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Boston Scientific Corporation (BSX) CEO Michael Mahoney on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-23-19 Earnings Summary

Press Release *10-Q* *Slides*

EPS of $0.39 beats by $0.01 | Revenue of $2.71B (13.12% Y/Y) beats by $31.94M

Earning Call Audio

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Boston Scientific Corporation (NYSE:BSX) Q3 2019 Results Earnings Conference Call
October 23, 2019 8:00 AM ET

Company Participants

Susan Lisa - Vice President, Investor Relations

Michael Mahoney - Chairman and Chief Executive Officer

Daniel Brennan - Executive Vice President and Chief Financial Officer

Ian Meredith - Executive Vice President and Global Chief Medical Officer

Conference Call Participants

Robert Hopkins - Bank of America Merrill Lynch

David Ryan Lewis - Morgan Stanley

Frederick Wise - Stifel Nicolaus

Vijay Kumar - Evercore ISI

Robert Marcus - J.P. Morgan

Matthew Taylor - UBS

Lawrence Biegelsen - Wells Fargo Securities

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Boston Scientific Q3 2019 Earnings Call. Now, at this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will be given at that time. [Operator Instructions]. As a reminder, today's call is being recorded.

I will now turn the call over to your host, Susan Lisa. Please go ahead.

Susan Lisa

Thanks, Kevin. Good morning, everyone, and thanks for joining us. With me on today's call are Mike Mahoney, Chairman and Chief Executive Officer, and Dan Brennan, Executive Vice President and Chief Financial Officer.

We issued a press release earlier this morning announcing our Q3 2019 results, which included reconciliations of the non-GAAP measures used in the release. We have posted a copy of that release, as well as reconciliations of the non-GAAP measures used in today's call to the Investor Relations section of our website under the heading Financials and Filings.

The duration of this morning's call will be approximately one hour. Mike will provide strategic and revenue highlights of Q3 2019. Dan will review the financials for the quarter and then provide Q4 2019 and full-year 2019 guidance, and then we'll take your questions. During today's Q&A session, Mike and Dan will be joined by our Chief Medical Officers, Dr. Ian Meredith and Dr. Ken Stein.

Before we begin, I'd like to remind everyone that, on the call, operational revenue excludes the impact of foreign currency fluctuations and organic revenue further excludes the impact of certain acquisitions, including NxThera, Claret, Augmenix, Vertiflex and BTG in the relevant periods for which there are no prior period related net sales.

Also note, this call contains forward-looking statements within the meaning of federal securities laws, which may be identified by words like anticipate, expect, believe, estimate, and other similar words. They include, among other things, statements about our growth and market share, new product approvals and launches, clinical trials, cost savings and growth opportunities, our cash flow and expected use, our financial performance, including sales, margins, earnings and other Q4 and full year 2019 guidance, as well as our tax rates, R&D spend, and other expenses.

Actual results may differ materially from those discussed in the forward-looking statements. Factors that may cause such differences include those described in the Risk Factors section of our most recent 10-K and subsequent 10-Qs filed with the SEC. These statements speak only as of today's date, and we disclaim any intention or obligation to update them.

At this point, I'll turn it over to Mike for his comments. Mike?

Michael Mahoney

Thank you, Susie. Good morning, everyone. Boston Scientific delivered a very strong third quarter. We continued to grow above market and improve profitability, while we also invest for the long term and deliver meaningful innovation to address unmet patient needs.

In the third quarter, our team delivered 14.2% operational and 9.3% organic revenue growth, with another quarter of strong balance across our businesses and geographic regions.

In addition, we delivered adjusted EPS of $0.39, which is the high-end of our guidance range, while generating $526 million in adjusted free cash flow.

We're also narrowing our guidance for the full year 2019 organic revenue growth to approximately 7.5% and bringing up the bottom end of our adjusted EPS guidance range to $1.55 to $1.58.

We've also increased our expected contribution from acquisitions from 140 basis points to 360 basis points, resulting in operational revenue growth guidance of 11% to 11.5% for the full year.

I'll now detail some key aspects of our third quarter results and thoughts on our Q4 2019 prospects. All growth rates refer to organic sales growth versus the prior year unless otherwise stated.

MedSurg sales accelerated to 10% organic and 14% operational revenue growth. Endoscopy organic revenue growth of 10% was fueled by the breadth of our portfolio, including multiple launches across several franchises, most notably in infection prevention, therapeutic imaging, biliary and luminal hemostasis product lines.

We also enjoyed double-digit growth across multiple regions. And importantly, we remain on track for a year-end launch of our Exalt-D single-use duodenoscope and we're encouraged by the FDA's communication in September regarding single-use technologies.

We continue to believe that our therapeutic imaging portfolio represents a significant opportunity in 2020 and beyond, with an incremental $2 billion market opportunity by 2024.

Urology and pelvic health also grew 10% organically and 19% operationally. And I would say this is particularly impressive as the team offset 150 basis point headwind to organic growth from the market withdrawal of transvaginal mesh for the treatment of pelvic organ prolapse.

Double-digit growth organic sales in uro/PH was led by strong momentum in our core stone where we are uniquely positioned to treat the broadest range of kidney stone cases via our innovative LithoVue, lithotripsy and laser portfolio.

SpaceOAR, which is a hydrogel that temporarily creates space between the prostate and organs at risk during radiotherapy for prostate cancer, contributed 900 basis points of operational revenue growth and went organic in October 1. SpaceOAR continues to deliver excellent results and is tracking $100 million for full year 2019.

In the quarter, NxThera, which offers a unique minimally invasive treatment for BPH, also accelerated our growth and we continue to engage with insurers, physicians and patients to strengthen this exciting platform.

