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# Baxter International Inc. (BAX) CEO Joe Almeida on Q3 2019 Results - Earnings Call Transcript

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## Earning Call Audio

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Baxter International Inc. (NYSE:BAX)

Q3 2019 Earnings Conference Call

October 24, 2019, 08:30 AM ET

## Company Participants

Joe Almeida - Chairman, President and CEO

Jay Saccaro - EVP and CFO

Clare Trachtman - VP, IR

## Conference Call Participants

David Lewis - Morgan Stanley

Robbie Marcus - JPMorgan

Bob Hopkins - Bank of America

Matt Taylor - UBS

Pito Chickering - Deutsche Bank

Larry Keusch - Raymond James

Danielle Antalffy - SVB Leerink

Vijay Kumar - Evercore ISI

Larry Biegelsen - Wells Fargo

Matt Miksic - Credit Suisse

### **Operator**

Good morning, ladies and gentlemen, and welcome to the Baxter International Third Quarter 2019 Earnings Conference Call. Your lines will remain in a listen-only mode until the question-and-answer segment of today's call. [Operator Instructions]. As a reminder, this call is being recorded by Baxter and is copyrighted material. It cannot be recorded or rebroadcast without Baxter's permission. If you have any objections, please disconnect at this time.

I would now like to turn the call over to Ms. Clare Trachtman, Vice President, Investor Relations at Baxter International. Ms. Trachtman, you may begin.

### **Clare Trachtman**

Thanks, Katherine. Good morning, and welcome to our third quarter 2019 conference call. Joining me today are Joe Almeida, Baxter's Chairman and Chief Executive Officer; and Jay Saccaro, Baxter's Chief Financial Officer.

As you saw in today's press release, the company recently initiated internal investigations into misstatements in our previously reported non-operating income related to foreign exchange gains and losses. While the investigation is ongoing, we are not able to provide full financial results and will be focusing today's call on preliminary operating results for the third quarter of 2019. As such, we will not be commenting on any financial measures other than those above the operating income line for the third quarter or any future periods.

A supplemental presentation to complement this morning's discussion can be accessed on our Web site. This presentation includes related non-GAAP reconciliations and can also be accessed on Baxter's external Web site in the Investors section under Events & News.

With that, let me start our prepared remarks by reminding everyone that this presentation, including comments regarding our financial outlook, new product development, business development, and regulatory matters, contain forward-looking statements that involve risks and uncertainties and, of course, our actual results could differ materially from our current expectations. Please refer to today's press release and our SEC filings for more details concerning factors that could cause results to differ materially.

In addition, on today's call, non-GAAP financial measures will be used to help investors understand Baxter's ongoing business performance. A reconciliation of the non-GAAP financial measures being discussed today to the comparable GAAP financial measures is included in our preliminary operating results press release issued this morning and is available on our Web site within our investor presentation. On the call this morning, we will be discussing operational sales growth, which adjust for the impact of foreign exchange and generic competition for cyclophosphamide in the U.S.

Now, I'd like to turn the call over to Joe. Joe?

### **Joe Almeida**

Thanks, Clare. Before we get into a discussion regarding our third quarter performance, I want to address the ongoing internal investigation that we disclosed in today's press release. First, I want to emphasize that our Board and leadership teams have taken this matter very seriously.

Baxter recently began an internal investigation assisted by experienced outside investors into misstatements in our previously reported non-operating income related to foreign exchange gains and losses. These misstatements were in part a result of the company's historical use of a foreign exchange rate convention that was not consistent with GAAP.

Our Board's Audit Committee is overseeing the investigation with the assistance of independent, experienced external advisors. We voluntarily advised the SEC that the internal investigation is underway and intend to provide them with additional information as the investigation progresses.

The investigation is in its early stages and we cannot predict its duration or outcome. As a result, we do not expect to file a quarterly report on Form 10-Q for the period ended September 30, 2019 on a timely basis.

Upon completion of the investigation and our evaluation of the materiality of the misstatements, we expect to either amend our periodic reports previously filed with the SEC to include restated financial statements that correct those misstatements, or include in reports for future periods restated comparative financial statements that correct those misstatements.

As part of any corrections to previously issued financial statements after completion of the non-operating income investigation, Baxter also expects to correct certain operational items that were immaterial to its previously reported results of operations.

These items include the impact of the use of the foreign exchange rate convention to translate the results of the company's foreign operations into U.S. dollars and the impact of the incorrect accounting for placed equipment that the company leases to its customers.

Across Baxter, we're taking steps to strengthen and enhance our internal controls and look forward to sharing our full financial results as soon as it is appropriate. We will continue to execute against our business strategies targeted to deliver top quartile industry performance and our 50,000 employees remain focused on building our positive momentum and maintaining ethics and compliance in everything we do.

Please note that there isn't additional detail regarding the investigation that we can share beyond what we have provided in our press release. We, therefore, ask that your questions during the Q&A portion of this call be focused on our preliminary operating results, business progress and innovation efforts.

With that, I will now turn the call over to Jay.

