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PRESENTATION
Operator
Good afternoon. And welcome to the conference call of Fresenius investor relations, which is now starting.

May I hand over to Markus Georgi, investor relations? Please go ahead.

Markus Georgi  Fresenius SE & Co KGaA - SVP, IR
Thank you. Good morning, and good afternoon, all. Welcome to our Q4 and full-year 2016 conference call. With us today, Stephan Sturm.

Stephan will give you an update on fiscal 2016. Afterwards, he will explain our guidance for 2017, as well as our new mid-term targets 2020, in more detail; followed by a Q&A session.

For good order, the reported numbers of 2016 are according to US GAAP, while the outlook is according to IFRS. As you may have seen in our respective press release from December, we will report solidly in accordance to IFRS, starting 2017. We have decided to do so in the interests of harmonizing the reporting of Fresenius Group, and all of its business segments. You will find a detailed reconciliation of our 2016 results, from US GAAP to IFRS, on slide 46 and 47 of this presentation.

Before I hand over to Stephan, please pay attention to our usual disclaimer, which you will find in the presentation. After the call, a replay and the transcript will be available on our website. Now, it's my pleasure to hand over to Stephan for his opening remarks.

Stephan Sturm  Fresenius SE & Co KGaA - CEO
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.
The acquisition of Quironsalud was definitely our 2016 highlight. We successfully closed the acquisition end of last month. And our new colleagues will make a meaningful, positive contribution to Group earnings and EPS, right from being with us. Even more importantly, Quironsalud will be both a platform for future growth and a lead example for Helios, in many aspects.

With regard to Fresenius’s financial performance last year, we were, yet again, very satisfied with the large consistency across our four business segments. That has allowed us, once again, to post a double-digit earnings increase. Looking ahead, both our 2017 outlook and the new mid-term guidance should give you confidence regarding our growth prospects for the year to come.

Let’s move to page 4, and our dividend track record. Based on our earnings-linked dividend policy, we will propose to our Supervisory Board a dividend increase of 13% to 62 eurocents per share. This will mark our 24th consecutive dividend increase. And our compounded annual dividend growth since 1993 has been 16%.

Over to page 5, which shows our key financials. I believe our results bear very few surprises, so I’ll be rather short on the first slides.

Growth rates, on this slide, are on a constant currency basis. And so, we have delivered sales growth of 6% in the full-year 2016. Fresenius Medical Care’s and Vamed’s finish were a bit softer than expected, but a strong 10% EBIT growth, and at 13% net income growth, was fully in line with our guidance. Let’s take a look at the Group P&L, on slide 6, where, again, the growth rates are on a constant currency basis. Also in Q4, we have shown 6% sales growth; and EBIT growth nicely accelerated to 11%, from 6% in Q3.

Net interest was EUR149 million in the quarter; up EUR7 million from Q3, mainly due to the Quironsalud financing, as well as a bit of currency headwind. That takes us to EUR582 million for the full year, in line with our expectations. For 2017, we aim for EUR670 million to EUR690 million; an increase of, roughly, EUR100 million. The major driver behind that is, obviously, the Quironsalud acquisition financing. Moreover, our interest calculation assumes increasing US dollar interest rates, and a bit of currency exchange headwind.

The Group tax rate was 28.1% in Q4 and the full-year 2016, respectively, in line with our expectations; a bit below normal, given some non-recurring items at Fresenius Medical Care. And I’d, therefore, assume a slightly higher tax rate for 2017: likely, between 28% and 29%.

That leads us to 7% earnings growth in Q4; slightly below Q3, but that merely reflects a very tough comp. Q4 2015 had a massive 24% year-over-year earnings growth so that slowdown was well anticipated. And, accordingly, we ended the year at 13%, well within our guidance range.

Page 7 illustrates the momentum at our four business segments. Sales growth rates, shown on the left, are organic; and EBIT growth, on the right, is on a constant currency. I hope the slide convincingly illustrates the high degree of consistency I was referring to earlier, as well as our reliability, given that we made all our guidance ranges.

Fresenius Kabi ended the year with 5% organic sales growth, and 5% EBIT growth. Considering the exceptional 21% earnings comp from 2015, we believe that is quite an accomplishment.

A brief word on Fresenius Medical Care. The Company has successfully launched, or extended, several growth initiatives last year, and whilst growing its profitability. So if it’s about care coordination in the US, or Australia, enhancing innovative technology with XENIOS acquisition, or sowing more seeds for emerging markets growth in India and China, we, at Fresenius, commend and support all of these initiatives. More details on FMC later this afternoon, from Rice and Mike.

Let’s turn to page 8, for a review of Fresenius Kabi’s organic sales growth by region. In a nutshell, Europe, a notch stronger than expected; North America, with the expected soft Q4; and the emerging markets, with a very decent finish. In Europe, we have seen a nice, sequential acceleration to 4% in Q4, driven by enteral nutrition and an improving product-partnering business. 3% growth in the full year, that marks the mid-point of our guidance range. North America, minus 1% organic growth in Q4, for 3% in the full year, that’s fully in line with our guidance.

Given the massive 15% organic growth in the fourth quarter of 2015, it is great that we managed to about match that level. You will recall that the top line, at that time, was boosted by launches of key products, like NeoStigmine, and that has come under competitive pressure since.
For those of you tracking IMS data, and maybe expecting a higher number, let me remind you that IMS captures pull-through of product from wholesalers and is, therefore, phased differently to our reported sales. Our sales are typically ahead of IMS and include the earlier stocking of wholesalers ahead of launches, or following drug shortages.

