIT, here, with 4% growth year-to-date, we leave the guidance range for the full year unchanged at 3% to 6% growth. However, considering the softness of the North American business, we feel that the lower end of that guidance range is now more likely.

For Helios, in terms of organic sales growth, with 5% growth year-to-date, we feel confident to confirm the outlook range of 2% to 5% for the full year. Please keep in mind that Q4 will be slightly softer since the Christmas and New Year holidays are completely on working days. Nevertheless, on the back of the strong year-to-date performance, we think that the upper end of the guidance range is now more likely. As far as EBIT is concerned, we've seen an EBIT decline of 7% year-to-date. Taking into account the more material positive effects of the initiated growth investments, the softer comps for Helios Germany in Q4, as well as the consistent growth of Helios Spain, we feel confident to confirm our outlook range of a 2% to 5% decline for the full year.

And then Vamed, with 24% organic sales growth year-to-date, and considering the company's well-diversified order book, we feel confident to confirm the outlook of around 10% growth and now believe that a result of more than 10% is likely. We also confirm the 15% to 20% EBIT growth guidance.

So taken together for the group, and that's on **Slide number 18**, starting with sales, we have a 6% growth year-to-date, and we are confident to confirm our guidance of 4% to 7% constant currency growth for the full year. As we indicated in Q2, we believe the lower end of the range is less likely, but at the same time, the tailwinds we need to hit the very top end seem not to be materializing. Over to net income, we feel confident to confirm our expectation of earnings growth of around 0% for the full year. As we said in the Q2 earnings call, we continue to hope to avoid negative income growth for the full year 2019.

We've had to absorb some negative effects which were not included in the original earnings guidance, namely the earnings dilutive effect of NxStage and the negative effects from Fresenius Medical Care's ESCO and receivables adjustments. On the other hand, we have also seen some positive one-time-like items, such as the Humacyte effect and FX gains and the biosimilars and North American revaluations in Q2. So net-net, we remain on track. As to the currency translation effect, if current exchange rates prevailed until the end of the year, we would see a tailwind of 2 percentage points, mainly from the US dollar, and that's applicable for both sales and net income.

With that, I'd like to say many thanks for your interest. And Stephan and I are happy to take your questions.

Q&A Session

Operator: We are now starting the question-and-answer session.

Veronika Dubajova: Good afternoon, and thank you for taking my questions. I will keep it to two please. I was hoping to start with Kabi North America and sort of two parts to my question. One, Stephan, you alluded in your prepared remarks to Q4 '16 maybe being a good proxy for how things play out. From memory, that was roughly a 30% margin. Is that what you were hinting at and we should be bearing in mind for the fourth quarter?

And then more conceptually, thinking about 2020, I know you've given some very headline guidance for the business, but I just wonder if you can give us sort of the moving parts for Kabi North America that we should bear in mind as we move into next year, in particular when it comes to profitability.

I'll leave at that, and I'll ask a follow up after that, if that's all right.

Stephan Sturm: Thank you, Veronika. Q4 '16, as a matter of fact, so a margin just above 30% for Kabi North America, that would be a meaningful drop, but at the same time, I can't and don't want to exclude it. Something in that magnitude is factored into our internal models that underpin our guidance.

More structurally, moving parts are essentially those that I have been referring to over the course of this year as well, so development of shortages, development of new product launches, development of the opioid market, buying patterns from our major customers.

I was referring earlier in my prepared remarks to our assumption, and I think it is a valid assumption, that we're going to see the same pricing pattern as we've seen it historical. So the key moving bits that I was referring to are largely volume related.

What you're going to see, 2021 is our new investments in the plant infrastructure kicking in. So at the same time as we're having expanded capacities, we will also be looking at a somewhat larger depreciation charge. In order to offset that depreciation charge, I was very consciously talking about insourcing. I think, overall, operating leverage, scaling, and better distribution of our overheads at these manufacturing plants is key.