Our rhythm and neuro team group grew 4% in the quarter, which we believe represents above-market growth in CRM at 2%, while EP sales did grow below market at 7% and neuromodulation sales grew 8%.

So, I'll start off with neuromodulation. The neuromodulation sales results of 8% organic and 18% operational growth represents an acceleration versus second quarter despite a challenging 23% comp in Q3 2018.

In our neuromodulation business, we have developed a strong and diversified portfolio in deep brain stimulation and across the continuum of care for pain patients via our complementary platforms in SCS, RF and Vertiflex.

In DBS, our Vercise platform nearly doubled sales year-over-year and is consistently gaining global market share and now offers patients full-body MRI labeling along with our differentiated Cartesia Directional Lead.

In our pain franchise, our SCS results, which were down low-single digits globally, showed sequential improvement as we're seeing some modest signs of market stabilization.

We aim to deliver continued improvement in SCS in fourth quarter with the launch of WaveWriter software enhancements and then into 2020 with the release of the COMBO randomized clinical trial data on WaveWriter at NANS in January.

The Vertiflex platform represents an important therapy for patients with moderate lumbar stenosis. Vertiflex continues to see growing demand and is on track to deliver full-year 2019 sales of $60 million. And, overall, we're enjoying strong momentum with our category leadership strategy across our neuromodulation portfolio.

Global CRM sales grew 2%. And in defib, global sales continued to grow faster than market and were up low-single digits, driven by our RESONATE platform and replacements, while S-ICD also continued to grow.

Pacer sales declined low-single digits in the quarter which were consistent with second quarter, but we're wrapping up the limited US market release of our new program which should enable an improved implant experience and unique remote service capabilities.

So, looking ahead, we remain on track to launch LUX-Dx, which is our implantable cardiac monitor by midyear 2020.

EP sales grew globally 7%, but, importantly, we received US IDE approval in late September to begin the clinical trial of POLARx single-shot cryotherapy and we plan to initiate enrollment before year-end. We're targeting the year-end launch of POLARx and excited to enter this large vascular and single shot market with this next gen cryo platform.

Shifting now to cardiovascular. The group sales were up a strong 13%. Peripheral intervention sales increased 8%, led by continued momentum across our arterial, venous and interventional oncology platforms.

The launch of our VICI venous stent is going very well and global Eluvia results were consistent with our previous commentary at TCT in September.

On August 19, we closed the BTG transaction and welcomed the team to Boston Scientific. Sales of legacy BTG interventional grew high-single digit in third quarter and we're very pleased with the integration process thus far and expect this business to deliver double-digit growth in 2020.

We're focused on adding additional commercial capabilities, initiating product registrations in Europe and Asia, and delivering productivity synergies as previously communicated.

Specialty pharma sales declined in the quarter largely due to rebates and timing of product expirations, and they were slightly above our internal plan as CroFab continues to do well both clinically and in maintaining high market share.

For the third quarter stub period, which is August 19 through September 30, all of BTG is reported separately for both sales and operating income as we integrate operating and reportable segments.

Our interventional cardiology business accelerated from 5% in the first quarter to 8% in the second quarter and now 15% in the third quarter. This represents strong growth across all regions, led by structural heart sales across all product lines and excellent growth in coronary therapies, up 6% globally.

The diversification of our coronary therapies business continues to deliver results, with mid-teens growth across the board in complex PCI products, while our PCI guidance business, which is IVUS and FFR grew in the mid-20s.

Drug-eluting stent sales were down mid-single digits which is an improvement from first-half trends. And in Europe, we recently launched SYNERGY MEGATRON, which is a purpose-built stent for large proximal vessels. With a mid-2020 US launch targeted, MEGATRON is an important extension of our market-leading SYNERGY platform.

With respect to DBS business, I'd like to comment on some recent concerns regarding the potential impact of the ischemia trial which is scheduled to be presented at AHA on November 16. We won't know the results in ischemia until then, but we believe the impact will be highly manageable in all scenarios, with a potential future dollar impact ranging from slightly positive to negative $40 million. So, I'll leave additional details on this topic for any interest in Q&A where Ian can provide more detailed commentary about the trial design and physician practice.

So, now turning to structural heart. The combined strength of Watchman, Lotus Edge, ACURATE, and Sentinel positions very well to deliver toward the high-end of our guidance of $700 million to $725 million in structural heart revenue in 2019.

Watchman year-over-year growth accelerated from second quarter's rate as the platform continues to build global momentum with physicians and patients. And Watchman recently received reimbursement in Japan and we're building out this new therapy with a focus on opening new accounts and physician training.

We continue to enjoy strong demand for next generation Watchman FLX in Europe and we're enrolling both in the OPTION trial as well as the ASAP-TOO.

The US reimbursement outlook for Watchman remains very positive, with an 8.6% weighted average increase in 2020 Medicare reimbursement.

So, turning to our catheter business. ACURATE neo sales grew faster than the market in third quarter and the product is now available in 45 countries. We continue to enroll in the ACURATE neo2 IDE trial in the US with a targeted 2021 launch. And we also continue to expect European launch of our next generation ACURATE valve in mid-2020.

And post the Scope I results and prior to the launch of ACURATE neo2 in Europe, we do estimate that ACURATE neo growth will likely slow on a percentage basis, but will likely remain accretive to growth for both IC and BSC overall.

The Lotus Edge launch is going extremely well and we're building momentum in both the US and Europe. We remain on pace to open 150 accounts in our first 12 months in the US and we're currently in limited market release for the 15 FR iSLEEVE introducer sheath.

We also remain on track to launch in Japan in 2020 and continue to enroll the REPRISE IV US clinical trial to expand indication to intermediate risk patients.