On to the emerging markets, where we are pleased to report, yet again, healthy growth rates in Q4, for an aggregate 10% in the full year; also here, fully in line with our guidance. Both the 6% in Asia Pacific and the 8% in LatAm and Africa should be judged against a particularly strong fourth-quarter 2015. And with that knowledge, we are very pleased about the strong financial performance in the emerging markets.

Let's turn to slide 9, and EBIT, where total EBIT, at the bottom of the page, came in at EUR308 million; down 1% at constant currency. That took the full-year rate to plus 5%; fully in line with our 4% to 6% guidance.

Let's take a look at the regions, and start with Europe, at the top: an outstanding quarter, driven by enteral nutrition, and, after several softer quarters, an improving product partnering business.

North America, minus 15% in Q4 took the full-year growth to the low end of our 5% to 7% guidance range. The result in Q4 reflects stronger competition for key molecules; the expected ramp up of R&D expenses related to our pre-filled syringe business; and, in particular, the planned shutdown at both our Grand Island and Melrose Park facilities. We have told you that, at the end of an excellent year, we consciously extend our regular shutdown to accelerate investment at both facilities, because quality is, and will remain, key; and because we're eager to increase our production capacity to support future growth. As you know, we have been keen supporters of US manufacturing for the US market, long before it became politically fashionable.

Emerging markets have shown nice EBIT growth at 21% in Q4, for 19% in the full year; strong contributions not just from China, but also from the rest of Asia and the LatAm countries.

With EUR63 million, corporate and R&D showed the expected sequential decrease. And for 2017, based on IFRS, we probably can't prevent a slight increase year over year. That should not exceed sales growth, though.

Over to slide 10, for Fresenius Kabi’s regional outlook. North American organic sales growth and EBIT development is particularly hard to predict, given the volatility in the IV generics business. Our best estimate, at this point, is mid single-digit organic sales growth, and low to mid single-digit EBIT growth. For good order, this outlook is according to IFRS.

And in the Fresenius tradition of fair disclosure, yes, under US GAAP projected EBIT growth for North America is slightly lower, given the 2016 IFRS base being below the US GAAP number. So why aren’t we more optimistic? Well, firstly, comps for Kabi North America remain tough. Average organic growth over the last two years is 10%; EBIT growth at constant currency, even 13%. Hence, we are looking at a challenging basis for 2017 growth. Secondly, for some of our larger drugs we have experienced competitive launches over the back half of 2016; therefore, in a number of instances, year-end market shares and ASPs are below their respective 2016 averages. And thirdly, our outlook generally does not assume a recovery, but rather, again, a gradual further easing of the IV drug shortages, and increased competition on some of our major molecules, as well as continued price pressure. If these assumptions prove too pessimistic, we’ll see upside to our expectations. Whilst we’re at it, a brief update on shortages. There were 16 Kabi IV drugs designated in shortage end of Q4; unchanged from the prior quarter. As a positive, I’d like to confirm that we are anticipating a vigorous IV drug launch, schedule this year, with more than 10 new product introductions. However, we currently expect those to be more weighted to the second half of the year.

Finally, on Daptomycin, we are very pleased by the successful launch. We were able to get to market as the first true generic, and we have a strong contract position. But I would caution you against getting too carried away with your expectations. This is not another Neostigmine. We share our Daptomycin margin with the commercial partner, and competition is already pretty intense, with further launches expected later this year.

Over to Europe, where for 2017 we expect low to mid single-digit organic sales growth. We assume the improved growth of parenteral nutrition and the contract manufacturing business is to continue in the coming quarters. And our Eastern European business should also continue to grow above par.
On to slide 11, and the emerging markets, where in China we expect that the introduction of the new tender policy will be completed in most provinces by the end of the first half this year. Due to the new tender process, we expect low to mid single-digit price reductions as a full-year impact. At the same time, we anticipate continued double-digit volume growth; and that will translate into low to very low, but still double-digit, organic growth in this key market. In Asia-Pacific ex-China, we’re seeing structurally growing demand, coupled with successfully concluded restructuring initiatives. And that will translate into an ongoing recovery with healthy growth rates in 2017. Latin America and Africa, no major change from 2016, meaning continued strong growth also this year. So, in aggregate, organic sales growth in the emerging markets will likely be in the double-digits this year.

Let’s turn to Fresenius Helios, on slide 12, where we have seen 2% organic sales growth in Q4; a bit softer than the previous quarters, but I’m not worried. I can’t see anything structural behind that; a bit of a tougher comp. And anyway, 2% in Q4 was enough for 4% in the full year, which is great.

With regard to German regulation, we are not aware of any meaningful change in the compensation for hospital services since the Krankenhausstrukturgesetz, the Hospital Structures Act, became effective one year ago. Hence, we expect this will be broadly neutral as Helios also has a large network and range of activities. In general, I’d say Helios is extremely well prepared for quality-based compensation. As you know, Helios has been a pioneer of measuring medical quality in a standardized process, and publishing those results. We’d welcome a stronger link between delivered quality and received reimbursement.

On the reimbursement front, the price increase for hospital services in Germany has been set at 2.5% for 2017; pretty much in line with the level of the recent past. For good order, just to make sure that your expectations don’t overshoot, the effective price increase will be lower, in particular, as treatments exceeding the pre-agreed budgets will continue to be reimbursed at a discount.