I was briefly talking about new product launches. You will have heard at least between the lines that I feel pretty good about the number of new launches because we have been doing a reasonably good job in at least replenishing our ANDA pipeline. At the same time, I have spelled out very clearly that we continue to focus rather on small- to medium-sized molecules.

That is a variety of the moving parts that we need to watch out for. Obviously, North America year-to-date has been somewhat below our expectations from the start of the year. We are adapting to what we believe is a temporary softness in volume demand. We are adapting to it pretty proactively and decisively. And therefore, we I believe we're going to enter 2020 with a -- from a fairly strong position. I hope that gives an answer to your question.

Veronika Dubajova: If I can just follow up on that, Stephan, I guess we've all been surprised by the top-line development year-to-date in North America. Would you expect next year to return to more normalized rates of growth, or do you still see risks as you think about the first half or next year that the growth maybe trends below what we might have been used to, that kind of mid-single-digit range?

Stephan Sturm: Very specifically, as to the first part of 2020, Veronika, it's very difficult to say. All I can tell you is that I would not be surprised if we saw more volatility along the way. I cannot rule that out. At the same time, I'm asking -- even though it's a tough ask, I'm asking for a bit more of your patience. We will be going, as every year, through our very detailed bottom-up budgeting process. And I really want to take a look molecule by molecule what we are -- what my friends at Kabi have in the hopper in terms of new launches, contract extensions, you name it. But again, from this year, where we clearly have seen a performance that is below our expectations is -- it is very difficult to tell you with conviction now that everything's going to be over in the first quarter of 2020, that I won't go that far.

Veronika Dubajova: Understood. Thank you. And then if I can switch tact briefly to Germany, I was intrigued to hear your comment on the consolidation tendencies or signs that you're seeing in the market. Anything you can share with us that -- where is that consolidation coming from? And how long until we might see you guys execute some transactions, if any?

Stephan Sturm: I will not disappoint you by not giving you specific targets, of course. But it was still remarkable from my perspective that, in a relatively short period of time, we have been confronted with a few situations, whereas beforehand, there was a complete drought. I want to say, given the regulatory headwinds that we're currently facing in the German market, we arguably are going to be even more disciplined than before. I would point you -- and what that specifically means is that we would be looking even more for regional synergies for our ability to enter into clusters, for the ability maybe to forego CapEx with such a consolidation project that otherwise we would have to do organically. But frankly, the lowered valuation that is also pretty obvious in our share price, that also needs to translate into valuation expectations for any such project. So I wouldn't be talking about it unless there was truly a bit higher activity level in the marketplace at the same time. It's by no means a given that we will transact.

Veronika Dubajova: Understood. Thank you very much.

Stephan Sturm: Thank you.

Tom Jones: Good afternoon. Thanks for taking my questions. I had just one quick one on Kabi. In the past, you've been prepared to give us an indication of the number of ANDAs you currently have sitting at the FDA. If you can, it'd be great if you could go there again.

And the second question really relates around Helios. With the changes to the DRG system coming in next year, it's been clear for some time what you're going to lose from each DRG rate in terms of reimbursement. But it's been far less clear on what exactly you're going to be reimbursed for in its stead. So I was just wondering if -- how much visibility/line of sight do you have going into 2020 on what specific care costs will be reimbursed in 2020 and kind of what kind of certainty that gives you regarding the outlook for 2020?

Stephan Sturm: Tom, the answer to your first question is easier than the one for the second. It is 57.

On your second question, there is still some residual uncertainty here. And I believe we will all learn a little as we go in the first parts of 2020. At the same time, as I indicated over the course of this year so far, as you would expect, we have run various scenarios in our models. And at this point in time, I would like to reiterate that the gross effect of the regulatory change with regard to the carve-out of nursing cost is a high double-digit million euro EBIT amount. And as we have indicated, at the same time, over the course of this year, we believe that we have identified tangible countermeasures to about half that gross amount. And that is where we continue to stand.