Finally, adoption of the Sentinel cerebral embolic protection device continues as penetration and account openings expand in the US, Europe and other markets.

Sentinel is now in 500 accounts globally and we're pleased to announce recently at TCT that, in 2020, we will initiate the global protected TAVR randomized clinical trial. We believe that definitive evidence focused on the stroke endpoint will continue to elevate Sentinel to become the standard of care for all patients and will help influence future clinical guidelines.

So, to close, I'd like to share my enthusiasm for the outlook of the rest of this year and in 2020 and beyond. We believe that Boston Scientific continues to be uniquely positioned to drive shareholder value due to our strong long-term growth profile, meaningful opportunity to improve operating margins, track record of delivery and double-digit adjusted EPS growth and our proven ability support to deploy capital.

I want to really thank our employees once again for their winning spirit and commitment to advancing science for life. And Dan will now provide a detailed review of our financials.

Daniel Brennan

Thanks, Mike. Third quarter consolidated revenue of $2.707 billion represents 13.1% reported revenue growth and reflects a $26 million headwind from foreign exchange, slightly favorable to the $30 million to the $35 million headwind expected at the time of guidance.

On an operational basis, which excludes the impact of foreign currency fluctuations, revenue growth was 14.2% in the quarter.

Sales on the Claret, Augmenix and Vertiflex acquisitions contributed 210 basis points, higher than the 180 basis points expected at the time of guidance.

As a reminder, the operational contribution from Claret only represents one month as the acquisition was considered organic as of August 1 this year.

The acquisition of BTG, which closed within the quarter and was not included in prior guidance, contributed an additional 300 basis points to operational growth with two-thirds from the interventional medicine business and the remainder in specialty pharmaceutical.

The divestiture of our legacy embolic beads portfolio partially offset acquisition contributions by 10 basis points.

The resulting organic growth of 9.3% in the third quarter exceeded our guidance range of 7.5% to 9%.

With the strong sales performance, we delivered Q3 adjusted earnings per share of $0.39 at the high-end of our guidance range of $0.37 to $0.39 and representing 13% growth versus the prior year. The FX impact on adjusted earnings per share was immaterial as expected at the time of guidance.

Adjusted gross margin for the third quarter was 72.7%, at the midpoint of our guidance range of 72.5% to 73% and flat versus prior year as favorable FX impact and manufacturing improvements were offset by price erosion in coronary drug-eluting stents

and pacers as well as a mix shift within our coronary therapies franchise from DES to complex PCI products.

Adjusted SG&A and expenses were $949 million or 35.1% of sales in Q3, a 40 basis point improvement year-over-year due to ongoing operating expense control and optimization initiatives, but just outside our guidance range, driven by the acquisition of BTG which was not included in guidance since the transaction had not closed at the time.

Adjusted research and development expenses were $297 million in the third quarter or 11% of sales, at the high-end of our range, again partially driven by BTG expenses which were not reflected in guidance and relatively flat to Q3 of last year.

Royalty expense was 0.6% of sales, also roughly flat over prior year.

With solid topline results, balanced by the funding of key commercial launches and supporting acquisition-related initiatives, Q3 2019 adjusted operating margin achieved the lower end of guidance at 26.1%, increasing 50 basis points year-over-year.

While immaterial to earnings, BTG did create an approximate 10 basis point drag to adjusted operating margin in the quarter.

Now, I'll move below the line to interest and other expense. Adjusted interest expense for the quarter was $83 million and now includes BTG compared to $58 million in Q3 of last year. Our average interest rate was 3.5% in Q3 of 2019, slightly higher than the 3.2% in Q3 of last year.

Adjusted other expense was $11 million in the quarter and primarily includes dilution from our equity method investments and transactional foreign exchange losses, including hedging costs.

Our tax rate for the third quarter was negative 38.7% on a GAAP basis and 10.3% on an adjusted basis, below our guidance of approximately 11% for the quarter as we realized a net benefit from stock compensation accounting.

Adjusted free cash flow for the quarter was $526 million compared to $569 million in Q3 of last year. We now expect full year adjusted free cash flow to be closer to $2.1 billion due to increased working capital requirements, mainly in inventory to support new product launches and overall sales growth.

We continue to work to resolve fully the mesh litigation, with over 95% of all known claims now settled or in the final stages of settlement, including additional settlements reached during Q3.

Our total legal reserve, of which mesh is included, was $568 million as of September 30, 2019. This is a decrease of roughly $35 million versus June 30 and includes an additional $25 million reserve for international settlements. There is no change to the US outlook where the known claim count remains flat at 53,000 as does the anticipated amount required for settlement.

Including these international settlements, we now anticipate payments into qualified settlement funds to total $270 million, which will then resolve all significant existing contingencies related to mesh.

However, as the legal and administrative processes are taking a bit longer than previously estimated, we now expect payment of this $270 million to extend into 2020, with $120 million paid in 2019 and the remaining $150 million to be paid in 2020.

As a reminder, this liability is released from our balance sheet as payments are made out of the qualified settlement funds to plaintiffs.

Capital expenditures for the third quarter 2019 were $121 million. We expect capital expenditures to be towards the high-end of our guidance range of $375 million to $400 million for the year as we build capacity, integrate acquisitions and position the company for continued growth.

We ended Q3 with 1.412 billion fully diluted weighted average shares outstanding.

I'll now walk through guidance for Q4 and full year 2019. For the full year, we expect 2019 reported revenue growth to be in a range of approximately 9% to 9.5%. On an organic basis, we're narrowing our full-year revenue growth guidance to approximately 7.5% and

expect the net contribution from acquisitions and divestitures to provide an additional 360 basis points of growth. Of that 360 basis points, we expect a contribution of approximately 155 basis points from BTG interventional medicine and 70 basis points from BTG specialty pharmaceuticals.