## **Jay Saccaro**

Thanks, Joe, and good morning, everyone. Our third quarter results reflect strong performance across our three geographic segments and all six global business units. Given the ongoing internal investigation, we are not able to provide year-over-year comparisons for segments and global business units but we'll speak to the specific drivers of performance in the quarter.

In the third quarter, global sales of \$2.85 billion increased 3% on a reported basis and 5% on both a constant currency and operational basis, reflecting strength across our diversified portfolio. Adjusted operating margin of 19.5% was driven by our solid top line performance and ongoing operational efficiencies.

Now, I'll walk you through performance by our geographic segments and global businesses. Starting first with our three geographic segments, sales in the Americas totaled \$1.5 billion, sales in EMEA totaled \$730 million and sales in our Asia-Pacific region totaled \$587 million.

Moving to performance by global businesses, global sales for renal care were \$918 million. Performance in the quarter was driven by strength in PD therapies globally with patient volumes advancing approximately 7% year-over-year and representing the highest quarterly patient volume growth year-to-date.

Partially offsetting this is lower sales of select in-center HD products, including the Bloodline's business exited earlier this year which negatively impacted sales in the quarter by approximately \$18 million. Renal care sales were also impacted by the temporary supply constraints associated with the REVACLEAR Dialyzer. The impact was less than \$10 million in the quarter.

Sales in medication delivery of \$701 million represented the focused commercial execution of our U.S. hospital product team. Performance in the quarter benefited from strong sales of Spectrum IQ Infusion System in the U.S. where we continued to increase

our install base of pumps and also from improved sales of small and large volume IV solutions globally, as we continue to build momentum. We are pleased with the ongoing improvement in the business, particularly in the United States.

Pharmaceutical sales were \$527 million in the quarter. Contributing to performance in the quarter was robust demand for our international hospital pharmacy compounding services as well as increased sales of certain generic injectables. Partially offsetting these results were lower sales of anesthesia and critical care products as well as Brevibloc due to increased generic competition. U.S. cyclophosphamide sales totaled \$41 million in the quarter.

Moving to nutrition, total sales were \$219 million driven by improved sales of multi-chamber bags and micronutrients globally. International demand for automated nutrition compounding also contributed to performance in the quarter. Third quarter sales reflect the efforts taken to rebuild our U.S. business coupled with our focus on new product launch execution.

Total advanced surgery sales were \$216 million in the quarter. Performance was driven by strength of hemostats and sealants which benefited by more than \$10 million of sales related to previously discussed competitive supply constraints, which are not expected to continue contributing at this level.

Third quarter sales in our acute therapies business of \$130 million were driven by increased global demand for Baxter's continuous renal replacement therapies, supported by the launch of new products including PrisMax, Baxter's next-generation CRRT system. Finally, sales in our other category which primarily includes our contract manufacturing services were \$140 million in the quarter.

Moving through the rest of the P&L, our adjusted gross margin of 45.7% benefitted from strong top line performance as well as positive manufacturing variances. Issues associated with our Dialyzer supply constraints negatively impacted gross profit by approximately \$15 million in the quarter.

Adjusted SG&A totaled \$614 million as we strategically reinvest savings in general and administrative expenses to support our sales and marketing initiatives, while maintaining our disciplined focus on managing discretionary expenses.

Adjusted R&D spend in the quarter was \$134 million. We continue to fund our product development programs to deliver on our innovation pipeline, while also realizing benefits from our ongoing optimization initiatives to optimize our R&D processes and the organization.

Adjusted operating margin in the quarter was 19.5% due to strong top line performance, manufacturing efficiencies and ongoing efforts to improve operational effectiveness across the company.

Let me conclude by commenting on the sales and adjusted operating margin outlook for the fourth quarter of 2019. We remain confident in the health of our business and in strength of our commercial execution. Given the ongoing investigation, we are providing limited guidance for the remainder of the year.

Specific to the fourth quarter of 2019, we expect sales growth of 3% to 4% on a reported basis and approximately 5% on both a constant currency and operational basis. We expect operating margin to be between 15.2% and 15.9% on a reported basis and between 18.5% and 19% on an adjusted basis.

Finally, I want to comment on our 2020 outlook. We're currently in the process of completing our annual operating plan, and as part of that activity we're considering several factors and their potential impacts. Some of these items include the proposed Advancing American Kidney Health initiative and the related capital investments to support this along with other government renal policy initiatives.

Capital investments and operational improvements we are making to enhance our quality and manufacturing capabilities and the finalization of our agreements with various GPOs and IDNs in our U.S. hospital products business. As a result, it is premature to comment on 2020 guidance and beyond but anticipate providing more detail on our next earnings call.

With that, I'd like to turn the call back over to Joe.

## **Joe Almeida**

As Jay shared, our strategic transformation yielded positive performance across all of our business units and regions in the third quarter. The fundamental health of our business remains strong and reflects our growing momentum.

We're continuing to drive operational excellence and strategically deploy capital to create shareholder value and advanced compelling innovation in our core areas and attractive adjacencies both through robust internal research and development and strategic business development.

In renal care, for example, we continue to believe that the Advancing American Kidney Health initiative will offer tremendous benefits to patients with home dialysis embraced as a frontline option. We also continue to nurture our innovation pipeline in this space including advancements in early stage technology that could have a transformative impact on the treatment of end-stage renal disease.