Tom Jones: Perfect.

Stephan Sturm: The net effect from that carve-out is going to be rather mid to then low double-digit million euro EBIT, which does not mean, for the avoidance of doubt, that we would expect a decreasing EBIT for Helios Germany next year. Also here, I'd like to stick to what I was indicating earlier from today's perspective, and still from today's perspective, we would expect that EBIT at Helios Germany is going to be about at the level of 2019.

Tom Jones: Perfect. And then just within that one quick follow up, obviously, the DRG rate or the headline number of 3.66 sounds great on paper, but it is a little bit of a double-edged sword because it's based on wage cost inflation. Usually, by now, you've kind of concluded your wage negotiations for the forthcoming year. So I just wondered if you could give us any color on what you expect your unit wage costs to grow in 2020.

Stephan Sturm: Tom, it is going to be at the same -- at about the same range, same level of magnitude as we have seen it in the past. I -- anything above that would be a surprise and a disappointment. But I'm asking for your understanding for those negotiations that we still have to lead. I do not want to be too transparent.

Tom Jones: Okay. That's very fair. I'll jump back in the queue and let someone else ask some questions.

Stephan Sturm: Thank you, Tom.

Julien Dormois: Hi, good afternoon, Stephan. Good morning, Rachel. Two quick questions on my side. One is just a clarification of what you said in your preparatory remarks about the benefits from the shortage situation in the US. I don't know if I got you right, but you -- did you basically say that, at the moment, you're not benefiting anymore from any kind of shortage? Did I got it right? So would that mean that, entering 2020, this would not be a source of concern on your side?

And the second question relates to the drivers of the stellar growth you get in emerging markets at Kabi. Is there any way you could help us reconcile where that's coming from? Is that majority volume coming from your nutrition portfolio, or is that also related to some kind of geographic expansion, to potential market share gains, or the broad earning of the product portfolio? So any insight here would be particularly helpful.

Stephan Sturm: Julien, you will appreciate I need to hedge myself at least a little bit. And so from time to time, there's a bit of a softener in my statements. But you got it, with regard to your first question, essentially right, as I was saying that there are virtually no shortage benefits left right now.

As far as your second question is concerned, Kabi emerging markets is predominantly Kabi China. And when we're talking about the growth -- and Kabi China is, to a very large degree, clinical nutrition, both enteral and parenteral. And when we're talking about growth there, then it is predominantly -- I'm sorry, then it is almost exclusively volume growth, which typically is offset by low single-digit annualized price erosion. That has been the theme over the years, and I'm very happy to keep on watching that.

Julien Dormois: Okay. Thank you.

Stephan Sturm: Thank you, Julien.

Patrick Wood: Perfect. Thank you very much. I have two, please. The first would be for the devices in the transfusion business. Obviously, very healthy step up in growth there. And I gather, obviously, EM has a part to play in your recouping some of the investments that you've put on that side. But it would just be helpful just to get a little bit more color on, from your mind, the durability of the growth there. And I'm not talking about just a Q4 thing. I'm just thinking about how you're thinking about that business over the next couple of years following the review that you guys took, just a view of how you -- a feeling about that and a durability of growth over time would be helpful is the first one.

Second one's a lot smaller. Just curious if we should read much into the Neupogen court ruling and what I should think about for my biosimilars numbers. I don't think I had Neupogen in there, but just in case, whether that's something that we should be thinking about from the aggregate biosimilars number that you gave a couple of years ago. Thanks.

