FRESENIUS

Transcript
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PRESENTATION

Markus Georgi: Thank you. Good morning and good afternoon, all. Welcome to the Fresenius Fiscal 2017 Q2 Earnings Call. I'm joined today by Stephan Sturm. Stephan will first provide a business update and then review the financial results for the quarter. After Stephan's comments, we'll open the call for the Q&A session. Before we begin, I'd like to remind listeners, please pay attention to our usual disclaimer, which you will find in the presentation. Without any further ado, I 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. Markus has pointed out the safe harbor language to you. So let's move right to page 3.

We're pleased to report that the strong start to 2017 did not ease in Q2, but rather, for the group, we continue to see healthy double-digit top-line growth, with strong contributions from all our business segments. Development of our bottom line is consistent with that. Also, in Q2, net income growth has remained north of 20%. On the back of these strong results and with bright prospects ahead, we feel very comfortable to confirm our group guidance. The integration of Quirónsalud is progressing smoothly. And our new colleagues' financial performance is fully in line with our expectations. And even though, strictly speaking, it's already a Q3 highlight, I am thrilled to welcome Rachel Empey, our new Group CFO. Throughout the search, she has impressed us not only with her financial expertise and sound strategic thinking, but also with her engaging personality. I expect her to add a few
new perspectives. And at the same time, I'm convinced she's an excellent fit for us. It took a bit longer until Rachel was able to join, but she's absolutely worth the wait. Today's call comes a bit too early for an active contribution from her, but I'm sure she'll join me for our Q3 call.

Let's move to page 4 and our Q2 key financials. As always, the group rates shown on this slide are on a constant currency basis and before special items. So they are directly comparable to our group guidance for sales and net income. We've delivered sales growth of 17% in Q2, towards the upper end of our guidance range. Quirónsalud this quarter consolidated for the entire three months contributed, 10 growth points. EBIT growth was 13%, so below sales growth. That's mainly due to some nonrecurring burdens at Fresenius Medical Care and currency swings. Leading to some transaction losses didn't help either. Rice and Mike will explain later. But net income at 21% growth in Q2 again substantially outpaced the top line. Also here, Quirónsalud made a substantial contribution.

Let's take a look at the group P&L on slide 5, where the growth rates are also shown at constant currency and before special items. Sales growth, you've heard it, was 17% in Q2 as well as in the first six months. And EBIT growth was a very solid 19% in the first half. Even excluding the VA agreement at Fresenius Medical Care, we're looking at a strong 14%. And that's despite Quirónsalud only being consolidated for five months. Net interest was €169 million in Q2, up €30 million year-over-year, primarily due to the Quirónsalud financing. It was also up €12 million sequentially because Q1 net interest reflected only two months of Quirónsalud financing costs. So Q2 is a much better proxy for the second half, but needs to be adjusted for euro strength. Based on current exchange rates, we now aim for €650 million to €670 million for the full year. That's €20 million less than last time we spoke, primarily because of currency effects and a small contribution from FMC's successfully amended credit agreement. Therefore, the effect on the group's net income growth at constant currency is minor. The group tax rate was 27.9% in the second quarter, in line with our expectations. For the full year, we continue to expect a tax rate between 28% and 29%. Q2 earnings growth of 21% has taken us to 23% in the first half, so still above our full-year guidance range. When Fresenius Medical Care's VA agreement helped our outperformance in the first quarter, a few one-timers there have weighed on our Q2 results. And when the Easter effect helped us in Q1, it has worked against us now. And yet we're at 21% growth, the upper end of the range, admitted helped by an accounting item at Kabi that I'll explain in a minute, but also that is one time in nature. What will stay to help us are full-quarter contributions from Quirónsalud.

Page 6 illustrates the momentum at our four business segments. Sales growth rates shown on the left are organic for ease of comparison to our individual guidance ranges. And EBIT growth on the right is at constant currency and before special items. All of our businesses have made a positive contribution again, and we're very pleased with that. Let's start with Kabi, 7% top-line growth, a repeat from Q1, and a meaningful step up to 9% EBIT growth, albeit over a soft comp I'll explain in a minute. HELIOS at just 2% organic sales growth, that's the effect of Easter being in Q2 this year, but in Q1 last. In my mind, the blended 4% organic growth in the first half are a better reflection of the underlying dynamic. EBIT growth of a massive 63% obviously reflects the first-time consolidation of Quirónsalud. Excluding this acquisition effect, EBIT growth in the first half was still at a very solid 8%. And I guess also you are familiar now with the larger fluctuations in Vamed's quarterly sales and EBIT growth, triggered by its lumpy project business and somewhat smaller absolute numbers. Before taking a more detailed look at Kabi, HELIOS, and Vamed, a brief word on Fresenius Medical Care. In Q2, EBIT couldn't keep up with solid sales growth. As already mentioned, a few special items were weighing on earnings, including some adverse currency transaction effects. Underlying, FMC is progressing well. The company is firmly on track to meet its full-year guidance. But more details later in the FMC call.
Let's turn to page 7 for a review of Fresenius Kabi's organic sales growth by region. North America, a strong organic growth of 9% in Q2 on the back of a softish prior-year comp, though, taking us to 6% growth year-to-date, fully in line with our expectations. A brief update on market shortages. At the end of Q2, 17 Kabi IV drugs were designated in shortage, up from 15 end of Q1, so fairly stable, maybe even bottoming out. But despite that, our model and guidance assumes a gradual easing over the second half because we note the FDA’s new commissioners’ focus on ensuring strong generic competition. We therefore have also factored in market share losses and price pressure in some of our key molecules. That is the nature of this part of the industry and underpins the enormous value that generic drugs generate for American patients and taxpayers. Good momentum on new product launches, three in Q2, leading to four so far this year, relative to our guidance of 10 plus for the full year. We have indicated in February that this year’s pipeline was rather backend loaded. So we continue to be well on track.