In medication delivery, we're building on our leadership in IV infusion systems and solutions with internal innovation that is complemented by our expected acquisition of Cheetah Medical, the combination of which will fuel the broader impact of our integrated family of pumps, fluids, medications and monitors.

In pharmaceuticals, we've continued to launch a steady stream of new molecules including the recent introduction of Myxredlin, our new ready-to-use insulin for IV infusion.

In sum, our business strategy objectives and capital allocation philosophy remains unchanged. We are focused on addressing the unmet patient and customer needs, building our pipeline and successfully launching products across the globe.

At the same time, we continue to actively pursue opportunities to extend our impact through strategic partnerships and business development initiatives. This all supports our goal to accelerate performance and deliver top quartile results for all the stakeholders.



Now we'll open the call up for Q&A, keeping in mind that we'll be limiting our ability to comment beyond the details we shared this morning.

## **Clare Trachtman**

Katherine, you can open up the call for Q&A now.

## **Question-and-Answer Session**

### **Operator**

Thank you. We will now begin the question-and-answer session. [Operator Instructions]. Our first question comes from David Lewis with Morgan Stanley. Your question, please.

### **David Lewis**

Good morning. I want to get the fundamentals guys, but just real quick, Joe, just in case we won't be able to get this information. Can you just give us any sense of how the issue was identified and any rough sense of when you hope to complete the investigation? If not, I'll jump to some fundamental questions.

### **Joe Almeida**

David, as we said before, the investigation is in early stages. Beyond what we shared in our press release, I cannot provide additional information when the investigation is ongoing. So let's move to the business fundamentals.

### **David Lewis**

Okay. So, look, given those FX dynamics, Joe, obviously it's cloudy in their reporting structure, but obviously underlying comps and currency growth this quarter was solid. So just first question is, can you just give us a sense of underlying trends this quarter, how you felt about those versus plan? As you think about underlying business performance into the end of the year, how do you feel about that sort of relative to plan? And any thoughts you can share about improving revenue performance in 2020? And then I got a quick follow up for Jay.

### **Joe Almeida**

So, David, let me start with our medication delivery business. This is one that our investors have asked so many questions and paying a lot of attention. That business was able to perform very well. It actually has slightly exceeded my expectations. And I will say that our new pump, our Version 9 of our pump is doing very well, extremely well as a matter of fact. We finish our first full integration of that pump in a two-way system in the hospital system in the Southwest. We have closed many, many deals that I'm very excited about. We also are seeing a very stable business in our IV solutions, the small and large volume parenterals with recovery now on its way and good contracts being signed, some of them surprisingly us being doing very well. And this is a reflection on the performance of the U.S. medication delivery in the U.S. As I said, our head of that business, Heather and her team in the U.S. are doing a wonderful job there. I want to highlight as well that our launch of PrisMax has been well received in the marketplace. It's one of the fastest launches I've seen. As soon as we launched in the U.S., within a couple of days we had purchase orders coming in. The system is really hitting the mark. And I feel the innovation of the company is really starting to bear fruit. So I'm excited about when we talked to you about 2020 about the impact of new products sales into next year. Also when we talk about the regions themselves, we see full recovery in Europe. Europe was a real ladder for us and it's coming up to be driving well performance and great performance in Asia-Pacific as well led by China. And I want to close by just saying the fundamentals of our PD business and this is one of the business when I first started here that we really were a bit concerned about because we had issues with contracts and we had issues with the ability to supply products. And seeing the patient growth on a global basis is so high in the U.S. nearing 10% gives me tremendous confidence that when we hear back on rule on AAKHI, that can really represent an opportunity for us. So the fundamentals of the business puts me quite at ease in how we are doing in the marketplace, the share that we are expanding and ability to really compete, this is a different Baxter.

## **David Lewis**

Thanks, Joe. Just two quick follow ups. One is, I know it's challenging to talk about forward guidance just given the dynamics that are going on. But can you talk at all about you said building accelerated momentum in the business in 2019, how are you thinking about that momentum into 2020? And then for Jay, margins always tick down in the fourth

quarter. Can you just bridge us to fourth quarter, any one-time benefits in the third, any headwinds into the fourth and how margin outlook is tracking relative to plan? And any comments you can make on pension which was sort of an inter-quarter announcement that we haven't yet got clarity on? Thanks so much.

### **Joe Almeida**

So, David, we don't have or I don't have any reason to think about any changes in dynamics that would slow down our ability to do our business in the future. Why is that? Baxter has, for the most part of this, largest markets either driven by contracts which are mid to long term as well as large tenders outside the U.S. and we see a steady position of our products through contracts that give me comfort. Doesn't make me relax but gives me comfort that we're hitting the right places. The innovation coming through our new pump platform coming out next year gives me tremendous optimism in terms of how we're going to be able to face new opportunities in the U.S. We're also launching – we launched the three-chamber back in Europe for nutrition that is doing very well. Our post-Maria recovery in nutrition which was very slow in the beginning is starting to see some momentum. So I don't have any reasons today to tell you that I'm concerned about the ability of Baxter to grow its top line.