Stephan Sturm: Thank you, Patrick. On transfusion, as I said in my prepared remarks, we have concluded a fairly thorough strategic review. We're happy with the growth prospects of that business, and we are basically reassured that what our thinking was at the time of the Fenwal acquisition 2012 essentially continues to apply. Yes, we are looking at a higher number of minimal invasive and therefore less blood-consuming types of surgery. And yes, we're also seeing a lower supply coming from blood donations. But at the same time, that market has continued to consolidate, not only on the demand, but also on the supply side. And therefore, what we would continue to expect is a growth rate that would be slightly below the Kabi average, but at the same time, would see less of a volatility in particular as compared to the growth that we're seeing in our North American injectables business. That is a characteristic that we enjoy, that we value also from an overall Kabi portfolio perspective. What did play quite a role in our strategic deliberations was our product pipeline, has been our product pipeline, as I should say, where we see quite some good new developments, where we would expect a further stabilization of demand going down the road.

As far as our biosimilars overall numbers are concerned, also here, I would like to ask you for your patience. We're happy with the development that we've seen year-to-date. But we are currently busy preparing bottom-up, molecule by molecule, our planning for 2020 and beyond. And I would like to give you a much more detailed update as part of our Q4 results.

At the same time, with regard to the specific case that you're mentioning, this has not been brought to my attention as something that would stand in our way in the short term.

Patrick Wood: Perfect. Fair enough. Thanks, guys.

Stephan Sturm: Thank you, Patrick.

Michael Jüngling: Thank you and good afternoon. I have three questions in relation to Kabi, please. Firstly, on heparin, can you comment why heparin for you is growing so strongly in the third quarter, despite I think Fresenius sending out a letter in July to customers limiting the allocations due to swine flu? I'm just curious what the situation is and whether you think the strong heparin growth can continue for the remainder of the year.

Question number two is, for the US in 2020 or Kabi US, would it be correct to assume that the major growth driver is likely to be Fulvestrant with an opportunity of maybe sort of €50 million to €100 million, if you can sort of confirm the idea that that drug is going to be critical for your growth in North America?

And then thirdly, on biosimilars, can you comment on what the sales were in the third quarter and what you've learned so far in terms of maybe the skills that you need to acquire to become more successful in biosimilars in Europe? Thank you.

Stephan Sturm: Thank you, Michael. I believe, as far as heparin is concerned, the swine flu phenomenon has been pretty visible already for quite a while. And as most participants on this call will probably also know, most of the raw material for heparin is coming out of China. We have a variety of sources, and we saw this coming early. We feel pretty well prepared, but at the same time, what we did expect with quite some lean time then also materialized. And that is that there is a bit of a shortage of supply. And therefore, at that time, primarily as a precautionary measure, we were telling our customers that we would be taking a look at historical demand and make sure that everybody would get a fair share.

As far as the implied EBIT is concerned, I still would like to stick to my statement earlier when I was answering Julien's question in that there are virtually no benefits left. The raw material cost has surged in line with the ASP. And therefore, I am not looking at a meaningful extra EBIT contribution.

Michael, before I hand you over to Rachel for your biosimilars question, I'm sorry, as far as individual products are concerned, you know our policy. In order to protect our competitive position, I really would like to stay away from commenting on individual molecules. Thank you for your understanding.

Rachel Empey: Hi, Michael. Rachel. For your question on biosimilars, so as a reminder, I think we've been very clear. 2019, if you like, is our launch year. As you heard from Stephan earlier, we're now present in nine markets in Europe, in line with our plans. But nevertheless, for the full year, we are expecting a very limited financial contribution coming from biosimilars sales.

Just launching in the country is not the only thing you need to do. You clearly need to be, let's say, properly established within the selling processes, tendering processes. And that just takes a little bit of time. So we are not expecting a significant contribution this year. And with that in mind, the Q3 sales I would put at the very low single-digit million end of the spectrum. But as we said previously, very clearly in line with what we were anticipating.

In terms of the skills you asked about in terms of success going forward in biosimilars, we have discussed that it is a mixture of skills that we already have in terms of our positioning within the hospital network and with the relevant purchasing parties there, but also more broadly with further specialists, for example, skin specialists, where we have previously been less represented, and clearly making sure that we are positioning our products in terms of its ease of use and the differentiation that we are able to take within the biosimilars market and making sure that is well understood, as we build our brand and build our overall position as a player within that market. We are pleased with the progress so far, but clearly are looking forward to the ramp up in the nine countries where we've launched and then step by step in further countries over time.