And so with 6% organic growth year-to-date and considering our expectations on shortages, competition, and product launches, we feel comfortable to confirm our guidance of mid-single-digit organic sales growth for the full year. Specifically for the third quarter, please bear in mind that we’re working against a much tougher comp because of last year’s daptomycin launch and our wholesale partners stocking initial inventory. Over to Europe, where we’ve seen healthy organic growth of 4% with a broad-based positive development across virtually all product segments. With 6% organic growth year-to-date, we feel very comfortable to confirm our low to mid-single-digit outlook. Actually, we’re still aiming for the upper half of this range.

And over to slide 8 and the emerging markets, where we’ve seen yet another quarter with a strong performance in China, 12% organic sales growth. Progress on the introduction of the new tender rules remains slow. Only about half of the provinces have concluded a tender process so far. But we still expect a fairly comprehensive implementation by yearend. In our minds, that should trigger price erosion in the low to mid-single digits as a full-year effect for 2017. At the same time, we continue to expect double-digit volume growth. And as a result, we remain confident of sustainably attractive sales growth in this key market. In India, the nationwide introduction of VAT, or GST as they call it, from the 1st of July, that resulted in distributors destocking inventory in June. And that effect was weighing on sales growth in Asia ex-China. But I’m sure that effect will correct itself in the third quarter. And also, yet another strong quarter in Latin America and Africa, 8% organic sales growth despite a tough prior-year comp. So for the emerging markets as a whole, 10% organic growth in the second quarter has taken us to just above 10% in the first half. And given bright prospects ahead, we feel comfortable to confirm our outlook of at least 10% organic sales growth for the full year.

Let's turn to slide 9 and Kabi’s EBIT, where total EBIT at the bottom of the page came in at €309 million, a strong increase of 9% at constant currency. For good order and to avoid overshooting expectations for the full year, Q2 last year was a particularly soft comp. You will recall me pointing you to the lower IFRS versus US GAAP earnings base as part of our earnings call in February. We also provided a reconciliation showing the delta primarily resulting from us writing off certain R&D projects that were capitalized originally as part of our APP acquisition in 2008. Now the major part of that full-year delta occurred in the second quarter last year, thus lowering the comp base. Adjusted for that accounting effect, Kabi’s Q2 EBIT growth was broadly flat and, with that, very much in line with our expectations. Let's take a more detailed look at the regions, from top to bottom. Europe was flat in Q2, not exactly what we hoped for, but also not the end of the world. It is primarily product mix effects and delays at a major medical device order. We now expect the bulk of
that order to materialize in the second half, with maybe some spillover into early 2018. And so we project a material acceleration of growth in the second half and feel comfortable to confirm our mid to high single-digit growth expectation for the full year, albeit now rather mid than high single digits.

North America, with the expected acceleration to 11% year-over-year growth, driven by last year's IFRS write-down, though. Adjusted for that, EBIT growth was broadly flat, also here as expected. For the full year, you heard me anticipating more competitive entries and pointing you to a tough Q3 comp, given last year's launch of daptomycin. On the other hand, I do expect a stronger Q4, given our backend-loaded new product launches and last year's planned shutdowns at our Grand Island and Melrose Park facilities. So given these factors and assumptions and 4% growth year-to-date, we feel comfortable to confirm our low to mid-single-digit EBIT growth expectation for Kabi North America.

The emerging markets, with a fairly soft 5% EBIT growth in the second quarter, there, we were up against a tough prior-year comp, and the VAT introduction in India took its toll. Thus, we chose to invest into an expansion of our salesforce in Asia ex-China. I'm sure there'll be a return on that expense in the not-too-distant future. Overall, we feel reassured by the robustness of Kabi's emerging markets business. Q2 has turned us even more optimistic, at least gradually. And given 15% EBIT growth in the first half, we're confident that, also for the full year, we'll be in the double digits. With minus €81 million, corporate and R&D costs are 2% lower than in 2016. Due to the acquisitions of Akorn and Merck, we'll see a changed phasing of R&D projects or even a replacement of current R&D platforms. Hence, we still expect broadly flat year-over-year development in corporate and R&D expenses for the full year.

Over to page 10 with an update on the acquisition projects we announced end of April. Akorn filed its Q2 results last night, no doubt, below what I would've hoped for. But this is a volatile industry. Swings like this happen, in particular at smaller players. We thoroughly analyzed and discussed results and driving factors with Akorn's management last week. And on that basis, we continue to believe in our expectations for 2018, as communicated at the time of transaction announcement.