Niederberg, the privatization of that 500-bed facility in North Rhine-Westphalia, is a success story. The hospital has already made a positive contribution to our earnings, and will continue to do that. So, how unfortunate that there aren’t more Niederbergs out there. But it’s rather the opposite: attractive privatization opportunities are still few and far between, a key reason why we decided to enter the Spanish market.

Which brings me to Quironsalud. The Company met the full-year 2016 outlook that we provided as part of the transaction announcement, EUR2,540 million of sales, and an EBITDA of EUR461 million; in line with our expectations. We have successfully financed the acquisition with a broad mix of financing instruments. The average interest rate over the roughly EUR5.3 billion of debt is around 1.7% at an average maturity of just below nine years; very happy with that. The transaction closed, as planned, end of January. And Quironsalud will be consolidated from February, onwards. Next steps: well, the joint project teams had obviously been assembled already prior to closing and the integration work is already well underway.

On to slide 13, with an overview of the EBIT development at Helios. Total Q4 EBIT, bottom-left, came in at EUR175 million, up 4% year over year; and also, margin-wise, an improvement to 12%. Total full-year EBIT, bottom-right, was EUR682 million, about the mid-point of our guidance range.

Now, over to Vamed, on slide 14, where organic sales growth was 10% in Q4, for 5% in the full year. That is a bit softer finish than originally expected, driven primarily by a project cancellation in Turkey, and a few project delays in Asia Pacific. But EBIT growth was a strong 12% in Q4, for 8% in the full year; in line with our guidance. And we are optimistic for this year. The, yet again, strong and nicely diversified order intake in 2016, for example, from Austria, Ghana, Senegal, and many other countries around the globe, has taken Vamed’s order backlog to a new all-time high.

On to slide 15, and a very strong cash flow quarter. Group operating cash flow of EUR1,315 million, bottom-left, corresponds to a margin of 17%. My highlight is Kabi’s Q4 cash flow of EUR345 million, top-left, at an extraordinary margin of 22.3%. That took the full-year cash flow to a record EUR991 million, with a margin of 16.5%; all-time high. But also, Helios delivered a very decent Q4 cash flow of EUR185 million, and a margin of 12.7%. For the Group, this outstanding performance took the full-year margin to a very strong 12.3%.

Deduct Group CapEx of 5.5%, middle column, and you’ll arrive at a free cash flow margin, bottom-right, of 6.8%. That allowed meaningful progress in de-leveraging, post-Rhoen and pre-Quironsalud.
We finished 2016 at 2.34 times net debt-to-EBITDA, so well below our target corridor. Pro forma Quironsalud, we’d be at 3.1 times, so just above. And expect to return to the bottom half of our self-imposed target range by the end of this year.

Let’s turn to slide 16, for the 2017 outlook by business segments. Kabi’s organic growth first, where we project 5% to 7%. That’s the blend of the regional contributions I mentioned: low to mid-single digits for Europe, likely double-digits for the emerging markets, coupled with mid single-digits for North America. On to EBIT, with the same 5% to 7% growth range at constant currency, off the slightly lower IFRS base. I gave you the reasons for the expected low to mid single-digit EBIT growth in North America; blend that with mid to high single-digit growth in Europe and high single-digit growth in the emerging markets and you’ll get there.

Over to Helios, where, for the seventh consecutive year, we made our 3% to 5% organic sales growth guidance last year, and so we’d like to stick to that range also for 2017. Yes, we do expect Quironsalud to grow at a slightly faster pace, say, 4% to 6%; but given the relative weight, that still leaves us with 3% to 5% for the combined entity, even though we should find it a bit easier to make the bottom end. For our enlarged hospital business, we expect aggregate sales of around EUR8.6 billion: thereof, approximately EUR2.5 billion from Quironsalud. That is consistent with the EUR2.7 billion mentioned at the time of transaction announcement, last fall, given that we’re now only accounting for 11 months. For EBIT, we project an aggregate EUR1.20 billion to EUR1.70 billion; and Quironsalud’s contribution to that should be EUR300 million to EUR320 million. Also, that is consistent with the target EBITDA range of EUR520 million to EUR550 million we communicated last September adjusted for an only 11-month contribution, and deducting an amortization of EUR80 million for 11 months, as well as depreciation of EUR100 million. Following a very detailed exercise with the auditors, it is clear now that our original expectations for the amortization charge were just too conservative.

Now, for Vamed, we have reviewed the project delays that slightly jeopardized our 2016 finish and have concluded that they are truly temporary. I already mentioned Vamed’s huge and well-diversified order book as a factor giving us confidence. We, therefore, see no reason to amend our, by now, already traditional guidance ranges of 5% to 10% for both sales and EBIT growth.

For the Group, on slide 17, I would like to start with sales growth, where we expect 15% to 17% at constant currency. For the avoidance of doubt, this range does not include any major unannounced acquisitions.

And as to the currency translation effect, if current exchange rates were prevailing until the end of the year we’d see a tail wind of 2 percentage points to 3 percentage points of extra growth, mainly from the US dollar.

At 15% growth, at the bottom end of our guidance range, our current simulation results in Group sales of approximately EUR34.6 billion.