Michael Jüngling: Okay. Thank you, Rachel. Can I just follow up? When do you expect the ramp up then in 2020? Is it a 2020 event where you might be able to get maybe €20 million or so in sales or maybe even a bit higher?

Rachel Empey: So I think those two things that are important, it's the ramp up within the countries where we are and then the further rollout into further countries, but we do expect a nicely steep curve in 2020 with a further acceleration in '21.

Michael Jüngling: Thank you.

Falko Friedrichs: Thanks for taking my questions. I also have two, please. Firstly, can you speak about the measures you implemented to attract more patients in Spain in the quarter, despite the pretty warm weather? And can these help in the upcoming quarters as well?

And then secondly, also on Spain and Helios, you said EBIT was impacted by cost for temp workers. Given the apparently higher volumes, do you plan to hire more people there so you don't have to really on these temp workers in the quarters to come, or was this just a Q3 effect?

Rachel Empey: Thank you for your questions. I'll take both of them. I think, in the Spanish market, the Quirónsalud brand is very well known in terms of its attractiveness to patients and patient satisfaction. And that has been over time a very important lever of our success.

Percentage growth rate in the third quarter can always be, I would say, a little bit exaggerated because the overall volumes themselves remain very small. But I would say we've been more successful than we had anticipated in our activities over the summer in attracting patients to do elective activities beyond just emergency treatment. And that has made that small absolute difference, but relatively high percentage difference in the quarter.

To your point in terms of the temporary workers, again, a relatively small impact from an absolute million euros perspective, but nevertheless making an impact on the percentage EBIT growth. Clearly, that is something that we are constantly looking to address in terms of optimizing the usage of our hospitals over the summer, but at the same time, optimizing the cost base which we have to serve those patients. And that is obviously something that we constantly review on a hospital-by-hospital, even specialism-by-specialism area to try to optimize. And that is clearly something we will continue to do every quarter, but particularly in the summer quarters, where those volumes are particular difficult to manage.

Falko Friedrichs: Okay. Thanks very much.

Stephan Sturm: Falko, let me complement that by saying that, to some degree, this is demand driven, but also supply driven. So encouraging some of our staff, some of our key doctors to change to a somewhat different routine as far as holidays is concerned is also part of the equation.

And as far as your second question is concerned, as you would expect, we are encouraged by the effects that we have seen, and we will closely monitor -- continue to monitor this and obviously jump on opportunities that do present themselves. But it's a bit too early to say that this is truly something consistent, and therefore, bear with us. Thank you.

Falko Friedrichs: Okay. Thank you.

Sebastian Walker: Hi there. Thanks for taking my questions. I've got three if I could. So on Kabi North America, can you maybe give some more details to what underpins the assumption that pricing pressure won't accelerate in Q4?

And then also on Kabi North America, just in terms of the pressure that you're seeing, is that exclusively coming from Hospira reentering the market, or are you seeing some of the kind of challenger or nontraditional players there?

I'll leave the Helios question for afterwards.

Stephan Sturm: Sebastian, thank you. We have seen a pricing development, but for very few individual molecules. That is consistent with the historical trend. Frankly, I couldn't point you to a catalyst for a changed assumption.

And as far as your second half question is concerned, this has primarily to do with competitors returning to the market after shortage situations and to a much lesser degree with new market entrants.

Sebastian Walker: Great. Thank you. And then just the last one on Helios Germany. So could you give an update as to whether there are any other regulatory proposals or discussions ongoing that we should be aware of, for example, expanding the scope of staffing requirements or anything like that? And if you have a timeline on when those decisions would get made, that would be very helpful.