Why is that? A) as I said a few minutes ago, revenue erosion in existing products is a well-known fact in the generics business, not a real surprise for us so far. All along, we were expecting more competitive pressure on ephedrine and other key molecules in Akorn's portfolio. We just need to watch where this bottoms out. B) with regard to the supply disruptions Akorn mentions as weighing on its Q2 performance, we also expect these will lessen in the second half. Plus, we'll be there to help this particular issue after closing. C) whilst some planned drug launches are delayed, Akorn's pipeline remains robust. Obviously, any delay always bears the risk of being late to market formation. We believe, though, that in quite some instances, Akorn still has a good chance to be first to launch. And so delay by no means necessarily leads to lower 2018 revenues. And D) whilst the direct-to-consumer campaign for TheraTears scheduled for the fourth quarter will weigh on this year's earnings, we view it as a good investment into 2018 and beyond. So taken all together, whilst I would've preferred a stronger Q2, our expectations for 2018 sales and EBITDA remain unchanged.

But let us put aside Akorn's Q2 results for a moment. In a sense, they even confirm our strategic rationale for the transaction. And I'd like to take this opportunity to remind you of that. The Akorn transaction was always planned as a defensive and an offensive step at the same time. Defensive means, further expanding and enhancing our already leading injectables franchise and, with that, leveraging our already strong institutional market
access. Our broader and deeper product portfolio will help us become ever more relevant to the powerful purchasers on both the institutional and retail sides of our business. Offensive means diversifying our product portfolio into adjacent segments with strong growth. Take ophthalmology and dermatology as examples and getting access to new distribution channels, such as retail pharmacies and clinics. Onto the actual acquisition process, you will have seen our July 20 investor news. Akorn shareholders have approved the merger agreement with a vast majority. 99.7% of all votes cast were in favor of the transaction. With that, the most fundamental closing condition is fulfilled. No surprise, we have received a second request from the Federal Trade Commission in the US. That's standard. We knew that, as a result of the antitrust probe, we will have to divest a number of smaller products. So far, no surprises in our dialogue with the FTC. We have taken a rather conservative approach as to how long it might take us to complete these imposed disposals. And that was driving our expectation that the acquisition would only close in early 2018. But actually, the divestiture process has already started, and we’re seeing good interest. And whilst getting management control fast has always been a priority, it has now even grown in weight. I believe our new colleagues at Akorn will benefit from our support, and we’re ready to provide it as soon as the transaction closes. And I believe that is now more likely to be the case still this year.

The Merck biosimilars transaction is fully on track, and we expect a closing later this quarter. Bigger picture, regulatory environment for biosimilars, we feel there is increasing evidence for our basic underlying hypothesis, namely that there will be a clear pathway and a level playing field for biosimilar applications. The US Supreme Court decision from June with regard to the BPCIA is good for patients and for us. With regards to the pipeline we’re going to acquire, all clinical studies are well on track. All processes are running smoothly. It doesn’t feel like our transaction announcement has created major uncertainty, let alone disruption. Specifically, adalimumab is well on track. And we expect to file ada under our name for approval in Europe in Q4 this year.

Now let’s turn to Fresenius HELIOS on slide 11. Bottom left, 2% organic sales growth at HELIOS Kliniken in Germany in Q2, yes, a bit soft, but well anticipated, given Easter was a Q2 event this year. As I said before, I believe the 4% in the first half are a much better reflection of the underlying dynamic. Top left, HELIOS concluded wage agreements in the second quarter and has now substantial planning certainty until yearend 2018. The average increase of 2.5% per annum is fully in line with our budget/planning assumptions for 2017 and ’18. On the back of our recent decision to build a proton beam therapy center at Quirónsalud in Madrid, we have now resolved to do the same at HELIOS in Berlin for an estimated amount of €35 million, scheduled for opening in 2021. It will be the first facility of this type in northeastern Germany, also here, good for patients, good for us.

Over to Quirónsalud, which is consolidated since February 1st this year. We’re very pleased with the financial performance in the first five months, solid 11% sales growth year-to-date. And that can be roughly split half and half between organic and nonorganic growth. EBIT growth exceeds sales growth, as it should be. Drivers are general operating leverage and a growing contribution from synergy projects related to the original merger between IDCsalud and Quirón. All very well, but I remain keen to ensure you’re not getting carried away by Quirónsalud’s strong year-to-date performance. As I said post-Q1, please don’t extrapolate. Don’t take a cue from our German hospital business. There is a much more pronounced seasonality in Spain. And the typical summer break is bound to take its toll on Q3 sales and earnings. Most to-be patients are on holidays and visiting their families. Also, doctors and nurses are concentrating their vacation on the summer months. You know that the vast majority of medical interventions are elective or planned. So by and large, only emergency
cases are treated during summer. And given that, from a financial perspective, Q3 will be light.