We expect foreign exchange to be a $175 million to $180 million headwind to revenue for the full year and we continue to expect FX to be neutral to earnings per share for the year due to our currency hedging program.

We now expect our full year adjusted gross margin as a percentage of sale to be in the range of 72.25% to 72.5% for the full year, narrowing towards the midpoint of prior 72% to 73% guidance. We will continue to execute on our ongoing standard cost reductions and also expect a positive full-year FX impact to adjusted gross margin of 60 basis points, which remains partially offset by pricing declines.

We expect full year adjusted SG&A to be approximately 35% of sales and down slightly year-over-year. There's no change to expectations from full-year adjusted R&D expense to be in a range of 10.5% to 11% and full year royalty rate to remain at less than 1% of sales for 2019.

As a result, we expect to achieve 2019 adjusted operating margin in a range of 26% to 26.25%, up 50 to 75 basis points versus 2018. This revised range reflects the lower half of our original 26% to 26.5% guidance range due to the impact of closing BTG in August.

Although BTG contributes operating income, which is largely offset by the incremental interest expense, it is not yet at the company overall rate. So, it is dilutive to the total adjusted operating margin by approximately 20 basis points for the year.

We remain committed to our improvement goals outlined at Investor Day with a sustainable goal of 50 to 100 basis points of annual operating margin improvement.

We expect our full-year 2019 adjusted tax rate to be approximately 9%. This is based on an operational tax rate of approximately 11%, slightly more than 100 basis points of benefit from the accounting standard for stock compensation and nearly 100 basis points

from the discrete tax benefits in Q2, which will not impact our tax rate outlook beyond 2019.

We expect below the line expenses, which include interest payments now inclusive of BTG, dilution from our venture capital portfolio and costs associated with our hedging program to be approximately $400 million for the year.

Note that yesterday we announced a cash tender offer for up to $1 billion of our outstanding debt securities subject to financing conditions and target launching a Eurobond offering shortly, given attractive rates in European bond markets.

We expect a fully diluted weighted average share count of approximately 1.415 billion shares for Q4 2019 and 1.411 billion shares for full year 2019.

We're raising the low end of our full-year 2019 adjusted earnings per share guidance to $1.55 and maintaining the high end of $1.58. This represents a full year adjusted earnings per share growth of 11% to 13% excluding the 2018 net tax benefit of $0.07 in the base. On a GAAP basis, we expect EPS to be in a range of $0.72 to $0.75.

Now, turning to Q4 2019, we expect reported revenue growth to be in a range of approximately 13% to 15%. This represents strong year-over-year organic revenue growth of 8% to 9%, with an approximate net 600 to 680 basis points of operational growth contribution from acquisitions and divestitures. Of the 600 to 680, we expect roughly 390 to 430 basis points from BTG interventional medicine and 160 to 200 basis points from BTG specialty pharmaceuticals. We expect the foreign exchange impact on Q4 revenue to be a $20 million to $25 million headwind.

For the fourth quarter, adjusted earnings per share is expected to be in a range of $0.42 to $0.45 per share, representing 10% to 18% growth excluding the Q4 2018 net tax benefit of $0.01 in the base and we do not expect any adjusted EPS impact from foreign exchange.

GAAP earnings per share for the fourth quarter is expected to be in a range of $0.22 to $0.25 per share.

Please check our investor relations website for Q3 2019 financial and operational highlights which outlines Q3 results as well as Q4 and full year 2019 guidance, including P&L line item guidance.

With that, I'll turn it back to Susie who will moderate the Q&A.

Susan Lisa

Thanks, Dan. Kevin, let's open it up to questions for the next 30 minutes or so. In order to enable us to take as many questions as possible, please limit yourself to one question and one related follow-up. Kevin, please go ahead.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions]. First question from the Bob Hopkins, Bank of America. Please go ahead.

Robert Hopkins

Great. Thank you and good morning. And congrats on a good third quarter. Two quick questions for me. First, I think we all appreciated the encouraging comments you made on the ischemia trial. I was wondering if you wouldn't mind just quickly walking us through why you see only maybe a $40 million negative case impact if there's no difference between PCI and drug therapy, just kind of walk through the math there if you don't mind. Thank you.

Michael Mahoney

Hey, Bob. Good morning. So, I'll start with a quick summary. Then I'll let Ian walk you through with some more color. First of all, to start off by saying, it's important to recognize – we certainly have a very long history of clinical evidence in the space and innovation demonstration for the right patient. It's clearly appropriate and can be life-changing therapy.

And second, we do think there's a decent amount of confusion regarding this study and its impact. And as I mentioned in the script, really the third point, we think the financial impact could be anywhere from a positive impact to a slightly negative impact of up to potentially $40 million based on a 5% to 10% reduction in our revenue related to treatment of these patients with coronary syndromes.

So, Ian, maybe you could just follow on with some color as to why we feel the impact in that kind of positive to minus $40 million range.

Ian Meredith

Thanks, Mike. Thanks, Bob. To elaborate on what Mark just said, as you know, the population of patients in the ischemia trial of stable patients undergoing revascularization and not those patients that receive the vast majority PCIs in the US and indeed globally. 80% of patients undergoing PCI in the US, and similar outside the US, are done in patients with unstable angina or acute coronary syndromes. And, of course, the role of PCI in those settings is not in dispute nor the focus of the current trial. It's important to note, though, that in the ischemia trial, not all patients with stable ischemic heart disease were eligible even to be enrolled in this study and then there were significant exclusions after enrollment before randomization. Many of the more complex and sick patients – for example, those with low small ejection fraction, heart failure, left main coronary disease, end stage renal disease, concomitant valvular heart disease, dilated cardiomyopathy, previous unstable angina now stable are all ineligible for this trial. So, in all, there are 28 major exclusions from the stable ischemic population in this study. So, the translatability of this data set to the 20% who are in the stable ischemic population probably accounts for significantly less. And so, it is on that basis that we think that the impact would be significantly less.