### **Jay Saccaro**

Great. David, in relation to your question on margin versus expectation and sequential, I will tell you that Q3 was a very solid margin performance relative to our expectations. We were supported by top line in line with our expectations which was great. But then as a result of savings initiatives and focus on efficiencies, we were able to come in maybe 1% ahead of our internal expectations. Now, as we move from Q3 to Q4 you'll note that the margin does deteriorate which as you pointed out is largely attributable to normal seasonality. In the case of this fourth quarter, gross margin will come down in large part if our shutdowns occur in Q4 and that has a period of expense impact in the fourth quarter. But then secondly, R&D in the third quarter I believe was a little bit below 5% of sales. We will expect it to go a little bit above 5% of sales in the fourth quarter related to the timing of certain milestone payments attributable to advancing the pipeline. So that's really the story on the overall margin evolution. As it relates to the pension, the overall goal of the pension

approach is to really reduce volatility. As part of the transaction that we engaged in, we have reduced the liability by approximately \$2.4 billion. That is very substantial long-term benefits to us in terms of managing the predictability of future financial results. But as it relates to commenting on the 2020 impact in particular because this is in other income line item, I'll refrain from talking about whether this is a benefit or headwind or tailwind. I'll stop my comments there and stick to the fact that this is more about a long-term reduction in volatility which we why we pursued this transaction.

**Joe Almeida**

Thanks for the questions, David.

**David Lewis**

Thanks so much.

**Operator**

Thank you. Robbie Marcus from JPMorgan is on the line. Please state your question.

**Robbie Marcus**

Hi. Good morning, everyone. Joe or Jay, I was just hoping – we didn't get constant currency by segment, we didn't get guidance by segment like you typically have. Any comments you could add to maybe where you're seeing pluses or minuses versus your internal plan or any deltas we should be expecting after third quarter results here?

**Jay Saccaro**

Sure. Robbie, just as a matter of clarification, the reason that we have not provided sales growth by segments or by region is that as part of any correction to previously issued financial statements after we complete this investigation, we do expect to correct certain items that are immaterial to our previously reported results of operations, which include the impact of translating our foreign operations back to U.S. dollars in the exchange rate used. Like I said, this is an immaterial impact but you can imagine how sensitive we are to any minor changes in growth rates that may emerge as a result of comparisons and this kind of situation. So I think Joe – so that's why for your information, we haven't shared

anything in relation to growth by segment, by region. But I think Joe said it well. Look, we had strength across the portfolio. Our renal care business continues with great momentum. Medication delivery had a very solid performance, in particular in the U.S. as we look to continue to drive performance in that area. The pharmaceuticals business, not only did we couple solid performance in the quarter but we added to that the launch of Myxredlin which becomes an important driver for our long-term growth. So I would say generally speaking we sit here very pleased with the business momentum across the board.

### **Joe Almeida**

I echo Jay and I'll tell you – I just want to point to the acceleration in the PD business. The patient growth has been impressive and not surprising because the therapy is a desirable therapy for the home. But this is one of the levers that we have. And the other lever that we have is also the momentum in our U.S. medication delivery business which we started to see the fruits of our change in sales force structure and organization.

### **Robbie Marcus**

Great. And then a quick clarification, Jay. Might there possibly be cash flow restatements or is this purely just a P&L item?

### **Jay Saccaro**

So at this point, Robbie, we can't comment on any – we're limiting our comments today to operating income. We have an investigation ongoing. Upon the conclusion of that, we'll be prepared to share further comments. But for purposes with our discussion here, we're not commenting on anything below operating income.

### **Robbie Marcus**

Okay. And then just last quickly from me, Jay, we saw some recent news reports that you might be in discussion with a pharma company for a specific drug. Can you just give us your latest thoughts on the use of capital specifically for M&A and what type of deals you're looking for that might be most appropriate for Baxter here? Thanks.

**Joe Almeida**

Robbie, this is Joe. Great question. We don't comment on any M&A activity that we are contemplating or not. But I think you have a great question when it comes about capital allocation. Capital allocation, as we've mentioned, remains unchanged. We are – we always prefer a strategic deployment of capital into acquisitions. We said before that adjacencies are more reasonably priced and easier to integrate and we are very, very open to those. We also have not changed our view on dividends at all. And at the end of the day we're not going to be hoarding cash. So if we find ourselves with excess cash in our balance sheet, we'll make a decision to appropriately buy shares back. So I just want to say to you and to the folks on the call that no change has been contemplated neither in sight to our current capital allocation policy. Jay, anything you want to add?

**Jay Saccaro**

No. That's a great summary. The only thing to add is and Robbie of course we have very ample liquidity with significant cash on hand to fund business development or any other activities we are interested in pursuing.

**Robbie Marcus**

Thanks a lot.

**Joe Almeida**

Thank you.

**Operator**

Thank you. Bob Hopkins of Bank of America is on the line. Please state your question.