As for net income, based on the slightly lower IFRS result last year, we are projecting 17% to 20% growth. Also here, with regard to currencies, we expect a tailwind of 2 percentage points to 3 percentage points. So at 17%, the bottom end of the guidance range, our simulation results in Group earnings of approximately EUR1,860 million. Just as last year, this is an operating guidance. And we do not foresee any below-the-line items, which does not mean it couldn’t happen. If something truly one-time in nature were to arise, say a potential impairment charge triggered by massive currency fluctuations, or a major legal settlement, that is obviously not covered by this earnings guidance. Also this year, definitely, no reason to be alarmed, I just wanted to bring it up for the sake of good order: in the absence of any such large one-time items, we feel very comfortable with that 17% to 20% of earnings guidance. Brings us to our new set of mid-term targets, which you were keenly waiting for, and will have seen already in our investor news.

In the next three slides, I’d like to outline the growth prospects of our business segments in the medium term. And I will, hopefully, bring across why we feel so optimistic; why our new targets are ambitious, but, at the same time, realistic. I won’t go into detail on Fresenius Medical Care. The Company has a very well articulated growth strategy, which we firmly support. I mentioned some highlights for 2016 already, which will have a bearing on medium- to long-term success.

Rather now, over to slide 18, and Fresenius Kabi. Opportunities within our established business on the left, while adjacent new growth areas are on the right. Organic growth of our legacy business remains at the core of Kabi’s mid-term strategy. It is driven by a strong pipeline in each of Kabi’s business lines. Take IV drugs in the US; at year-end 2016, a record 52 ANDAs were pending. Another example is parenteral nutrition, with additional specialty formulations for our three-chamber bags.
In the medical devices business, we see good growth opportunities for reliable pumps, with improved connectivity. This ever-growing depth and breadth of our product portfolio plays an important role when it comes to serving our customers with more comprehensive solutions and leveraging our market access. In addition, we continue to have a lot of confidence in our fill-the-blanks strategy. In many markets, we still have the potential to develop business lines in which we already have a good penetration elsewhere. IV drugs in Asia and standard solutions in North America are good examples for this. And in the US, we are encouraged by our launch of Smoflipid; and we are working on the cooperation model, as you know, with Becton Dickinson for standard solutions. Wherever it makes sense, we will fill the blanks by opportunity-driven bolt-on acquisitions. These are often minor in size, but central to our strategy. Looking ahead at new opportunities, we will, of course, continue to enter new countries that are attractive for us. On the product side, we will continue to closely evaluate our portfolio and assess potential extensions.

Take enteral nutrition. Traditionally, we sold our EN products virtually exclusively to hospitals. In the recent past, we have successfully intensified initiatives to also serve outpatients; Scandinavia, Eastern Europe, Hong Kong are noteworthy examples here. And the use of digital tools is allowing us to better reach our customers; customers, not patients. Home care is the key word here, a very attractive growth area for us; not everywhere, but in a growing number of countries. And we're open to expand our product portfolio via selective acquisitions, either to enter new market segments, such as biosimilars or complementary therapeutic areas, or to reach customer groups we are not reaching today.

Our existing strengths, either on the manufacturing or the distribution side, are the foundation for our non-organic growth strategy. We are looking for useful supplements for product lines or assets that we already have, always with a close eye on complementarity. And so, we have no intention to add a fifth leg to the already existing four business lines within Kabi.

Brief word on Generics Plus: what we mean with that is the attempt to differentiate our existing generic products in order to improve the patient's safety and/or enhance handling by a nurse. Take pre-filled syringes or pre-mixes in Freeflex bags as good examples for that. That differentiation has translated into higher market shares and/or better prices already, and will continue to do so.

On to slide 19, and Fresenius Helios and Quironsalud, we see plenty of room for growth in the hospital space. Looking at our German business, we will continue on our well-proven path of organic growth, complemented by selective acquisitions. And we will continue to integrate our hospitals into clusters, typically, a combination of a maximum care hospital; smaller, more specialized satellite clinics; and surrounding outpatient centers. With these clusters, we are aggregating cases where the expertise is, for the sake of our patients, because we can prove the positive correlation between case numbers and medical quality, which, eventually, one way or the other, will also lead to higher profitability.

In particular, given its size, we also see our German business as a great platform for digital technology to improve care and service processes. For one, there is telemedicine that allows us to have access to specialists remotely within our network. But we are also, and increasingly, pursuing projects to provide our patients with a better consumer experience. For that, we are running an accelerator, called helios.hub, to develop digital healthcare solutions.

One of our core projects is the hello platform, which will allow patients to interact with Helios online. We will provide them with all the useful information well in advance of their admission. All the necessary forms can be completed conveniently from home; patients can book doctor appointments, access their medical records, and check the all-important menu. The launch of hello is planned for later this year, pending approval by the data protection authorities. We will treat the increasingly knowledgeable and mobile patient increasingly as a consumer. And, in that respect, there are a few things we can learn from our new Spanish colleagues.

So let’s move on to Quironsalud, where we have a firm idea on how to drive both organic and non-organic growth. First of all, value for patients. We are a quality and technology leader. Quironsalud offers its patients well-trained doctors and nurses, state-of-the-art technologies and facilities; and, at the same time, a shorter waiting list. We will support Quironsalud in maintaining that position, in a growing Spanish market. The around 300 occupational risk-prevention centers across Spain, acquired more recently, represent a meaningful cross-selling opportunity that we’ll try to exploit. And we’ll also stand ready to fill local or regional gaps in providing the Spanish population access to high-quality medical services. To that end, there are already a few Greenfield projects in Quironsalud’s pipeline right now.