Robert Hopkins

Okay. Yeah. Appreciate you framing that. Just one other quick follow-up. Mike, over the last couple of months, there's been sort of three things that have caused a little concern about the 2020 outlook – the BTG growth, the neo data from TCT and ischemia. And you've kind of addressed all of them in your prepared remarks. But I just want to make

sure I heard the message right. The message on BTG that you're comfortable with high single digits going forward. And I just want to make sure, on neo, that despite the data you still expect that product to grow going forward.

Michael Mahoney

We think the Street worries about these things more than we do because we feel like we can manage all of this very effectively. As Ian – we laid out on the DES piece, this is still an important business for us, but now it's approaching 7% of our mix. Urology alone can be three times bigger than DES given the strong diversification of our – in the US, I should say. So, we think that one has clearly been we think overblown in terms of some of the writeups that we received.

On the SCOPE I, on the reports I gave in the written script, we do expect – there's a likelihood that that growth will slow down on a percent basis in 2020, but we're quite confident that will grow above the BSX corporate average as well as the IC corporate average really based on the followership that we have in Europe with that valve. Current users are very pleased with the performance of that valve. They continue to use it. They continue to increase their utilization. And so, we'll be anxious to get the second-generation valve approved hopefully mid-2020 in Europe. So, we feel good about that.

We feel very confident in the full-year guidance that we provided. The company has a very broad range of diversified portfolio. We continue to advance ourselves in high-growth markets and we have very durable high-growth outlook.

Operator

And the next question is from the line of David Lewis, Morgan Stanley. Please go ahead.

David Ryan Lewis

Great. Thanks so much. Just a couple of quick questions. Dan, I just want to start with you. Guidance into the fourth quarter – actually, a very strong third quarter – reflects some deceleration, but there are some one-timers and some comparability issues from the third

to fourth. Can you help us quantify some the comparability dynamics from the third to the fourth quarter and how you see or how investors should see kind of underlying business momentum into the fourth quarter?

Daniel Brennan

Sure, David. Yeah. As we look at the sequential going from Q3 to Q4, true, the comp gets a little bit easier as you go from Q3 to Q4. We do have a little bit less of a benefit of days. We talked about we had a benefit of days in the second half versus the first half. Saw more of that benefit in Q3 than we will in Q4. So, as we look at the 8% to 9%, I think that's very solid guidance for the fourth quarter. It gets us 7.5% for the full year. And that would be, as Mike had alluded to, acceleration again this year versus last year and feel that's a good place to be for the fourth quarter. We, obviously, have some good launches as well. We had some momentum with Lotus. We have the Watchman going in Japan. We have endo which is kind of – had been single digits in the first half, back into the double-digits. Urology is going strong. A little bit of a wait and see on spinal cord stimulation. We did see a bit of stabilization in the quarter, but, obviously, not to the levels that we've seen in the past.

So, given the headwinds and tailwinds we have, we think 8% to 9% is strong guidance for the fourth quarter that get us to that 7.5% for the full year, which is acceleration versus last year.

David Ryan Lewis

Just wanted to come back to BTG for a second. I think this is one of the issues that, with a delayed integration, that business has slowed a bit. Actually, in the third quarter, the number came in much better than we were expecting. So, has there been sort of stabilization in recovery in BTG in the early days of integration?

And recent events, Jeff has sort of talked about the ability of taking that business to sort of 50-50 global mix over the next several years. Just maybe, Mike, your recent trends in BTG and sort of your just confidence in getting that 50-50 global mix implies some pretty dramatic growth dynamics for BTG over the next two to three years. You're confident that kind of global mix is achievable here in the near term or in the intermediate term?

Michael Mahoney

Sure. And I saw. I missed that earlier, your BTG comment. So, just on BTG overall, very excited to finally get this closed. It did take three or four months longer than we planned. We did have some commercial turnover during that period which the team, now that it has closed, is shoring that up and really beeping up the resources on the commercial side.

As I said, focused on product registrations globally to enhance that international mix. For sure in Europe and Asia-Pac. And importantly, we feel very confident with the cost synergies that we've committed to.

And based on really just early feedback from physicians, the combined portfolio in interventional is really kind of we laid out. It makes sense for interventional radiologist in the interventional oncology space to have these therapeutic capabilities that we have now with cryo and Y-90 as well as additional capabilities that we have with EKOS and Varithena and so forth.

So, the portfolio fix is really kind of a dream for the commercial team. And based on that, we do feel comfortable that BTG will grow faster than the BSC composite in 2020 and beyond and be nicely accretive to the PI business. And we're comfortable with the double-digit growth scenario in 2020 and going forward with BTG interventional.

So, really, all systems go there. The team is focused on integration and we're pleased that we closed the deal.

Operator

Next question is from the line of Rick Wise, Stifel. Please go ahead.

Frederick Wise

Good morning. Let me turn to Lotus for a moment. Sounds like everything with the launch is on track. Can you just expand on your comments on the 15 FR sheath launch? It sounds like you're still on limited launch. We've heard from physicians that the smaller

sheath size really makes a big difference. You said it was going to be the fourth quarter for a full launch. I think where in the fourth quarter is it happening? And with that launch, would we expect to see a step up or an acceleration in Lotus utilization into 2020?