Onto slide 12, with an overview of the EBIT development at Fresenius HELIOS. Total Q2 EBIT came in at €282 million, up 63% year-over-year, and also margin wise, solid improvement to 12.6%. Q2 EBIT growth of 3% for HELIOS Germany, also affected by the shift of the Easter holidays. The 8% growth for the first half are a much better proxy of the underlying growth rate and consistent with our guidance. A very solid €104 million contribution from Quirónsalud in the second quarter. With only five months of consolidation, Quirónsalud already managed to achieve 57% of the midpoint of the expected guidance range. But you heard my caveat with respect to the summer break. I would not be surprised if Q3 EBIT came in at less than half of a normal quarter. Take Quirónsalud's year-to-date performance as a strong start indeed, but we will maintain our full-year guidance.

Over to slide 13, with a brief update on the Quirónsalud integration process as well as further growth prospects. The joint analysis of procurement terms for goods being used in both organizations has been successfully completed. On that basis, we have already entered into new contracts. For example, a procurement contract for lab disposables is already renegotiated and signed. Quirónsalud is a highly professional and truly well-organized company. And we feel great openness to share expertise, but also to learn and to compare our experience on medical practices. And I'm confident that that will drive synergy benefits going forward. The company has bright growth prospects. Just two examples, first, the €50 million greenfield project in Córdoba, a 115-bed hospital with state-of-the-art medical equipment and care. Opening is expected for 2018. And second, the expansion of the Madrid University Hospital in Pozuelo with an investment volume of approximately €30 million. Opening of the new areas there is scheduled for 2019. Just two flagship projects, in line with our well-communicated growth strategy, good for patients, good for us. Finally, let me highlight Quirónsalud's solid position in the Spanish market. While delivering excellent financial results, Quirónsalud has built highly regarded and extensive hospital network as well as an ORP division quite that are leading their markets in terms of size with quite some lead. Those market positions have been and are built to last. Beyond the many facilities Quirónsalud does own, where I don't see how they could be replaced, the company holds an enviable position in public-private partnerships. We do the necessary investments and, on that basis, deliver high-quality healthcare and, yes, receive an appropriate return, good for patients, good for us. Our investments are protected by contract maturities running up to 2041. And they aren't challenged. Why would they be? Quirónsalud continues to deliver highest medical quality and care to its patients and continues to enjoy an excellent reputation. That not only but in particular applies to the four public hospitals operated by Quirónsalud in Madrid. In recent years, these hospitals continuously ranked in top positions in the annual patient survey carried by the Healthcare Authority of Madrid. And for 2016, we just received the results. And once again, Quirónsalud excelled. The University Hospital Fundación Jiménez Díaz in Madrid was ranked the best hospital throughout Spain for the second time in a row.

Over to Fresenius Vamed on slide 14. Q2 sales growth of 2% is a reflection of the typical quarterly fluctuations of Vamed's rather lumpy project business. Rather positive volatility in EBIT, but I'd rather focus on the 6% year-to-date growth than the 22% in the second quarter. Strong order intake, even though it could not quite match 2016's excellent level. We're optimistic for the second half, also because that order intake again showed some nice regional diversification. New orders, for example, from Papua New Guinea, Mongolia, and they have taken Vamed's order backlog to a new all-time high, a sound basis for growth in the project business in the second half and beyond.
Onto slide 15, and yet again, a very solid cash flow quarter, with a massive year-over-year growth rate of 21%. Kabi posted a Q2 cash flow of €203 million, top left. A 12.7% margin is strong for a second quarter and took the LTM margin to 16.9%. I’m very happy with that. At Fresenius Medical Care, we saw the expected sequential catchup after those transitional timing issues in the first quarter. And group operating cash flow at the bottom of the slide of €1.2 billion took the LTM margin to 12.2%. Deduct CapEx of 5%, middle column, and you’ll arrive at a free cash flow LTM margin, bottom right, of 7.2%. So we remain close to the upper end of our historical track record.

With that, let’s turn to slide 16 for the 2017 outlook by business segments, and Kabi’s organic growth first. On the back of a good first half, we stick to our guidance range of 5% to 7%. That’s the blend of the regional contributions I mentioned. Low to mid-single digits for Europe, skewed towards the upper half of that range. At least 10% growth for the emerging markets, coupled with mid-single digits growth for North America. And on EBIT, we also stick to our guidance range of 6% to 8%. I gave you the reasons for the expected low to mid-single-digit EBIT growth in North America and the mid to high single-digit growth in Europe, albeit now more towards the lower end of that range. Blend that with our slightly improved outlook for the emerging markets, where we firmly expect double-digit growth, and our expectation of broadly flat corporate and R&D expenses, and you’ll get there.

For HELIOS, in terms of organic sales growth, 4% year-to-date, smack in the middle of our 3% to 5% guidance range. So we feel good to confirm that. And for EBIT, we’ve built quite a cushion for the expected light Q3 in Spain, and so we firmly stand behind our guidance range of €1.020 billion to €1.070 billion for the full year. Vamed, yet again, Vamed’s large and well-diversified order book gives us confidence for the traditionally stronger second half of the year. And therefore, we feel good to confirm the guidance ranges of 5% to 10% each for sales and EBIT growth.