**Bob Hopkins**

Thanks very much and good morning. First question is, I just wanted to clarify something in your 8-K and make sure I'm reading it correctly because it says the FX gains for '14 to '18 list those out. Should we view those as representing the magnitude of the misstatement or could those misstatements be I guess in the end larger or smaller?

**Jay Saccaro**

The misstatements could be larger or smaller on then what was reported as gains in the 8-K that we issued.

**Bob Hopkins**

Okay, thank you for that. And one of the other things in the 8-K was on Claris. It sounds like the FDA process is going really slower. Jay, can the contingency plans that you guys have talked about prevent the potential for disruption there or just how should we be thinking about that?

**Joe Almeida**

Bob, we are just being cautious. We can't predict when the FDA will come in and re-inspect the plant. We have not been re-inspected yet, and we're coming towards the end of 2019. We have done everything that we've committed to do to date for the FDA. We have improved our operations. We have modified facilities. We have done a lot of different things as we promised. But we can't predict, so we're better off just not counting on something. And if it comes, fine. If it doesn't, at least we're upfront telling you. But what you need to think about is that we are committed for a backup plan and we're investing money to have most of these products on a CMO basis if we ever need to activate CMO. So our pharmaceutical group not only is very busy right now with significant amount of new opportunities in pipeline they'll be formulating and example is Myxredlin, but they also will be working on continue and closely all the CMO opportunities as a backup.

**Bob Hopkins**

Okay, so it sounds like the potential for disruption is low there. That's it for me. Thank you.

**Joe Almeida**

I just want to rephrase. I incorrectly used the contract manufacturing organization and I used CRO which is contract research organization. I apologize. Please strike that from the record. It's C-M-O. I'm very sorry.

**Jay Saccaro**

Thanks, Bob.

**Operator**

Thank you. Matt Taylor with UBS is on the line. Please state your question.

**Matt Taylor**

Thanks. Good morning. So I was hoping you could comment on the PD dynamics and do you think you're seeing a pickup in the patient volumes because of technology, because of the initiatives that the government has talked about or some combination thereof?

**Joe Almeida**

Well, I think that the therapy's benefit was always very clear but I think that there is an acceptance of therapy probably more widely today than was before. But I have to say that our partners, DaVita [ph] being one of them, have been working very closely with us in a very collaborative manner and that has created the opportunity for us to continue to deploy our resources to train nurses and patients. I also underscore that Baxter has made significant operational changes in making products what we make, how much capacity we're putting in place giving confidence to our partners that we can actually supply the market versus perhaps back in 2013, '14 and '15 when we had some constraints and allocation of resources. So if now the clinics and the doctors and our partners feel more confident, then that plays a role. But I also think the move into the home is becoming more definitely apparent to our constituents. This is a good result and we'll be working very hard to make sure that we continue on with these partnerships.

**Matt Taylor**

Thanks, Joe. And then just a follow up on med del. So the U.S. number was very strong but the OUS was a little below what the consensus was expecting. Can you talk a little bit about the dynamics OUS if that growth could improve? And then when do you think we'll start to see more inflection from the new pump launches?

**Joe Almeida**



So I think there was some timing on the performance outside the U.S. Also we have focused tremendously in making sure that we have launched our new pump Evo IQ outside the U.S. We had a slow launch of that product in the UK, which is going to be picking up momentum later this year into next year. There was a little bit of weakness that we found there as well. But we had a very good momentum in Latin America, very good momentum and we're on track on that. And then we also in Canada we just launched our new pump there. So don't read anything on the OUS numbers. More so you should feel comfortable that in the U.S. we got this thing addressed and we've got the numbers right. And we don't talk about comparison at the moment. We're not going to be talking about quarter-over-quarter or year-over-year, but I can tell you that based on my expectations this business is doing well. It's doing well and I'm very happy with the performance that we have demonstrated. At one point in time it was being quite challenged by other constituents. We are on track on that.

**Matt Taylor**

Great. Thanks, Joe.

**Operator**

Thank you. And our next question is Pito Chickering with Deutsche Bank. Please state your question.

**Pito Chickering**

Good morning, guys. Thanks for taking my questions. Two quickies for me. What is the process for getting Theranova approved for the Medicare conditional add-on payment in 2020?

**Joe Almeida**

Well, I don't want to get into the sausage making because there's a lot being done. We have a full team. But we submit our comments to HHS and we also have submitted our Theranova for the de novo process. So I'm very happy. Our team led by Laura Angelini and Tony Woodson have done a great job in getting this on time to the FDA. Now the comments need to go in and they need to come back with the final resolution about the

process itself. Remember, it does not only affect our product but affects other categories of medical devices. But we're confident. We see some of the early data that was done outside the U.S. on TheraNova and we find that to be very compelling. I think HHS saw that as well. So we're on track, but remember this is not a 2020 conversation. This is a 2021 conversation, okay, because it's going to take us time by the time we get to the product approved and get the reimbursement confirmed will take about 12 months to start implementing.

**Pito Chickering**

Perfect. So assuming that this is accepted for the add-on payment, the providers will start getting paid with that add-on payment in 2021, correct?

**Joe Almeida**

That is correct. This is our best estimate right now. If anything changes we'll let you guys know in one of our calls.