Stephan Sturm: This, on the one hand, is a fluid environment. At the same time, we do get the impression that there is a bit of a standstill in terms of legislation for at least a little while. So I am not aware of any meaningful new legislative initiative, at least not as far as -- or including not as far as staffing levels is concerned. But obviously, with regard to our budget for 2020 and beyond, we'll have a close eye on this and would obviously put that into the equation. But for now, the answer is no, and I am also not aware of anything being in the process.

Sebastian Walker: Great. Thanks very much.

Stephan Sturm: Thank you, Sebastian.

James Vane-Tempest: Hi, thanks for taking my questions, please. Just firstly, you mentioned last quarter I think you could be in a more competitive positioning on pricing for some of your US injectables products. So I was wondering if this is still the case, and was that a contributor to lower margins in 3Q?

And then secondly, just on Kabi, you stated you're now not seeing any benefit from shortages in your prepared remarks. But I guess, when looking at some of the industry data, it appears that the number of shortages has actually remained quite high in the industry. And some of your competitors have been able to continue to benefit. So I'm just curious why you aren't able to capitalize on the industry opportunity.

And then my final question, if I can, on Helios Spain. Again, to come back to some of the other questions here, you did mention higher temporary staffing. But can you comment on the overall wage inflation you're seeing and how we should think about profitability next year? Thanks very much.

Rachel Empey: James, I will start on your first question in terms of pricing trends in Kabi North America in the last quarter. So Stephan commented somewhat in his prepared remarks already. We saw a low to mid-single-digit price erosion in the third quarter, which was a slight acceleration from what we had seen in the preceding quarters. But nevertheless, we still had, I would say, a more volume-driven evolution in the third quarter than associated with price. And of course, to some extent, that did have an impact on the margin. You should also remember that there was a one-timer in the Q2 margin, which means, if you're doing the quarter-on-quarter comparison, the Q2 margin was somewhat inflated. So nevertheless, I would say that low to mid-single-digit price erosion is not unusual and is what we believe is a sustainable level, given the trends that Stephan was describing in quite a lot of detail in his prepared remarks.

Stephan, I don't know if you want to comment on the second question around industry trends.

Stephan Sturm: James, remind me of the industry trends. What did -- specifically were you interested in?

James Vane-Tempest: Yes, thank you. Just reclarifying, I guess, as you said, you weren't seeing any benefit --

Stephan Sturm: I'm sorry, the shortage benefits. Now I got it. The overall headline number, that is what I alluded to in my prepared remarks. That has come down slightly but is still meaningful. The number of situations that relate to us, so where the underlying molecule is part of our product offering, that has decreased pretty meaningfully. And those situations that are still formerly on the shortage list from our perspective have resolved to a very large degree and are very close to normalized market shares already. So relative to the situation that we were looking at primarily or in particular over the course of last year, where one of our largest competitors was to a very large degree shut out of the market, this is now a completely different situation.

As far as Quirónsalud is concerned, I would like to tell you that qualified nurses are a very scarce resource, not only in Germany, but across Europe, and hence also in Spain. We had alluded to a wage inflation becoming or already being a factor now also in Spain already on prior occasions. I believe that this is still at a level that is manageable. At the same time, we will also take a very close look at this when it comes to our budget process. And the profitability at our Spanish facilities is healthy. And I am encouraged by the patient and admission growth that we're seeing. As you know, this is also to quite some degree a fixed cost business, where operating leverage does play a role, and therefore, I would not be working on the assumption that wage inflation will have a very meaningful impact on our profitability.

James Vane-Tempest: That's really helpful. Thanks very much.

Stephan Sturm: Thank you. Thank you for your interest today. We kept the prepared remarks deliberately a bit shorter and reserved a bit more time for your questions. Hopefully, that did accommodate you. And we will work away, as I alluded to on various occasions now, no our budget planning, but at the same time, we're not going to lose sight of the performance in Q4. And as both Rachel and I said, we are absolutely determined to deliver on our commitments. Thank you for your interest. Thank you. We'll see many of you on the road in the coming days. Best of luck. Thank you.

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