Take all that together for the group, and that’s now on slide 17, with 17% sales growth in the first half, we have good reasons to believe in our guidance range of 15% to 17%. And that’s on constant currency. As to the currency translation effect, if current exchange rates prevailed until the end of the year, we’d see a headwind of 1 to 2 percentage points, mainly from euro strength/dollar weakness. Net income, with 23% net income growth in the first half and 21% in the second quarter, we fully confirm our guidance range of 19% to 21% in constant currency. Also here, as of today, we expect a 1 to 2 percentage points currency headwind. In the good Fresenius tradition of no surprises, at least no bad ones, let me reiterate that we expect the soft summer quarter of Quirónsalud to take its toll on growth of the group’s top and bottom line. So we expect Q3 to be a somewhat light quarter, but we expect to end the year with quite some strength.

With that, I’m happy to take your questions. Thank you for now.

Operator: Ladies and gentlemen, we are now starting the question-and-answer session.

Patrick Wood, Citi.

Patrick Wood: Hi there. Thank you very much for taking my questions. I guess the first one, to be boring I’m afraid, is on Akorn. Appreciate the supply issues. I was wondering if you could give us some color around the size of those. The reason I’m asking is, if we consider Q3 and Q4 to look more like Q2, obviously, that would require very large growth rates in 2018 off the 2017 base to hit the midpoint of the guidance range. So I was wondering if we could sort of understand a little bit about the supply issues and what it was during that conversation that made you comfortable maintaining your guidance 2018.
And then secondly, on top of that, if you could give us a sense for Akorn how many molecules you expect generally to sort of come through in 2018, should that look like a normal kind of year for Akorn because it's quite a backlog there, or should that be a better year than you think the typical average? Thank you.

Stephan Sturm: Thank you, Patrick. And no, you're not boring at all. Yes, I am afraid have to be a bit boring. But as you know, Akorn at least for the time being is a separately listed entity. And my legal advice is that I must not go beyond what the company has filed itself. And therefore, for the size of these supply disruptions, I'm afraid I can't help you with a public answer. But as I said in my prepared remarks, and actually, as we said already at the time of transaction announcement and ever since, one of the key observations during due diligence has been that the company is capacity constrained, probably because they have been capital constrained. And that is why, in my prepared remarks, I was making a mention of the fact that we are going to be there to further lessen these issues, should they still prevail at the time of closing. As far as new product launches are concerned, Patrick, also here, I'm afraid I'm not going to be very constructive. I will say just that, in good Fresenius and Fresenius Kabi tradition, we will provide you with that outlook at the appropriate point in time. And that's going to be at the start of 2018, namely as part of our full-year earnings call. Sorry about that.

Patrick Wood: That's quite all right. If I can cheekily try for one more then, on Quirónsalud, obviously, you've got the 12.5% margin structure for the full year, assuming I've understood correctly. If Q3 comes in, let's say, at around about half or maybe just under half of Q2 at the EBIT level, at least by my math, that should still put you somewhat towards the upper or slightly above end of that range. I know you don't want to talk numbers up in that way, but would we expect around a 5% or more margin for Q3 at Quirónsalud? I'm trying to work out how much the seasonality drops through the unmovable OpEx, so to speak.

Stephan Sturm: Patrick, I'm sorry, but also here, you heard us confirm a fairly narrow guidance range, and that for Quirónsalud in itself stands at €300 million to €320 million. I think that is a fairly narrow guidance range in particular for the first year of a company's consolidation, when we still have got to know each other a bit more. I think I was alluding to a bit more upwards pressure within that range as part of the Q1 call. So at least qualitatively, I narrowed that range even more. But beyond that I really don't want to go today. I think this is as specific as you'll find it somewhere in the market.

Patrick Wood: Sure. Had to try my luck. Thank you for taking my questions. Thank you.

Stephan Sturm: Thank you, Patrick.

Operator: Veronica Dubajova, Goldman Sachs.

Stephan Sturm: Veronica, you're on mute.

Operator: Ms. Dubajova, your line is open.

Veronica Dubajova: Hello? Can you hear me now?

Stephan Sturm: Yes, we can.

Veronica Dubajova: Excellent. Apologies for that. I'll now say good afternoon and thank you for taking my questions. My first one's also going to be on Akorn. And, Stephan, I appreciate
you can't comment on the operational performance until you own the business. But maybe can you walk us through some of the assumptions that you had made for ephedrine specifically when you were looking at the target and when you provided that 2018 guidance? What did you assume in terms of the number of competitors, the market share loss, and the pricing development? And to the extent that you can talk about what happened with ephedrine in the second quarter, help us contrast and compare that. I think that would be quite helpful today. And then my second question is on the Kabi Medical Products Division, which seems to be -- I think, so far, as I look at the growth rate year-to-date around 5%, that seems a pretty meaningful acceleration from what the historical trend has been. Can you give us a little bit of insight into what's driving that and how sustainable that growth might be? Thank you.

