Q3 2019 Earnings Call

Company Participants

- Calvin Darling, Senior Director of Finance, Investor Relations
- Gary S. Guthart, Chief Executive Officer, Member of the Board of Directors
- Marshall L. Mohr, Executive Vice President and Chief Financial Officer

Other Participants

- Craig Bijou, Analyst
- David Lewis, Analyst
- Imron Zafar, Analyst
- J.P. McKim, Analyst
- Jason Mills, Analyst
- Lawrence Biegelsen, Analyst
- Richard Newitter, Analyst
- Robert Hopkins, Analyst
- Tycho Peterson, Analyst
- Vijay Kumar, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Intuitive Surgical Q3 2019 Earnings Release Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. Instructions will be given at that time. (Operator Instructions) And, as a reminder, this conference is being recorded.

I would now like to turn the conference over to our host, Mr. Calvin Darling, Senior Director of Finance, Investor Relations. Please go ahead, sir.

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon, and welcome to Intuitive's third quarter earnings conference call. With me today, we have Gary Guthart, our CEO; and Marshall Mohr, our Chief Financial Officer.

Before we begin, I would like to inform you that comments mentioned on today's call may be deemed to contain forward-looking statements. Actual results may differ materially from those expressed or implied as a result of certain risks and uncertainties. These risks

and uncertainties are described in detail in the Company's Securities and Exchange Commission filings, including our most recent Form 10-K filed on February 4, 2019, and 10-Q filed on July 22, 2019. Our SEC filings can be found through our website or at the SEC's website. Investors are cautioned not to place undue reliance on such forward-looking statements.

Please note that this conference call will be available for audio replay on our website at intuitive.com on the Latest Events section under our Investor Relations page. In addition, today's press release and supplementary financial data tables have been posted to our website.

Today's format will consist of providing you with highlights of our third quarter results as described in our press release announced earlier today, followed by a question-and-answer session. Gary will present the quarter's business and operational highlights. Marshall will provide a review of our third quarter financial results. Then I will discuss procedures and clinical highlights and provide our updated financial outlook for 2019. And, finally, we will host a question-and-answer session.

With that, I'll turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Thank you for joining us today. Intuitive has been enabling customers in their delivery of high-quality minimally-invasive surgery for 20 years. And we believe the adoption of robotics and computer-aided interventions is early relative to its long-term potential. We measure our efforts by their ability to positively impact the quadruple aim; better outcomes, better patient experience, better care team experience and lower total cost to treat per patient episode. This third quarter of 2019 was another solid one for Intuitive in pursuit of these aims. Our performance in the quarter is a reflection of our progress with procedures and system placements showing continued strength.

For the quarter, global procedure growth was nearly 20%, aided by an increase of approximately a surgery day relative to Q3 of 2018. Growth, again, centered on general surgery in the United States with positive contributions to the global growth rate from Germany, Korea and Japan. China procedure growth continues to be limited by installed base growth. Total procedure growth in China is responding positively considering the release of system quota and subsequent placements.

In the United States, year-over-year procedure growth for the quarter was 18%. General surgery, again, accounted for the largest increase year-over-year, accompanied by solid growth in urology and stable growth in gynecology. We also saw strength in bariatrics and cholecystectomy.

Hernia repair and colon resection growth rates were solid in the quarter. Improvements in system utilization by customers and alternative capital placement models are having a positive impact on our business. Our US sales force productivity improved in the quarter

as our new team members gained experience. Calvin will take you through procedure -- global procedure dynamics in more detail later in the call.

With regard to our installed base, placement of new systems in the quarter was solid with growth in total placements rising 19% from Q3 of 2018. Net of trade-ins and retirements, our da Vinci installed base grew 12% over Q3 2018 to approximately 5,406. The mix of system placements this quarter moved towards our flagship Xi system and trade-ins were healthy. The proportion of systems placed under operating leases was 33% this quarter compared with 32% last quarter. As a reminder, total placements and the percentage of systems placed under lease or usage-based arrangements can vary substantially quarter-to-quarter.

Turning to expenses. We are investing in building our capability in international regions, launching new platforms, strengthening our computational capabilities and executing projects that support future sale and provide leverage opportunities as we grow. Our spending is on track with our expectations. It is supported by solid procedure growth, capital placements and product cost reductions.