Already at the time of transaction announcement, we alluded to the Spanish hospital market being highly fragmented, arguably even more than the German one. So over time, assuming our expectations will have been met, we will support Quironsalud in any attempt to further consolidate...
their home market via small- and medium-sized acquisitions. However, let me make clear, one step at a time. Also, our new colleagues will have to earn their right to spend capital, one step at a time. And so, for now, we will collectively focus on making our 2017 guidance, while reserving the right to react to a compelling reverse enquiry. On the bottom of the page, we list the three over-arching themes of our combined hospital business. One, we are committed to delivering the mid-term incremental synergies of at least EUR50 million per annum. Two, having a footprint in two major European countries creates a powerful platform to attract international patients; a trend and opportunity that we expect to grow over the next couple of years. And three, we have great expectations for Quironsalud, and an ambitious guidance. If everything works according to plan, we’d be bound to investigate a further international expansion. But also here, one step at a time. Before even thinking about adding a third country we are keen to deliver on our promises. So think about this rather as a potential growth path for 2019, and beyond.

Quickly on to Vamed, on page 20. Vamed has a very unique, but solid value chain in place, integrating its projects with its services business, so it’s all around managing lifecycles and being an attractive, if not, irreplaceable, partner for our customers. The best way to do that is to strengthen the existing value proposition by adding high-end services, such as education programs, or the more complex technical management of healthcare facilities. From a regional perspective, Vamed has been very successful in further penetrating the markets it is already active in. Coupled with a high single-digit number of organic new market entries year in year out, this offers substantial, yet tangible, growth prospects.

Let’s turn to slide 21, which is meant to summarize and translate those growth prospects of our businesses into ambitious mid-term targets.

We’re looking at EUR43 billion to EUR47 billion of sales, and EUR2.4 billion to EUR2.7 billion of net income by 2020. These targets assume a stable exchange rate regime from today. Contributions from small- and mid-sized acquisitions are included, as last time, but large transactions will be reflected in adjusted targets, if and when they materialize.

In my mind, those targets, again, reflect a significant aspiration level.

Take sales. From the 2016 base, the mid-point of the new target range implies a compounded annual growth rate of 11.2%. And methodologically, maybe more relevant, from the mid-point of our very strong 2017 guidance, EUR45 billion of sales still imply a CAGR of 8.7% for 2018 to 2020. And that is broadly in line with our previous mid-term target.

For net income, it’s pretty much the same story. From the 2016 IFRS base, EUR2.55 billion, the mid-point, implies a compounded annual growth rate of 13.1%. And using the center of our 2017 guidance as a starting point, the implied CAGR is 10.5% for 2018 to 2020. Also here, broadly consistent with the old target range, despite the absolute numbers growing considerably.

I am convinced that Fresenius is well positioned for continued, reliable, and profitable growth, even in a volatile economic and regulatory environment.

My colleagues and I look forward to delivering on our commitment.

With that, I’m very happy to take your questions. That was a very long speech: give me a second to get some breath. Thank you.

Questions and Answers

Operator

Michael Jungling - Morgan Stanley - Analyst
I have three questions. Firstly, on 2017 guidance of 17% to 20% at net income growth, how much buffer do you have if CMS is successful in reducing premium assistance for FMC?
Question number two is on Kabi. Can you comment on your North American sales growth trend in the first quarter of 2017?

And question three is on Quiron. When are you in a position to evaluate why Quiron has lower inpatient days than Helios, and whether there is scope for improvement in Helios?

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Thank you, Michael. On point number one, I don’t think that you expected a quantitative answer. But let me say that, A, we are not working on the assumption that something like this is going to happen. B, even if it happened, as you know, our participation in Fresenius Medical Care’s profit is only at a 31 percentage point position and that, therefore if, in the theoretical case, something negative were to occur I am convinced that our current guidance range would cover that.

As far as Kabi in 2017 is concerned, I think you were specifically referring to North America, Michael?

Michael Jungling - Morgan Stanley - Analyst

That is correct. So the organic sales growth trend in North America, how that is doing in the first quarter, please.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Well, I can’t give you any precise actuals at this point in time, and you will have to bear with me until our Q1 announcement, end of April. In general, I would say, it should be in line with the overall expectation for the year. Because, basically, we have two off-setting trends; and, on the one hand, we would only expect a bit more market share loss and price pressure over the course of 2017. So in the early months we should still be, and our existing molecules be, in a more favorable position. But at the same time, once that becomes more pronounced, at least according to our expectations and the model, the more back-loaded new product launches should be kicking in. Your third question on Quironsalud, it is a different model as -- and that is most visible, I believe, when you do a straight side-by-side comparison of the number of beds and the number of patients treated. So, yes, Helios is substantially more into stationary care and Quironsalud substantially more into ambulatory. It is not that one thing is better than the other. And it is very much driven by different regulatory requirements. We would not work on the assumption, and you shouldn’t either, that now all of a sudden we can bring down the average length of stay at Helios to the Quironsalud level. It is just that, basically, Quironsalud is running a number of polyclinics, that is how we would call it here in Germany, and, therefore, the regulatory, as well as the infrastructure, prerequisites at the two facilities are different.

But that is just the very positive thing that I immediately fell in love with. It’s two different models; however, both of the two companies are active in both. And, therefore, with strengths in each of the two models there is a very clear opportunity to learn from each other and to adopt best practice.

Michael Jungling - Morgan Stanley - Analyst

Great. Thank you.

Operator

Lisa Clive, Bernstein.
Lisa Clive - Bernstein - Analyst

A few questions. Number one, on the US nutrition market, could you give us an update on how the three-chamber bag rollout is going? I believe you had guided to EUR50 million to EUR70 million in sales last year, did you hit that target? And could you give us your expectation for this year?