Stephan Sturm: Veronica, at the risk of again letting you down, but you are obviously aware of the general policy that we're not going to go into detail on an individual product. I will still try not to let you down completely, but to say that the number of competitors in ephedrine was known at the time of announcing the transaction. And you should work on the assumption that we have not assumed the status quo as far as that number is concerned. We are no novices in this part of the business. And therefore, yes, we did assume market share losses. We have experienced that ourselves on very many occasions and also price pressure. When we -- when I would've hoped for a somewhat higher Q2 result, you should take from that, that market share loss and also price pressure came about a bit faster than originally assumed. In our minds, that by no means necessarily will lead to a lower market share and price point for 2018. The way towards that assumption for 2018 has been a bit steeper than originally assumed. But again, that does not mean in our minds at all that our 2018 assumption now all of a sudden is rendered unrealistic. Much rather, given cost positions in the industry, I would like to believe that we have taken here a very sensible approach.

As far as medical products business is concerned, you are right. We're happy with the run that we're having. The -- when we look at some of the product innovations that we have brought to the market, albeit still small, we're seeing a good reception by our customers. What we have to admit is that, obviously, this growth comes over a somewhat lower base because you will recall that, on the blood bag side of the business, there was more severe price pressure than we had assumed at the time of the Fenwal acquisition. And therefore, that growth, that stabilization is now coming over a somewhat depressed base. As far as our pump business is concerned, we continue to enjoy a good ride. And you heard me talk about a large, but unfortunately a bit delayed larger order for that pump that we believe to quite some degree is going to materialize in the second half. We have a very good pump product in the market here in Europe. And as you know, one of the key focus areas right now, but also spilling into 2018, is to make that product more compatible with US market practice so that we can replicate the success that we do have in the European arena also there. Is that helpful?

Veronica Dubajova: Yes, that's incredibly helpful. Geographically, is that growth being driven more by the US or Europe today or rest of the world I guess?

Stephan Sturm: I would -- look, I don't have the specific numbers off the top of my head, but I think, given that that's the case, I would give you a safe answer by saying there is not much difference in the growth profile between the different regions, and none of them truly stands out.
Veronica Dubajova: Fantastic. Thank you, Stephan. And a quick housekeeping one, any further charges you anticipate in the second half of the year for either Akorn or biosimilars that we should be putting into our models?

Stephan Sturm: We have guided you to €50 million of biosimilars R&D expense that we would treat outside our guidance, and that estimate still stands. And we had also guided you to €50 million transaction expenses related to both transactions that we’re also treating separately below the line. Also, that guidance remains valid.


Stephan Sturm: Thank you, Veronica.

Operator: Tom Jones, Berenberg.

Tom Jones: Good afternoon. Thank you for taking my call. I have three, if that's all right. The first was just on the move at the FDA to speed up the process of generic drug approvals. And it's kind of a two-part question really. One, do you think this is going to end up being a net positive or a net negative for the industry in your business? I guess, on one hand, if the FDA approves drugs quicker, that's good because you can get more products out to the market in a shorter timeframe. But on the other hand, it would -- could likely speed the pace of price erosion and share loss in the post-launch phase. So just wondering kind of how you're thinking about that and whether it results in any change in R&D strategy for you because I guess, at the moment, the name of the game is to be first to file. But if the FDA gets sat together and speeds things up, that becomes less important. Second question, just a housekeeping one, wondered if you could give us the D&A figures for Quirónsalud in Q2. Just wanted to compare those to Q1, which you very kindly gave us. And then the third question is just on your capital structure of the business. You've given us, obviously, the levels of leverage you expect at the group level. But FMC seems to be tracking a little bit light on the acquisition front, and it is progressively deleveraging. They're down to the 2.2 range now, which effectively means the leverage at the stub side is going up. And on a kind of a gross debt-to-EBITDA basis by my calculation, you're kind of at a run rate of around 4. And then with the Akorn and biosimilars acquisitions, which sort of net off against each other in terms of EBITDA, you'll get more debt, but not much EBITDA in the short term. That could end up, given your guidance of 3.3 for the group, end up creeping up towards sort of 4.5, maybe even a little bit higher. And just wondering kind of how that level fits with you and how that influences your ability to perhaps do more M&A, albeit maybe on a smaller scale, over the next 12 to 24 months.

Stephan Sturm: Well, Tom, thank you. Those have been, with the exception the housekeeping one that I'll try and get out of the way quickly, some pretty comprehensive questions. In the second quarter, we're looking at a D&A charge at Quirónsalud to the tune of €45 million.