Financial highlights for our third quarter results were as follows. Procedures grew nearly 20% over the third quarter of last year. We placed 275 da Vinci Surgical Systems, up from 231 in the third quarter of 2018. Our installed base grew 12% from a year ago. Revenue for the quarter was approximately $1.1 billion, up 23%. Pro forma gross profit margin was 72% compared to 71.5% in the third quarter last year. Instrument and accessory revenue increased to $606 million, up 25%. Total recurring revenue in the quarter was $817 million, growing 24% over Q3 of 2018 and representing 72% of total revenue.

We generated a pro forma operating profit of $462 million in the quarter, up 18% from the third quarter of last year. Pro forma net income was $409 million, up 21%. And we've repurchased $70 million in shares at an average price of $493 per share.

Turning to our investments in products, I'll start first with systems. We are in our Phase 1 launch of da Vinci SP as we work to expand clinical clearances and build SP products at scale. In the quarter, we proactively held shipments on SP endoscopes and limited new system installations for a limited time as we investigated a robustness concern on the SP endoscope.

We resumed shipping endoscopes and systems in the quarter. Given the slowdown on endoscopes, we installed four systems to bring our installed base with SP to 38. Customer response and early clinical results using SP remain encouraging. In addition, utilization rates for SP in Korea, where clinical indications are the broadest, are at Xi levels already, a testament to surgeons' engagement and our team's skill and design for usability.

With regard to additional indications for SP, we have been in discussion with FDA regarding data requirements for a colorectal indication. We expect this to require an IDE trial that includes follow-up analysis. This implies we do not expect a third indication of SP in the US in 2020. While we had planned for a smoother launch of SP and product

availability and new indications time lines, our teams are focused on building at scale and satisfying regulatory requirements for additional indications.

Interest in SP is healthy and clinical outcomes are encouraging, forming the basis of our belief in the long-term potential of the platform to improve care. The combination of additional indications for SP and our readiness for deployment at larger scale pace the speed of our SP commercial expansion.

In flexible diagnostics, our Ion platform is focused on the need for accurate and timely biopsies to support definitive early diagnosis of suspicious lesions. Since our 510(k) clearance in Q1 of this year, we initiated our first phase launch focused on clinical use, customer feedback and production optimization. First cases on the cleared system were performed at the end of Q1. There are now nine systems in the field, performing cases with the total case experience in the hundreds. To date, the rollout is meeting our expectations with a mix of clinical trial sites and commercial sites. User feedback during this initial launch period has been strong.

For instruments and accessories, our team moved to full United States launch of our 45-millimeter SureForm stapler and obtained clearance forward in Japan and Korea in the quarter. We also obtained 510(k) clearance for our new Curved-Tip SureForm 45-millimeter stapler and a new gray reload designed for stapler pin structures. Recall that surgical stapling is a family of products that help surgeons in a range of procedures covering parts of the body from the rectum to the thoracic cavity. Robotically held staplers are sophisticated technology, and our team is doing an excellent job in filling out the product portfolio.

Our experience has shown that procedure adoption occurs when the holistic needs of the care team are met when the right system and imaging products come together with the right instruments and accessories. Stapling is another example of this synergy with surgeon adoption of Generation 4 da Vinci Systems with SureForm staplers gaining momentum.

Turning to imaging and analytics. We're working on computing and real-time cloud technologies to allow for tests from telementoring to augmented reality. We now have over 20 active telementoring sites that together have supported hundreds of cloud-enabled, real-time surgery sessions as we progress in building our real-time cloud capabilities. Feedback on the utility of these sites for case observations and mentoring has been supportive.

In augmented reality, we're working through logistics and installation of our first IRIS accounts to gather customer and clinical feedback. We expect first clinical cases on the IRIS system in the next few months.

Lastly, our surgical simulation products have become widely adopted in the installed base with more than 3,200 da Vinci simulators in the field.

Before turning the time over to Marshall, let's step back and consider Intuitive's evolution over the past few years. Over this period, general surgeons have increased their adoption of our offerings, underpinned by improvements in the quadruple aim and procedures they perform, from colon and rectal procedures, to hernia repair, cholecystectomy and bariatric surgery.