**Pito Chickering**

Okay. And then from a manufacturing capacity of the dialyzers, it sounds like there's some capacity constraints this quarter. Can you talk about what investments you're making in those facilities and how fast you think those facilities can get ramped up?

**Joe Almeida**

Well, listen, we at one point in time a few years ago, say about three years ago, we had two lines within our plant in Alabama that were not operational. We did not enable them to start operating because the capacity versus demand was balanced. As we start getting more success both in the dialyzer business and start selling more product, we activate those lines. Those are complex lines and we had issues in getting them started out. So we will have some investment that we're making in quality and operations in this plant for the next 12 months. We're going to increase the amount of investment in that plant to make sure that the lines will be ready to be converted to TheraNova if we decide to do so. But we need to do some investments, some expenses that will go up a little bit next year in

terms of enabling that plant to be fully capable of making TheraNova or Revaclear and then we're going to decide which is the best mix for our patients and for our customers and also for Baxter in general.

### **Pito Chickering**

Great. Thank you so much.

### **Operator**

We have Larry Keusch with Raymond James on the line. Please state your question.

### **Larry Keusch**

Thanks. Joe, I just wanted to maybe talk a moment about the delivery business. Obviously you did achieve a medical deal, which is interesting. But as we get past this year and we kind of stabilize the business, what's really the right way to think about the growth outlook and what you'll be focused on over the next several years?

### **Joe Almeida**

Well, I had a great discussion with the head of that business, David Ferguson, the other day and for us the vision of that business is preventable harm. How do we create a system that integrate pumps and fluids that you continue to treat the most critical patients in a way that they can recover and exit a critical stage faster even in a septic stage or any acute other stage. So we find that the hemodynamic balance of the patient to be very important, so we started PIVA, which we started our clinical trials a couple of weeks ago. Then Cheetah comes in and gives us more qualitative data in terms of the treatment of that patient. But there are other things that we're looking around, a series of monitoring technologies that will come to surround our patient in the ICU to be able to get that patient out of the critical condition as fast as possible. And to that we can also think about – don't think about medication delivery exclusively, think about our acute renal care therapy, our CRRT therapy because that plays a role also not only treating but also helping diagnose and determining when do we start. Because the patient when it gets to the point that you check in the hemodynamic balance, you're checking the quality of that treatment is also a patient that sometimes has acute kidney injury and is incapable of doing – the kidneys are

not operating any more. So all of this together, how do we create a business for critical care patients that prevents harm and improves the ability of that patient to get out of the critical stage. So you're going to see a lot of this movement from Baxter in this area that was not in the past a priority for us. Because we think having the best pump platform that is coming out next year is one lever. Having the fluids available for the hospital is the second lever. But now how do you create this safety net that can bring the patient to a better outcome faster.

### **Larry Keusch**

Okay. So just a quick follow up on that, one question. So it sounds like the aspirations are clearly to grow this business in totality sort of faster than the low single digit growth of the markets. Is that fair?

### **Joe Almeida**

That is fair. Remember, we have a very large and stable business within medication delivery which are fluids and for that we're working very hard and have worked very hard to stabilize, get the contracts in place, get the supply chain in place. So this was Phase 1 because without that, it's a nonstarter. So we start doing that and that became our priority. Now the second priority is let's get a pump platform that has all the pumps that they need and they are connected, they're two-way communications and how do we make them more intelligent. Third, how do you surround that patient with a safety net that prevents harm and allows the patient to get out of critical care faster? So you see this all comes together but we had to do it in phases, because we had a business that was a little bit in disarray and now we have that business quite organized, quite ready to go. And by the way, when we look at the people selling this, the whole restructuring of the sales force that we're putting in place not only in the U.S. but other parts of the world because we're going to have a global pump product – this is not about the U.S. anymore – then makes it the fourth pillar of having this business completely revamped.

### **Larry Keusch**

Okay, perfect. And then just quickly, Jay, just while you're moving through the investigation here on the accounting misstatements, I just want to confirm whether you can deploy capital during that period, meaning are you free to do M&A and more specifically are you free to buy back stock?

**Jay Saccaro**

So just to be clear, obviously, we commented on this a number of times. The organization here takes the matter incredibly seriously; the management team, audit committee of the Board. There is an ongoing investigation and we intend to move through it expeditiously. As far as capital deployment, on the M&A side, our principles have not changed and we have ample cash to deploy. And so that's what I would say in terms of our current deployment of capital that would be the priority focus.

**Larry Keusch**

Okay. Thank you.

**Operator**

Danielle Antaffy with SVB Leerink is on the line. Please state your question.

**Danielle Antaffy**

Hi. Good morning, guys. Thanks for taking the question. Joe and Jay, I know you're not going to provide 2020 guidance and not asking you to, but just at a high level as I look out to 2020, it feels like you have a lot of tailwinds in place, new product launches that you had here in 2019 across most of the businesses. And I know some of the headwinds, I appreciate some of those back half med delivery comps will get tougher you also had in the acute surgery business that supply disruption from a competitor. Just at a high level, can you help frame for us the tailwinds and headwinds from a top line perspective as we head into 2020, especially as you're exiting the year here what seems like it would be a 5% organic growth rate?