Ian Meredith

Thanks very much. We could see in here. The 15 FR size sheath will actually expand the option in terms of how many patients can be treated because we're always seeing patients excluded from either our clinical trials or commercial use because their peripheral vessels aren't large enough for the existing, but very functional delivery sheath. So, the limited market release is going very well. It's on track and the plans haven't changed thus far. [indiscernible] have an impact on the ability to take in more patients. There will be fewer exclusions, probably 5% of patients are being excluded on vessel size. But the roll out of Lotus Edge, of course, is a planned, controlled release. In the short term, it will be determined by training.

Unidentified Participant

Okay. And if I could turn to sort of a big picture and looking at 2020 question. Mike, you've addressed obviously some of the key concerns on acute ischemia and BTG, but I think there has been a larger discussion and debate about potential 2020 growth headwinds from some of those issues and elsewhere. I know you're not ready to provide 2020 guidance today, but maybe you could help us think from a high level some of the puts and takes and maybe what we're underthinking on the positive side about as you look at 2020 and you sort of emphasize that you think that some of the negatives we're concerned about might be a little less challenging than feared. Thank you.

Michael Mahoney

Sure. Thanks, Rick. Clearly, we're not going to give 2020 guidance at this point. I just think there's a lot of very positive things going on in the company. You look at the momentum that we have really across each business. With the exception EP, each business we believe grew nicely above market and we have very strong momentum across each

region. Emerging markets growing at nearly 20%. Very strong above-market growth in Europe which is impressive given that most of our products get approved in Europe prior to get in the US and very strong growth in the US.

And importantly, since you said high level, each quarter, we continue to shift our mix of businesses into faster growth markets as we've outlined that numerous times in various calls. So, each quarter, that profile in terms of our growth potential gets stronger and the team continues to grow above market while investing for the long term. And we have many exciting product launches in 2020, with the Exalt scope which we think will be a really unique platform for us for many years, across our structural heart portfolio where the Watchman FLX would be approved, ideally the ACURATE neo2 in the second half and very a strong product cadence.

You can see the – for example, neuromodulation. That business really was solely based on US SCS. And now that business is very diversified with growth in Europe and you're seeing tremendous growth out of our DBS platform which nearly doubled in sales and we'll have that for a full year in 2020.

So, we have many different, I would say, tailwinds to offset some of these, I would say, overblown headwinds which were ischemia, the ACURATE SCOPE I as well as the BTG. We're very confident in ACURATE for the long term. We're very confident in BTG. And our DES business, although not a key growth driver, is an important contributor.

So I think, overall, we are excited about the future. I think if you look at our Investor Day deck, we talked about its acceleration. So, despite some of these headwinds in 2019, we expect to grow organically faster than we did in 2018, and that would clearly be our goal for 2020. And at our Investor Day, we talked about organic acceleration in 2020, 2021 and 2022 versus the previous three years. So, we think we have all the tools to do it and we have a lot of confidence in our team to deliver.

Operator

Next question is from the line of Vijay Kumar, Evercore. Please go ahead

Vijay Kumar

Thanks, guys. Congrats on a really nice print here. Mike, maybe turning to some of the positives. The one which really stood out for us was the interventional cardiology. I know you mentioned complex PCI, but that doesn't seem to have changed trends. It's been up teens, mid-teens, pretty consistent. So, it really looks like structural heart really changed trajectory here. So, I'm just trying to understand, how much of this is maybe possibly an acceleration underlying TAVR market growth versus standalone Boston outperformance? I think you mentioned Watchman coming in well above. So, maybe tease out what is Boston specific versus maybe underlying market strength?

Michael Mahoney

Yeah. So, in cardio, the value of complex coronary is probably understated across the company. It may be our most important platform in Asia-Pac. Our complex coronary business is growing much faster than BSC composite. We continue to invest quite a bit in new portfolio there. And that business is really quite a bit larger than our DES business. And so, again, that was a purpose strategy from Kevin Ballinger, Lance Bates and the team over the year. So, I think complex coronary will continue to be very bright as it gets significantly larger than DES. And also, positions us more uniquely in cath lab clinically with doctors.

And structural heart, I think we know Watchman is doing extremely well. Watchman continues to accelerate growth, continues to deliver strong outcomes, improve utilization and we're very excited about the FLX progress that we're seeing in Europe and our ability to take share in that market with that second gen product and that coming to the US. So, I think we're excited about Watchman as we head into fourth quarter and 2020.

And then, our TAVI plans are really on track. We're very excited where we're with Lotus. I do not think there is a – we have seen a tremendous change in terms of the market growth, but the outcomes with Lotus have been very favorable. We think it offers some very compelling differentiation versus our competition and we're really on track with opening the 150 accounts really per our plan. And I made comments on ACURATE before.

I think the combination of all these things within cardiology are going to lead to nicely above growth versus the BSX overall average as you look forward to 2020. And, slowly, that strategy of diversification into complex coronary and structural heart, that's working.

Vijay Kumar

That's helpful, Mike. And, Dan, maybe one quick one for you. I think I heard you mention BTG, about 20 basis points [indiscernible] margins. That would imply 40 to 50 basis points of dilution in 2020 and possibly some of that being offset by synergies. Is that the right math? Just to think about margins for next year.

Daniel Brennan

Yeah. I think as you look at 2020, we'll obviously give you a lot more color as we give guidance here at our next call. But, obviously, the $175 million in overall synergies, as Mike said, we're committed to that over that three-year timeframe. And the BTG operating margin will continue to improve where it will be – the interventional medicines piece will be approaching PI and then eclipsing PI and eclipsing the overall for Boston Scientific. So, it would start to be accretive to Boston Scientific overall. And we'll give you more on the timing on that when we talk about 2020 and specifics.