On the FDA, you heard my comment, and that probably has triggered your question. But we can't help but see that Commissioner Gottlieb is really stressing the point of more generic competition in the industry. Now first and foremost, in our minds, that is going to help generics over and above the patented original products. And the generic market as a whole, in our minds, is going to grow in volume. That, by the way, is also a good reflection of my comments as far as biosimilars regulation is concerned. And I would expect that, in general, we're going to get a regulation that is more pro cheaper, but just as effective generic drugs. When so far we have held the view that much of the increased effort by the FDA was focused on solid doses, we have not seen much change in that respect as yet. However, we
have reason to believe that the FDA is now taking on also with quite more vigor the liquid sphere of the generics field. And as I have said, I think all along at least for quite a while, as one of the largest incumbents in that market, obviously, with lowered barriers to entry, we have a bit at stake here that we may lose. On the other hand, with one of the richest pipelines in the industry -- and there again, I want to point you to the Akorn acquisition, which first and foremost we were buying for the pipeline rather than for ephedrine -- we feel that we are in a very good position. Is that, if it really materialized, going to change our R&D strategy? No, I don't think so. It's much rather going to change and will continue to drive, I should rather say, our manufacturing strategy. We have always been a bit more risk averse than many of our competitors. You will find hardly any Paragraph IV filings or at-risk launches bearing our name. And I have no interest in revising that. But what we do believe in is that, just as much as the FDA is likely to alleviate barriers to entry, they will be more and more stringent when it comes to quality requirements on the manufacturing side. And therefore, what we have set out to do already for quite a while is to spend meaningful amounts of capital to get ourselves in the position that our manufacturing is best in class and that we try our utmost to remove any possibility of human error in the so precarious manufacturing process of liquid drugs. Last week, right after my visit to Akorn's management, I spent a full day at our Melrose Park facility. I wanted to see for myself with an update as to what we're doing there. I'm very pleased with the progress that the team is making. In the not-to-distant future, we will have a first-rate manufacturing facility there. That will put us in a position to be quality leader and cost leader at the same time. And that makes me confident about our sustainable success in that market.

Lastly, on the capital structure, and, Tom, you're right in your observation that leverage between Fresenius Medical Care and the rest of the group is a bit drifting apart. That is not the first time that happens. I want to remind you of the fall of 2008, when right after the APP closing, FSE ex was trading at a 5.0 in a particular quarter, 5.0 net debt to EBITDA. And you know that, even at the worst possible time, we managed to delever fairly rapidly. I believe that you will agree with me that, as far as strategic initiatives outside Fresenius Medical Care are concerned, we have started quite a number of them. And not so much for capital constraints, but rather for management capacity constraints, I'd like to focus on properly closing the acquisitions, integrating them, and making them deliver the benefits that we are hoping for. And look, this is first and foremost a question to our debt providers. And they're the rating agencies and the banks as a good proxy. You know that we are operating at our highest credit rating ever, that the rating agencies did not blink when we had the announcement of Quirónsalud, biosimilars, and Akorn. Right now, we are in the market with a so-called Amend & Extend of our credit agreement. We're getting a very good reception for a transaction that will lengthen the maturity profile and decrease the margins that we're paying. So I am not worried about that, given that our debt providers don't seem to be worried about that either.

Tom Jones: Perfect. That's a very comprehensive answer to a couple of comprehensive questions. So thanks very much.

Stephan Sturm: Thank you, Tom.

Operator: Lisa Clive, Bernstein.

Lisa Clive: Hi, good afternoon. Just one question on Akorn and then some of the other divisions. Clearly, you haven't adjusted your guidance for your forecast for Akorn for next year. Your Q2 results were perhaps not outside of the range of what you expected could've happened. But in the scenario that something unexpected did happen, are there any claw-
back provisions in the structure of the transaction? Also, what about any breakup fees if for any reason the transaction doesn't close?

Second question on other areas within Kabi, can you give us a brief update on the progress of the three-chamber bag launch now that that product has been reformulated for the US market and I believe sort of properly relaunched?

And then lastly, if we just sort of think about the white spaces in the Kabi portfolio, obviously, you're going to be having your hands full with Akorn. So it may be a while. But what are the sort of nearer-term priorities? I understand you've recently or relatively recently ramped up your sales of IV generics in Latin America, for example. But am I correct in thinking you don't really have any clinical nutrition down there? I'm just trying to understand sort of, what are the opportunities beyond the US market?

Stephan Sturm: Lisa, to your first question, frankly, I'm not even thinking about that. This is a transaction that we have done, and I hope we did a halfway decent job in explaining to you to prepare Kabi for the next decade. I think I made it clear I also would've hoped for a better quarter. But what is a quarter for the strategic rationale that I hope we have laid out for you? Anyway, to your question, this is a customary public transaction in the United States, where Akorn's shareholders have given their approval in the meantime. There is no reverse breakup fee. There are customary material adverse change provisions in there. But for the avoidance of doubt, I am not under the impression that we have been fooled, tricked, that anything untoward has happened here.

As far as the three-chamber bag is concerned, yes, I would call that one of the white spaces because, given the success that we're having with this product in Europe and notably also in China, the North American market is a white space. Yes, you're right. We were relying originally on a too aggressive timetable. We underestimated what the FDA was looking for. But that is long behind us. What this is now about is to get the right formulation, what US market practice or medical practice I should say is looking for, and to convert a long tradition among US medical practitioners how to go about parenteral nutrition. We are optimistic, given the reformulation, that we can accelerate our market presence there. However, let me be -- let me also say that there's virtually nothing of that built into our forecast for Kabi in the second half. If it happened, it would be a positive surprise. And I guess we're also going to remain fairly conservative for 2018. This is not the end of the world. We are in this for the long run. And you may recall the mother of all slides, how I called it, at the time of the Akorn announcement, where we're shooting for an ever more comprehensive product portfolio in the US. The three-chamber bag is going to be part of that. If we take a cue from what happened to us in China, then yes, it will take a while to get key opinion leaders to recognize that this is a superior product. But at the end of the day, this could easily be a leading category for us.