**Jay Saccaro**

Thanks for the question, Danielle. Overall, what I will say is we're pleased with the momentum and the progress that we're seeing, as I said earlier, really across the portfolio. The third quarter from a sales perspective hit on a lot of different cylinders and furthermore as we looked at the performance of the pipeline and innovation in new products, those were all pointing in the right direction. As far as 2020 goes, as we always do this time of year, we really do hold off on specific guidance for 2020 and specific headwinds and tailwinds. And the reason is we are literally in the process of completing our annual operating plan. In the coming weeks and months we'll review it with our Board of Directors and walk them through it as we prepare for the new year at which point we'll share guidance. And then as we think about this year in particular, there are a number of different items that could have an interesting impact on our financials, things like the Advancing American Kidney Health initiative which is an important potential driver for us. We also have to ensure that we have the right capital investments and operational investments in our manufacturing and quality systems. That's another critical area we are spending a lot of time assessing that. And then finally one of the key areas to our long-term success relates to agreements with GPOs, IDNs and other major customers. And so that's another area that we are working – our U.S. teams are working very hard on that. And so we have full line of sight to the completed operating plan along with some further information on these numerous critical drivers, it's a little too early to get into on specifics on 2020.

### **Danielle Antaffy**

No, but that's helpful. And just one quick follow up as it relates to capital deployment. We touched on your ability to do M&A while this investigation is ongoing. What about your ability to continue to buy back shares? Can you do that before you file the 10-Q or are you limited in what you can do there?

### **Jay Saccaro**

So generally speaking, we don't comment on share repurchases for a lot of different reasons. What we typically do is after having repurchased shares, we make comments on how many shares we repurchased and there are a number of different reasons for that

that I think represent good practice. And so as it relates to going forward, stay tuned; we'll talk about share repurchases on an upcoming call.

**Danielle Antalfy**

Thank you so much.

**Jay Saccaro**

Thank you, Danielle.

**Operator**

Vijay Kumar with Evercore ISI is on the line. Please state your question.

**Vijay Kumar**

Hi, guys. Thanks for taking my question. Hello?

**Jay Saccaro**

Hi, Vijay. We're still here.

**Vijay Kumar**

Sorry about that. Can you hear me now?

**Jay Saccaro**

Yes, we can. We're good.

**Vijay Kumar**

Thanks for taking my question. So one maybe on the fundamental side, Joe or Jay. The 5% operational for Q4 and it looks like sequentially what changes I guess in the model because you do have a tougher comp Q4. I'm guessing some of this is on the pharma side. The Brevibloc headwind goes away. You spoke about Myxredlin. Are those the main drivers here to offset the tougher comp?

**Jay Saccaro**

Yes. As we always anticipated, there was an acceleration in Q4 in medication delivery that represents an important driver. The team's hard at work in terms of identifying new customers, doing a tremendous job on the pump side and also the large volume solution side. So that medication delivery does represent an important component as we look to close out the year successfully. And then we'll also see some improvements sequentially in nutrition. Again, that's an important business for us. The team has been hard at work recapturing some of the lost business in the U.S. but along with also successfully launching products. So those would be the couple of things that I would point out. I don't know, Joe, if you would add anything to that?

### **Joe Almeida**

I would say, Vijay, that compounding has had an effect on the sequential basis. We've been very successful with compounding, but compounding is a business that varies a lot based on what kind of drugs go into biosimilars and mineral compound in business outside the U.S. So biosimilars are very successful outside the U.S. when they go on. On biosimilars, we have not a reduction in profit but we have a reduction in sales just because of the purchase price. The other one is we're anniversarying dexmed. Remember, this is an \$80 million plus business that we're anniversarying right now. Myxredlin is just trying to pick up momentum. We're picking up to see sales go up on the ready-to-use insulin product, but the dexmed anniversary and then – so there are some puts and takes in the whole quarter, but it's not – now I don't see anything terribly different that would alter the momentum.

### **Vijay Kumar**

Thanks, Joe. And Jay just on the 2020 commentary that you made on – I think if I heard you correctly, you were talking about CapEx investments. So I just want to put that into context just given that free cash has been growing healthy. Are we looking at a step up in CapEx? Was that the genesis of the comment? And then just on the topic of free cash when you look at deploying free cash, between now and until the investigation gets resolved, can you buy back stock, right, I guess – and I apologize if this has been asked? With that, I'll stop. Hello?

### **Jay Saccaro**



Sorry, Vijay. A couple of things. As it relates to your question on capital, my comment about 2020 I highlighted a few drivers, the AAKHI. That initiative is an important long-term growth driver for us. We have not reflected on that particular initiative in our long-term plans but also in terms of our short-term capital plans. So that would be above and beyond our prior expectations in terms of CapEx investments. As it relates to manufacturing quality, one of the things we are intensely focused on is ensuring on the high quality manufacturing and that we have the right investments in quality. And that comes in two forms; OpEx certainly and also some CapEx. So that's another feature that we're looking at as we think about our 2020 planning. So those are a couple of highlights. And I've just chosen a few things to highlight as we think about our 2020 and which is why really we don't want to get into more detail on what our expectations are at this stage. As it relates to share buyback, like I say, our policy is simple and straightforward and frankly we really haven't varied from it over the last many years. We simply do not comment on share buyback until we've completed them.