Michael Mahoney

And maybe to go back to – follow-up on David's question on BTG O-US. I think given the strength that we have in the US and the concentration in the US, it's going to be difficult in the near term to get to 50-50 split between internal markets and the US, given the base that we have in the US and our expectations for double-digit growth.

But that being the case, Jeff and the team are spending quite a bit of resources and leveraging our capabilities in both Europe and Asia, particularly in the regulatory capability area to get these new products approved in Europe into our sales force. That's ready to take them as well as Asia.

And also, we're making investments – more strategic, long term investments, specifically in China, with our Y-90 and TheraSphere portfolio to ideally build a capability there where liver cancer is really 2x the size of the US.

So, it may take some time for us to – in terms of our revenue mix where it's more meaningful, but we're putting the efforts there. We already have commercial teams in place and a big focus area to grow O-US or international BTG.

Operator

Next question is from Robby Marcus, J.P. Morgan. Please go ahead.

Robert Marcus

Thanks. And congrats on a good quarter. One of the areas you continue to do well in despite some of the underlying market fundamentals is neuromodulation. I was hoping you could break down some of the growth trends of your different business, DBS versus spinal cord stim, and any commentary you can add to the market health overall?

Michael Mahoney

Sure. So, we're pleased with the overall performance of neuromodulation in the quarter. As I mentioned in the script, really the highlight there for that was our deep brain stimulation platform, Vercise, which is doing extremely well globally, taking quite a bit of share and really doubling the sales year-over-year. And we're excited for 2020 when we'll have the full body MRI capability and the Directional Lead for the full year in 2020 So, a lot of the optimism in neuromodulation.

I think the second highlight there would be our business in the pain overall. So, we essentially have diversified our capabilities there in both SCS, Vertiflex as well as RF. And our Vertiflex acquisition is really exceeding our deal model and we're really the best company to provide that continuum of care for RF lumbar stenosis with Vertiflex or SCS. So, I think that positions us more uniquely versus our peers in terms of that full portfolio to address that. We're seeing great results out of Vertiflex, great results out of RF.

On SCS, the results, we believe, have improved. So, it's a positive trend, but clearly not to the market levels that we enjoyed in the past. We do believe still that, going forward, this will be a mid to high single-digit growth market based on historical trends. And we'll have some easier comps next year in SCS. And, I guess, that's good to look forward to.

But we do have some new software enhancements that we'll be launching in fourth quarter to our platform, as well as the NANS data that I commented on. So, I think, overall, the marketplace still is clearly not to the levels that it was in 2018 and historical. Potentially, low negative single digits. But we believe we continue to grow above market in SCS and we're really buoyed and enhanced by the depth of the portfolio with Vertiflex, RF and our DBS platform, which is really kind of in line with our category leadership strategy. And as we go forward in 2020, we aim to see slightly better overall SCS market trend, which should help.

And then just, Robby, just the last point on that, with all of those things in place and obviously the SCS not where we had expected to be and many had expected it to be, the overall neuromod franchise grew 8% in the quarter. So, I think that just really speaks to the diversification within that entire business that it's not just an SCS portfolio that it was able to grow 8% in the quarter.

Robert Marcus

And then, a quick follow-up here. Complex PCI, over a billion dollar business, growing mid-teens. I just looked back for over two years now and double digits except for one quarter. PCI guidance, low 20s, I think you said in the script. What's driving such strong growth and how durable can this be?

Ian Meredith

Just to speak to what potentially would be driving this, first of all, we have an aging population with an increasing burden of risk factors, and so there is a greater proportion of patients who are elderly who are being treated by percutaneous intervention to the obvious benefits of being minimally invasive. And as you get older, you have more calcification and more disease. And there is a greater focus now on careful selection of lesions to make sure you're treating the right lesion and optimizing the treatment. So, the practice of interventional cardiology is really more sophisticated. And there's an expectation of better outcomes and you do that by PCI guidance and by functional assessment of the lesions at the time. And, of course, changing demographics means we're dealing with a significant burden of the elderly degenerative disease. And that is the reason it continues to grow.

Operator

Next question from the line of Matthew Taylor, UBS. Please go ahead.

Matthew Taylor

Hi. Thanks for taking the questions. I just want a follow-up on some of your comments on EXALT-D. You seem very excited about it. And you mentioned the FDA decree earlier this year. Can you talk about what that could mean? And also, any expectations that you have for the upcoming panel in November on duodenoscopes?

Michael Mahoney

Yes. So, really, in terms of our EXALT platform and the future products that fall behind it really on track and no new commentary other than we expect and we're still on track for year-end 2019 approval, which we – and we've also initiated a post market clinical trial which will start in the first quarter 2020. But we expect to see our first revenue with EXALT near the end of the year here and we think it will be a significant growth driver for us in 2020.

We think the trends in that FDA advisory certainly are a tailwind for EXALT and kudos to our team for really identifying this opportunity nearly three or four years ago. And so, we think the timing and the physician excitement and may be the FDA support of this are all nice tailwinds for this platform. And we think we're uniquely capable of delivery in this based on our results and expertise that we've created with both LithoVue in urology and digital SpyGlass in endo. So, we have the manufacturing and the ops and the supply chain and the R&D capability to deliver this one as well as the future scopes with it. So, it's one of our more existing launches in 2020.

Matthew Taylor

Thanks. Just a quick follow-up on the comments before on ischemia. I was just curious if you could expand on what you think drives the positive results? What do you think could come out of the trial that could actually drive more stenting or how do you see that as a positive, what's the probability of that?