White space in general, as a matter of fact, yes, irrespective of the good success that we're having in the emerging markets and notably China in particular there, I do recognize quite a few areas where I would like to see us establish or broaden a presence. You were referring to more IV generics in Latin America. Well, we have a manufacturing presence in both Chile and in Brazil. But obviously, in a growing market like this, you should watch for probably growing capacities. And given the political uncertainty down there, I'm wondering whether we should act countercyclical and to do some more investments. But at the same time, I'm even more bold about the prospects of our Asian markets outside China. You heard in my prepared remarks that we have done a very conscious investment in growing our salesforce out there. So that is an investment that's going through the P&L. And you will also note that the recent activity at Kabi was very much focused on North America and Europe. And when I
was talking about us being rather management capacity constrained, that doesn't seem to be the case to me for Fresenius Kabi in the Asia-Pacific region. And I will be more than happy to support more organic growth there.

Lisa Clive: Great. Thank you.

Stephan Sturm: Thanks, Lisa.

Operator: Gunnar Romer, Deutsche Bank

Gunnar Romer: Gunnar Romer, Deutsche Bank. Thanks for taking my questions, a couple remaining. First, again, on Akorn, I very much appreciate the comments you have made so far. And sorry in case I’ve missed it. But I was wondering whether you or the Akorn management have reacted to the weaker-than-expected development in the second quarter by launching any additional cost measures or alike. Second question would be on the planned filing of ada in Europe. I appreciate this is planned for the fourth quarter. Can you help us understand how we should be thinking about the presentation of data from the trial? And also, in that context, if you can briefly remind us of your strategy and the timeline for filing in other territories. And then third question, housekeeping one on guidance, will you officially adjust your group net income guidance for the additional R&D spend after closure of the Merck biosimilars deal? Thank you.

Stephan Sturm: Thanks, Gunnar. I have to be brief on Akorn, very obviously, given that we do not own the company yet and that we’re going through an FTC review at the moment. We must not go about any cost cutting measures. As far as the company’s management itself is concerned, again, I will have to defer you to their filing.

As far as adalimumab is concerned, yes, when, well, we plan to file for approval in Europe in the fourth quarter under our name, given that we do expect, as I said, to close the transaction by the end of Q3. I believe that we can give you an update as to where we stand as part of our full-year results next February. I believe that I also made it clear at the time of announcement that the focus, the geographical focus of our biosimilar efforts is going to be the US. I still wanted to bring this up as a point to reassure you that everything on this side is working as good as it can. As far as the guidance is concerned, no ultimate decision yet, Gunnar, but in line with past experience, I would work on the assumption that we’re going to give you a fully loaded number, but at the same time, provide you with all the transparency you need to strip it out, in case you and/or your investor clients have a preference for looking at it on an adjusted level.

Gunnar Romer: Okay. Thanks. And just a quick follow up, what does your current FX simulation suggest in terms of FX impacts on sales and net income for 2017, please?

Stephan Sturm: 1 to 2 percentage points headwind, both.

Gunnar Romer: All right. Thank you.

Stephan Sturm: And that is on the basis that the current exchange rate, so $1.18 roundabout, prevails for all of the second half.

Gunnar Romer: Thank you.

Operator: Michael Jungling, Morgan Stanley
Michael Jungling: Thank you, and good afternoon. I have three questions. Firstly, on US ANDA approvals, are you concerned that you have not received any material ones year-to-date? And should we expect a more powerful approval sort of drugs in the second half? Secondly, on daptomycin, can you describe the absolute sales trend in April, May, and June? IMF suggests it’s pretty stable. Is that a true reflection as to what you’re seeing in your business? And then question number three is on --

Stephan Sturm: Michael, we're losing you, or we have lost you. Are you still on? Michael? Well, he wanted to ask two questions anyway.

Operator: Mr. Jungling has disconnected his line.

Stephan Sturm: Okay. On ANDA approvals -- he's going to pick that up later in the transcript -- no, we're not concerned. We, as I said, were looking at 10-plus approvals all along. We never made any comments about the size, the magnitude of them. I think that is also a fairly risky strategy to do that. And if you had asked us some time ago what the level of revenue and earnings contribution from a drug like vasopressin or neostigmine would've been, we would've been completely off. And therefore, this is -- again, and that also frankly applies to Akorn -- this is a volatile industry, where you need to have critical mass to offset temporary setbacks. And with where we are right now, the critical mass that we have already allows us to withstand any headwind. And with the current pipeline and where we are right now, we're absolutely satisfied.

As far as daptomycin is concerned, I'm afraid I will not be able to go into much more detail, other than to say that the market trend in terms of market share development as far as -- and also, as far as price pressure is concerned is very much in line with our expectations.

Markus Georgi: Thank you, Stephan. Many thanks for your attention and joining today's conference call. If there are any additional questions, please contact the IR team. We are participating in several conferences after summer break. If you would like to meet us, give us a call or shoot us an email, and we try to make it happen. Thanks for today. Goodbye.

Stephan Sturm: And I'm looking forward to meeting many of you as part of these conferences. And that will also give me a chance to introduce you to Rachel, our new CFO. Looking forward to that. And for those who haven't been on holiday yet, have a good time. We'll speak after the summer break. All the best.

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