Second question, if you could just give us comments on the US infusion therapy business. With the Becton Dickinson agreement in place, how is that business developing? And specifically, have you made any plans to actually start setting up manufacturing for infusion therapy in the US yet?

And then, third question on enteral nutrition growth, you mentioned digital strategies. Is much of the growth that you cited coming from the rollout of that? I think you had mentioned a few countries, in particular. Are those the only ones you've rolled this out in? It's just interesting, this new business model. I'd like to get a sense of how far along in developing that you are, and what we should expect from that over the next few years.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Thank you, Lisa. On US parental nutrition, your first question, work in progress. We did not particularly say that EUR50 million to EUR70 million was the target for 2016. And, in any case, if it had been the target, we would have failed to meet it. We're late to this; on the other hand, by now, very much in line with our expectations. This is a process that we've gone through in very many other countries successfully. But it is a long-winded process, where, first of all, we need to convince key opinion leaders of a completely different medical practice that the medical petitioners aren't being taught, or haven't been taught. Therefore, this is a job of convincing people, and we're in the middle of doing that. Maybe, the positive news is in our assumptions for 2017 there is no meaningful contribution from the three-chamber bag included. In our US business, maybe there is a bit of scope for a positive surprise.

Also, to your second question, the infusion therapy is work in process.

As you know, we only got started with our supply agreement with Becton Dickinson. And we always said that this would be small at the beginning and that the much more relevant fact about it was that it gave us a very tangible alternative of how to go about the US standard infusion solutions market. But for now, we continue to ship product in small volumes over the Atlantic. Not exactly stellar in terms of profitability, but also not a loss maker; and, therefore, also here, nothing very meaningful in our budget for 2017. We are still deliberating as to what the best way forward is and, therefore, a formal decision has not been taken. Bear with us, please.

As far as enteral nutrition is concerned, as I said in my prepared remarks, this is an interesting growth avenue going forward, but horses for courses. It, very clearly, depends on the reimbursement environment in individual countries. And, in particular, where EN is not reimbursed we believe we have to get closer to the end customer.

This is an area where in very many markets we feel close to the customer and their needs. The three examples that I mentioned -- well, there aren't many more for the time being. But we are having a close eye on this and would look, in particular, if the initially positive experience is confirmed in these three countries, to roll that out to further geographies.

I hope those were comprehensive answers.

Lisa Clive - Bernstein - Analyst

Very clear. Thank you.
Patrick Wood - Citi - Analyst

I have two questions, if I may. The first would be on biosimilars. I remember when you guys were originally thinking about moving outside of Germany with Helios, you gave the market, maybe, nine months' forewarning by essentially saying we're talking about moving out of the market and looking at other countries.

Should we interpret the inclusion of biosimilars on a slide deck as a similar structural view? And if so, is that to address, from 2021 onwards, the slightly lower opportunity that exists with small molecules within the pipeline there, excluding Alimta?

The other question I had would be on the Krankenhausstrukturgesetz. I understand the EUR500 million nursing subsidy is a shift of investments; I'm comfortable with that. But I guess my question is, beyond this, is it that we expect the quality-based payments to offset the DRG adjustment that's going through on cardio and ortho procedures? Is that how we should be thinking about it? Thanks.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Patrick, as far as your first question is concerned, I have been always open to biosimilars, ever since they occurred on the horizon. And on numerous occasions, I told our shareholders and analysts that it had to be a conscious decision at the time in 2008, when everybody else got started, not to go there, because at the time we had our hands full with the acquisition of APP, both from a financial capacity and from a management-capacity perspective. I have also kept on saying that as long as regulation was unclear, uncertain, as it has been, there was no sufficiently clear business case for us. And when we were looking at opportunities out there, which we have over time, we always felt that the substitution rate was much too close to a small molecule generic and did not reflect the fact that those were just biosimilars, rather than bioequals. But it is no big secret that we have always viewed biosimilars as a useful complementary addition to our overall setup within Fresenius Kabi and, therefore, I would not view this as a new fifth business line. But I would rather view this as a very nice addition to our injectables portfolio, because in very many aspects we would have complementarity, at least in the distribution channel. Therefore, when you ask me about the medium-term growth perspectives, or when, alternatively, I feel the need to give you supporting evidence of how we believe we can get to these ambitious mid-term numbers, it is certainly one area that I would not rule out.

As far as the Krankenhausstrukturgesetz is concerned, Patrick, to us, it is pretty much a non-event. And the comment that I made in my prepared remarks was just a reaction of some of our competitors seeming to be unhappy about it, or feeling disadvantaged. And we just don't observe that, and I wanted to preempt the notion that this is something negative.

From our perspective, the hospitals are getting small amounts of incremental money. In the overall scheme of things, it is really negligible amounts. And what it does is that it does not take care of the, and that is a good thing, actual underlying political question of minimum staffing in individual wards. That is a political request that's being voiced here and there. And from our perspective, what's been done here is that the Krankenhausstrukturgesetz takes care of these matters, but in a very gentle way, and we're very much appreciate that.

Patrick Wood - Citi - Analyst

Very clear. I hear what you're saying. Thank you.

Operator

Veronika Dubajova, Goldman Sachs.
Veronika Dubajova - Goldman Sachs - Analyst

I have three questions, please, and they all have a similar theme running through them. The first one is just on the potential acquisition targets for Kabi.