Ian Meredith

Well, I don't think it would drive more stenting unless we changed guidelines. So, if we use the word positive to say could the trial actually have a positive result, in other words revascularization by other bypass graft surgery of percutaneous intervention be better than just optimized medical therapy. And the reasons for considering that as a possibility is that unlike previous trial, there was a dedicated effort here to determine that the patients who were enrolled in the studies did in fact actually have objective evidence of ischemia. And as you know, 80% to 85% of the patients in this study in both arms have moderate to severe objective evidence of ischemia, not symptoms, but ischemia on functional testing.

Now, by doing that, you know that you have the greatest likelihood of showing the benefit of revascularization. And many previous registries and small studies have suggested the great burden of ischemia you have, the more likely that revascularization is a better option than optimized medical therapy.

This is the first trial to actually test that out. And despite all of the potential vagaries around the trial, if that plays out, there is a possibility that it could be a positive result because we're treating the right patients in this subset to actually test that question.

So, that's why I would think that there is a reason to, not so much doom and gloom, because the burden of ischemia might favor an outcome that is positive.

I'll make another comment on the quality of life since everybody thinks that it is going to be positive on quality of life. Just remember that the Seattle questionnaire score was 80 out of 100, a 100 being perfect and 0 being terrible. So, the patients were already asked very minimal symptoms. 80% of the patients had monthly or less frequent angina. So, it is going to be hard to show an improved quality of life in patients who are having symptoms only a few times a year.

Operator

Next question, Larry Biegelsen, Wells Fargo. Please go ahead.

Lawrence Biegelsen

Hey, guys. I don't know, I thought I heard a joke in the background there, Mike, about an ischemia question. But thanks for taking the questions and congrats on a nice quarter. I guess I will ask one ischemia question, Ian, and then just one follow-up on emerging markets in China. Ian, I'm just curious if you have thoughts on US versus O-US implication for this study, if you think they'll be different.

And second, what is your – listening to your response on the last question, Ian, what's the base case here. It sounds like you think it's going to be hard to show quality of life benefit, but it sounds like you think there might be a hard outcome, death, MI, hospitalization for angina, et cetera, benefit based on what you said on the 80% to 85% of patients having moderate to severe ischemia. And I just had one follow-up.

Ian Meredith

Okay. Well, first to deal with the O-US versus US, as you know, Larry, there's been a significant shift towards – a greater proportion of PCI is being undertaken in unstable angina and acute coronary syndrome. That trend has been a global trend for over 10 years ever since the COURAGE trial in 2007. And we've done considerable research over the last few weeks to see whether that fact is sustained.

Just a look in the US. We know the NCDR CathPCI registry has shown that trend away from stable angina. And similarly, there is data from the Sweetheart Registry, the China pace registry and other international registries that all point to the same trend. Maybe a percentage point here or there, but overall we think there will be a consistent pattern in the response to this trial, positive or negative, US to O-US because, overall, the proportion of PCIs undertaken for unstable and acute coronary syndromes outside the US is essentially the same as inside the US. And there is very good data actually published this year from single sentence both inside and outside the US showing the same sort of trends over the last 10 to 12-year period. That was the first question.

The second question you asked was – I've forgotten.

Lawrence Biegelsen

Just what is your base case assumption kind of on the outcome of the trial?

Michael Mahoney

I really feel like the ischemia – the level of questions are so disproportionate to the overall business. The MEGATRON launch in the US will likely have a larger impact than the potential downside scenario that we are talking about with ischemia trial.

Lawrence Biegelsen

Fair enough. Just for my second question, just on emerging markets, you had a nice quarter there. There's been a little concern about slowing growth in China. So, I guess, my question is, kind of what are you seeing there, Mike? And any update on the drug-eluting stent price cuts in China, any more visibility on timing or magnitude? Thanks for taking the questions, guys.

Michael Mahoney

Sure. Thanks for the non-ischemia question. The emerging markets grew almost 20%. So, it continued to do extremely well. It's really a combination of our consistent – it's really the same playbook. We're seeing great growth in Latin America, great growth in China and really nice growth in the ASEAN countries as well as some parts of Europe.

But it's really a combination of a couple of things. It's the diversification of the portfolio. Whereas eight years ago, it was drug-eluting stents and now you're seeing complex coronary being larger than DES in those markets, with those tailwinds that we talked about. Ian mentioned the patient population. But as importantly, the portfolio investments that we've made have driven complex coronary to be very important businesses there. And then, you see the diversification of endo, amazing growth with PI, particularly in Asia, great growth of our interventional oncology business and we're starting to see the impact really just the diversification of BSE other than drug-eluting stents. You're seeing very strong growth with Watchman in China and we're excited to bring our structural heart TAVI portfolio to many parts of Asia-Pac.

So, it's the diversification of the business, the focus that our global presidents put on it, the allocation of resources and really the smart prioritization of which products and which countries makes the most sense to invest in and kind of the speed of the team to execute

on the plan.

So, we're confident in the emerging markets growth. I think in terms of the China DES tender that you'll see, again, there could be some upsides or downsides there based on how these tenders go, but I think, overall, we have very strong balanced portfolio in China that continues to grow very well beyond DES. So, we hope to win these tenders, but we have a very strong diversified business there.

Susan Lisa

Great. Thanks, Mike. With that, we'd like to conclude the call. Thanks for joining us today. We appreciate your interest. Before you disconnect, Kevin will give you all the pertinent details for the replay.

Operator

Thank you. Ladies and gentlemen, this conference will be available for replay, and that's starting today at 10:30 AM Eastern Time and will run through November 6 midnight. Once again, it will start today at 10:30 AM Eastern Time and will run through November 6 at midnight. You may dial the AT&T Executive playback service by dialing 1-800-475-6701, with the access code 472683. International callers may dial area code 320-365-3844; access code, 472683.

Now, that does conclude your conference. We do thank you for joining. You may now disconnect.