General surgery procedure span a broad range of complexity and economics. At the same time, we've extended our reach into key countries to support the adoption of robotic-assisted surgery into their healthcare environments. We have flexed our Company to better serve these customers with the launch of new systems, new instruments and updates to our software, along with changes to our sales and support models and pricing structures.

Given the large global opportunity to pursue the quadruple aim, we believe the next few years for the Company will be dynamic. We will guide the Company to meet our customers' clinical and economic needs across this wide range of procedures and geographies. Doing so will involve continued investment in innovation for both technology and economic models, and we see a path to both.

For the balance of the year, our focus remains in completing the task we set for ourselves. First, supporting adoption of da Vinci in general surgery and in key procedures in global markets; second, launching our da Vinci -- I'm sorry, our SP and Ion platforms; third, driving intelligent surgery innovation; and, finally, supporting additional clinical and economic validation in our focused procedures and countries.

I'll now turn the call over to Marshall, who'll review financial highlights.

Marshall L. Mohr {BIO 5782298 <GO>}

Good afternoon. I will describe the highlights of our performance on a non-GAAP or pro forma basis. I will also summarize our GAAP performance later in my prepared remarks. A reconciliation between our pro forma and GAAP results is posted on our website. Key business metrics for the third quarter are as follows.

Third quarter 2019 procedures increased nearly 20% compared with the third quarter of 2018, and increased approximately 2% compared with last quarter. There was one more operating day in the third quarter of 2019 compared with the third quarter of 2018. Excluding the impact of the extra operating day, we would have been in line with our full year average growth. Procedure growth continues to be driven by general surgery in the US and urology worldwide. Calvin will review details of procedure growth later in this call.

Third quarter system placements of 275 systems, increased 19% compared with 231 systems last year and increased 1% compared with 273 systems last quarter. We expanded our installed base of da Vinci systems by 12% to approximately 5,406 systems. The growth rate compares with 13% in both the last quarter and last year. Utilization of clinical systems in the field, measured by procedures per system, grew approximately 6%, which is higher than the 4% growth last quarter and below the 7% growth last year.

Our revenue overview is as follows. Third quarter 2019 revenue was $1.1 billion, an increase of 23% compared with $921 million for the third quarter of 2018 and an increase of 3% compared with $1.1 billion last quarter. Instrument and accessory revenue of $606 million, increased 25% compared with last year, which is higher than procedure growth, primarily reflecting customer buying patterns and increased usage of our advanced instruments. Instrument and accessory revenue realized per procedure was approximately $1,980, an increase of 4% compared with the third quarter of 2018 and an increase of 3% compared with last quarter.

Systems revenue for the third quarter of 2019 was $339 million, an increase of 23% compared with the third quarter of 2018 and a decrease of 2% compared with last quarter. Relative to the third quarter of 2018, systems revenue reflected higher system placements, higher ASPs and higher lease-related revenues. We completed 92 operating lease transactions, representing 33% of total placements compared with 58 or 25% of total placements in the third quarter of 2018, and 88 or 32% of total placements last quarter. As of September 30th, we have 560 operating leases outstanding and realized approximately $27 million of revenue related to these arrangements in the quarter compared with $14 million last year and $25 million last quarter.

Operating leases create a future source of recurring revenue and reduce the volatility of system revenue, while the increased number of operating systems placed in the quarter dampen short-term revenue growth for the quarter in which they're placed. Operating leases include usage-based financings that we provide to certain hospitals with advanced robotics experience. We believe that our lease financing alternatives align with customer objectives and have enabled faster market adoption.

Relative to systems purchased over the lease period, we earned a small premium reflecting the time value of money. And in the case of usage-based arrangements, the risk that those systems may not achieve anticipated usage levels. The proportion of operating lease and usage-based arrangements will likely increase long term and will vary quarter-to-quarter.

We've recognized $20 million of lease buyout revenue in the third quarter compared with $27 million last quarter and $8 million last year. Lease buyout revenue has varied significantly from quarter-to-quarter and will likely continue to do so.

116 or 42% of current quarter system placements involve trade-ins, reflecting customer desire to access or standardize on our fourth generation technology and contributing to an Xi installed base growth of 41% year-over-year. This is an increase compared with 65 or 28% of system placements in the third quarter 2018 and 103 or 38% last quarter. Trade-in activity can fluctuate and be difficult to predict. However, prior product trade-in -- however, given prior product trade-in cycles, we expect the proportion of installed base traded in in future quarters to decrease over time. 79% of the systems placed in the quarter were da Vinci Xis and 17% were da Vinci X systems compared with 74% da Vinci Xis and 20% da Vinci Xs last quarter.