Stephan, you're absolutely right, you have talked about biosimilars before. The one area that you haven't talked about is OTC, or at least not that I've been aware. So where would you see a synergy between an OTC portfolio and what you have in Kabi today? And as you think about and explore this market opportunity, will we see smaller steps from you? Or would you be open to a more sizeable acquisition in either OTC, or the biosimilar space? And that's my first question.

My second question is on M&A for the new Helios Group. I noticed that Quironsalud made a small acquisition in Latin America before you closed the deal. And following from that theme, I was wondering if you might be willing to tell us, as you think about the international expansion outside of Spain and Germany, what geographies you are open to? And should we be reading anything into the Quironsalud acquisition in Latin America at all?

And my third question is just one asking for an update on the CFO search process. Thank you.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Veronika, Kabi, OTC, what I've tried to summarize on these slides were factors underpinning our medium-term growth, and, therefore, small- to medium-size acquisitions, potentially. That does not rule out anything larger. But that is what I actually meant here.

OTC, from a distribution channel, is something that we are not that much used to. I will readily admit that. On the other hand, we were always clear that synergies and complementarities could also be had on the manufacturing side. I do believe that we have some strengths in manufacturing liquids, sterile liquids, and, therefore, that is an area that I could easily imagine that we could expand our manufacturing skills in and reap some synergy benefits.

On Quironsalud, no, you should not read anything into this. As a matter of fact, you picked that up correctly: Quironsalud, just prior to us closing the transaction, closed themselves a very small acquisition in Lima, Peru. That is something that Quironsalud management had gone about, even before the discussions with us had started. It is a small single hospital, nicely profitable in itself, and, therefore, we did not see a need to stop the process that was already well underway and to alienate people. Therefore, yes, that transaction did occur. For Quironsalud, strategically, or, I should rather say, for our hospital business as a whole, I'd like to stick to my statements from just now. First, we need to deliver relative to our expectations. Therefore, the 2017 EBITDA and EBIT guidance is a must; everybody is acutely aware of that. Once that is in the bag, I will be substantially more open to Greenfield growth, and potentially also to becoming more proactive on Spanish market consolidation. So let's say that would be more a 2018 event, 2018/2019.

And if then everything has gone according to plan, I will be open to a potential third country market. And that would then, as I said, be more a 2019 or 2020 event. I'm not going to rule out any particular market, just because it is way too early to do that. At the same time, you heard me in the run up to the Quironsalud acquisition, and in my post-announcement explanation, I'm keen on synergies. And I just feel that the closer to home we look the more likely we are to get to synergies between our hospital businesses.

And to your third question, Veronika, everything's okay. Just bear with us a little longer. My predecessor did the CFO job for more than 10 years, I did it for 12. This is a very important position that we need to fill and I think it is absolutely worth it to wait a little longer for the right candidate. But let me also reassure you, I have absolutely no desire to continue to do both jobs for substantially longer.

Veronika Dubajova - Goldman Sachs - Analyst

Very clear. Thank you very much, Stephan.
Operator

Gunnar Romer, Deutsche Bank.

Gunnar Romer - Deutsche Bank - Analyst

Thanks for taking my questions. The first one would be on Kabi North America, specifically the Q4 margin, which was, obviously, depressed by some of the overall work at your Grand Island and Melrose plant. I was wondering whether you can quantify the impact that you may have seen here in the fourth quarter, and also share with us your thinking about the North American margin in 2017.

Then secondly, also Kabi, when it comes to the greater than 10 launches you're anticipating for the current year, I was wondering how many of those would be new molecules, as compared to just the new dosing. Similar question also to the pipeline: how many of the 52 ANDAs you have pending is really new molecules, and how much is new dosing?

And then lastly, on Helios, or specifically Quironsalud, I think you've increased the guidance more towards the upper end of the range you provided back in September. I was wondering whether you can comment on that, and what has driven that upgrade?

And then, final question with regard to the Helios legacy portfolio, how should we be thinking about further margin progress here? Thank you.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Thank you, Gunnar. Four questions. On your first one, I'm afraid I'm not prepared to talk about the quantitative effect of those plant closures.

As far as margin development in Kabi North America is concerned, you will have seen that we're guiding to mid single-digit top-line growth, and low to mid single-digit EBIT growth, and, therefore, what we have factored in is a bit of a margin compression. On the ANDA pipeline, the 10-plus, in our minds, does not include any new dosage forms. This is all new molecules: small, smaller, but also potentially a few larger ones included.

Quironsalud, our guidance, Gunnar, operating-wise, remains unchanged. The EUR300 million to EUR320 million EBIT number that you find is -- or corresponds precisely to the EUR520 million to EUR550 million EBITDA that we projected last September. It has a lower amortization charge included, and it is reflecting the consolidation for only 11 months.

As far as Helios's legacy business is concerned, I would continue to believe that we're going to see 3% to 5% organic growth. As I mentioned already on earlier occasions, the higher end of that range typically has only come about on the back of successful privatizations. Therefore, if we were looking at a stable portfolio it would probably be rather a 3% to 4% in the current reimbursement environment, with those discounts on excess treatments. As far as margin is concerned, what you should expect is ongoing, however, increasingly small, margin increases, given that a growing number of Helios hospitals will, in particular, over the time frame of our mid-term guidance, get into that target range, between 12% and 15% EBIT.

Gunnar Romer - Deutsche Bank - Analyst

Thank you.

Operator

Julien Dormois, Exane.
Julien Dormois - Exane BNP Paribas - Analyst

Most of my questions have been answered, but I would just like to follow up on one, and, again, on the biosimilars. Sorry for that. But, quite clearly, you have been cautious for some time on that area, and now you are telling that it could possibly contribute to the 2020 guidance, so that would obviously assume some drugs are already on the market, or soon to be, let’s say.