**Vijay Kumar**

What I mean Jay was, is there – are you allowed to buy back I guess? I wasn't asking on -  
-

**Jay Saccaro**

So, Vijay, totally understood. But in conjunction with my comment regarding comment on share buybacks, furthermore we don't comment on our ability to buy back shares. That's how we do it.

**Joe Almeida**

Vijay, this has been a policy that's been here. Independent of this investigation, we wouldn't have given you this answer no matter what.

**Vijay Kumar**

That's helpful, Joe. Thank you, guys.

**Jay Saccaro**

Vijay, thanks for the questions.

**Vijay Kumar**

Thank you.

**Operator**

Larry Biegelsen with Wells Fargo is on the line. Please state your question.

**Larry Biegelsen**

Good morning. Thanks for taking the question. One on renal, one on nutrition. Joe, on the renal care initiative, what are the next steps there and when do you think you'll be in a position to tell us more about the impact not just from a capital standpoint in terms of the impact on your PD business? And is the point of care PD systems still a 2020 launch? And I have one follow up.

**Joe Almeida**

Larry, all the commentary, ours and a bunch of it, over a 100 comments that went into this system. I think the government original prediction was in November we would hear from the HHS. It can be January. We hope as soon as possible. So as soon as we hear from them, we are internally preparing several different scenarios in terms of growth rates and investments. That's why we announced \$500 million of investment, but there's some stuff that we can do in the meantime to increase capacity but we're going to have to invest money. So we have all these scenarios planned ready to go. We're just waiting to hear what is going to be the rule itself. Is this a mandatory or voluntary? Are there any changes that will make the demand go up or down? Is the population that they're experimenting with, the change in the policy, the same size that was originally conceived or differently? So there's so many variables. We are on it and we'll be ready to talk to you folks as soon as we hear from HHS when the rule is finalized and we're ready to go. Your question on point of care, point of care we are continuing with the clinical trial. We have more patients enrolled and that's a great thing for us to understand how to mix – how to compound a drug in somebody's home. And we've been successful in doing that. But don't get all focused on that alone. We are making investments in some very interesting early

technologies and we're very excited about it. So we're seeing some other stuff. We're being first there, getting to know. We're making investments, sitting on boards of these technology companies. We think the horizon has opened quite rapidly for innovation when it comes to treatment of patients at home. So I would say in about five to seven to eight years, this outlook how you treat patients may change and Baxter will be there because we are embedded in a lot of these new technologies that are being developed at the moment.

### **Larry Biegelsen**

That's very helpful. Just quickly for me on nutrition, what's the outlook there? You talked about new products in the U.S. and Europe, two new products but you talked about a three-chamber bag I think outside the U.S. Do you need that in the U.S. to accelerate your growth? Thanks for taking the questions.

### **Joe Almeida**

Larry, we do have products in the U.S. that will have multi-chambers. We think the U.S. is a slightly different market than the European market. The European market is a really early adopter of multi-chamber bags. Our multi-chamber bag in the U.S. will come at the right time. As a matter of fact, we have some very advanced plans we have in the product here. The thing that I want you to focus is that the opportunities outside the U.S. that we are very concentrated right now in putting together. There's opportunities in China, there are opportunities in other parts of the world and we are also developing and feel really good about a new multi-chamber technology that our folks in Belgium are looking and developing. So we'll continue to complete well. As you know, we are market leaders in U.S. in parenteral nutrition and we'll continue to firm our position by launching either multi-chamber bags either with fish oil, olive oil, whatever we think is the best combination for the patients here.

### **Larry Biegelsen**

Thank you for taking the questions.

### **Joe Almeida**

Thank you.

**Jay Saccaro**

Thank you, Larry.

**Clare Trachtman**

We have time for one more question, Katherine.

**Operator**

Okay. We have one from Matt Miksic with Credit Suisse. Your line is open.

**Matt Miksic**

Hi. Thank you. Just a quick one from me. I think we've covered a lot of the topics. But I've been hopping back and forth between calls, so I apologize if this was answered. But oddly, the topic is FX but not the investigation. Just maybe Jay if you could quantify maybe the impact of what looked like worse FX on some of your businesses if they showed up or in one place and another during the quarter just in terms of dollar terms? I know that's all netted out organic growth, but any color you can provide just because it did look like it stepped up during the quarter at least relative to estimates.

**Jay Saccaro**

Matt, I think you can appreciate our sensitivity with respect to discussions of FX on a business line for regional basis today. So I'll refrain from answering that question and perhaps at a future date we can get into more detail by line, by business and so on.

**Matt Miksic**

I understand. Thank you.

**Jay Saccaro**

I definitely appreciate your understanding.

**Clare Trachtman**

Katherine, I think we can wrap up the call now.

**Operator**

Ladies and gentlemen, this concludes today's conference call with Baxter International. Thank you for participating and have a nice day.