Should we think about it as being a rightful acquisition of a company with an established pipeline, and maybe already sales on that? And in which direction should we be looking at? Or could this just be like a distribution agreement with an already established player that would benefit from your distribution capabilities? Both options are open.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Julien, thank you. And you said it yourself, all options are open. But I'd like to add the option that we’re not going to go to get involved into this, because we have been successfully living without biosimilars since 2008. It is something that, in my mind, could be a good fit with the rest of our portfolio. It could play to the theme that, in particular, in the US we need to make sure that our product offering becomes ever broader, wider, deeper. But, at the same time, you heard me talk about the ANDA pipeline and various other ideas, how to get there. So it is something that I wouldn't rule out; at the same time, in my mind, it is clearly not a must have.

Julien Dormois - Exane BNP Paribas - Analyst

Okay. Thank you.

Operator

Chris Cooper, Jefferies.

Chris Cooper - Jefferies - Analyst

I have two left, please, both on Kabi; one on 2017, and on a bit longer term.

Firstly, just on your regional margins in 2016, clearly, we are expecting some improvement from the fourth-quarter exit rate. I think you've been quite helpful on how you expect the regions to develop on the sales line over the course of the next 12 months, but I was hoping also you could provide some color by segment. Do you expect one or more of the divisions to perform above or below the level of 5% to 7% organic? Or rather, do you assume all of them to be in that range?

And then secondly, please, just on the development of the legacy business. We've been hearing for some time about the upside opportunity from cross-selling and filling the blanks, I would just be curious to hear more about your progress here. I guess, my question is to what extent have these blanks now been filled?

And then separately, could you perhaps highlight some of the more obvious gaps which you will now be targeting in delivering your mid-term target? Thank you.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

On your first question, thank you for both, you know that we have a particular product focus in IV generics in North America. You heard my comment about low to mid single-digit EBIT growth in North America, and, therefore, I believe it is a fair assumption that IV generics, in general, will be slightly...
behind par, and correspondingly the others. And if I had to pick one I'd pick clinical nutrition will make up for that, so that we get to the blended 5% to 7% range.

Filling the blanks, what I was specifically referring to in the past, but I think also earlier today, is infusion solutions, and also the medical devices business, still in North America. North America, as we know, is dominated for Kabi, at least for the time being, by injectables, so any strengthening in the other three business segments would already go a long way to filling a blank. At the same time, just as much as North America is dominated by injectables, our second-largest market, China, is dominated by clinical nutrition, both parenteral and enteral nutrition. So anything we can do to strengthen that very important market for us, and to broaden our product offering there, would also be much welcome. I believe that, truly, the only region, the only area where we are truly playing with all our tools is Europe. But also, that is true only for the inner core Europe. As long as soon as we go to the fringes, so some southern, and, in particular, also some Eastern European markets, it becomes more patchy; and also there, I can imagine smaller additions, either organically, or with small to very small bolt-ons.

Is that okay?

Chris Cooper - Jefferies - Analyst

That's great. Thank you.

Stephan Sturm - Fresenius SE & Co KGaA - CEO

I think we have time for one last question.

Operator

Tom Jones, Berenberg.

Tom Jones - Berenberg - Analyst

Hopefully, you've got time for two, so I'll chance my arm. First up, on the medical products business in Kabi, for a business that doesn't like surprises, that big swing in the organic growth rate was quite a surprise. I was just wondering if you could give us some color on what's going on there, and perhaps the outlook for 2017.

And then, very quickly, just a technical question, I think, under IFRS you included EUR30 million charge on your bottom line, related to the write-off of capitalized acquired R&D. I'm just a bit surprised there's still some capitalized R&D left within that business, given you bought APP eight years ago.

Is that it? Or should we expect, potentially, further write-downs going forward? I guess, what I'm trying to get at is does that EUR30 million headwind go away in 2017, or should, to some degree, we expect it to recur?

Stephan Sturm - Fresenius SE & Co KGaA - CEO

Tom, on your first question, I think I mentioned that we were subject to a product shortage over the course of the year, and away from us, and we benefited from that. And that had created a bit of volatility that also spilled over into the fourth quarter.

And your second question, yes, under IFRS we had to capitalize R&D expense at the time of the APP acquisition, whereas everything that was R&D in process on the US GAAP was completely expensed at the time. So in answer -- to answer your question in short, there is not a lot left. And whatever
is there, I, as of now, would very much expect, is tangible. Therefore, I believe that it is unlikely that we’re going to see anything like this in 2017, at least not, that is what I feel very good about, to the same magnitude.

Tom Jones - Berenberg - Analyst
Okay, perfect. That’s very helpful. Thanks for squeezing me in at the end.

Stephan Sturm - Fresenius SE & Co KGaA - CEO
Thank you. Okay, ladies and gentlemen, I had a long speech, and was still trying to squeeze in as many questions as possible. We’re late, and I want you to be on the Fresenius Medical Care call in time. We’ve got to wrap it up now. I hope that was instructive.

Thank you for your attention. Thank you for your support. And I would like to welcome you back to our Q1 call, end of April. I’m sure I will see very many of you in the coming days, when Markus and I are road showing. Thank you for now. All the best.

Operator
Ladies and gentlemen, we would like to thank Fresenius, and all the participants, for taking part in this conference call. Goodbye.

Editor
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