We sold three Ion systems in the quarter. Ion system placements are excluded from our overall system count and will be reported separately. Procedures and other information associated with Ion are excluded from our prepared remarks and will be reported separately when they become more substantive.

Four of the systems placed in the third quarter were SP systems. Third quarter SP placements were impacted by our decision to hold shipments of endoscopes, as Gary outlined. Our rollout of SP Surgical System will continue to be measured, putting systems in the hands of experienced da Vinci users, while we optimize training pathways in our supply chain.

Globally, our average selling price, which excludes the impact of operating lease revenue and lease buyouts, was approximately $1.57 million compared with $1.45 million last quarter (sic - last year) and $1.54 million last quarter.

Similar to the second quarter, our mix of systems and customers in the third quarter was very favorable relative to prior periods. We had a high mix of Xi versus X and Si systems. We also had a low mix of distributor versus direct sales. Finally, in the third quarter of 2019, we had fewer multi-system arrangements where we provided volume discounts. The mix of systems, customers and the size of arrangements will vary over time. We expect system ASPs to be in a range of the midpoint of the first two quarters of this year.

Outside of US, results were as follows. OUS procedures grew approximately 23% compared with the third quarter of 2018 and increased 1% compared with last quarter. Third quarter revenue outside of the US of $332 million, increased 36% compared with the third quarter of 2018 and increased 6% compared with last quarter. The increase compared with the prior year reflects increased system instruments and accessories revenue of $37 million or 32% growth, and increased systems revenue of $40 million or 50% growth. The increase in instrument and accessories revenue was primarily driven by procedure growth and customer buying patterns. The increase in systems revenue, primarily as a result of the increased ASPs reflecting favorable geographic and product mix.

Outside of the US, we placed 90 systems in the third quarter compared with 75 in the third quarter of 2018 and 80 systems last quarter. Current quarter system placements included 36 into Europe, 27 into Japan, and 10 into China. 59% of the systems placed in the quarter were da Vinci Xis and 33% were da Vinci X systems compared with 43% da Vinci Xis and 48% da Vinci Xs last year.

21 of the system placements in the quarter were operating leases compared with nine last year and 12 last quarter. Placements outside of the US will continue to vary as some of the OUS markets are in early stages of adoption, some markets are highly seasonal, reflecting budget cycles or vacation patterns, and some -- and sales into some markets are constrained by government limitations.

Moving on to gross margin and operating expenses. Pro forma gross margin for the third quarter was 72% compared with 71.5% for the third quarter of 2018, and 71.3% last quarter.

The increase compared with the third quarter of 2018 and last quarter primarily reflects higher system ASPs and product cost reductions. Future margins will fluctuate based on the mix of our newer products, the mix of systems and instrument and accessory revenue, system ASPs and our ability to further reduce product costs and improve manufacturing efficiency. We expect the return of the medical device tax in 2020, which will reduce our gross margin by approximately 70 basis points to 100 basis points.

Pro forma operating expenses increased 31% compared with the third quarter of 2018 and increased 7% compared with last quarter. Spending is consistent with our plan and includes an order of magnitude of increase, cost associated with the expansion of our OUS markets, spending on our informatics capabilities, and investment in our infrastructure in order to scale the business. We believe we have the unique opportunity to expand the benefits of minimally-invasive surgery around the world and have been -- and will continue to invest in the business accordingly.

Our pro forma effective tax rate for the third quarter was 16.8%, reflecting $8 million of reserves -- of reserve releases primarily associated with the expiration of statutes of limitation in certain jurisdictions. While we expect our tax rate to be between 19% and 20% in the fourth quarter, our actual tax rate will fluctuate with changes in the mix of US and OUS income, changes in taxation made by local authorities and with the impact of one-time items.

Our third quarter 2019 pro forma net income was $409 million or $3.43 per share compared with $337 million or $2.83 per share for the third quarter of 2018 and $388 million or $3.25 per share for last quarter.

I will now summarize our GAAP results. GAAP net income was $397 million or $3.33 per share for the third quarter of 2019 compared with GAAP net income of $293 million or $2.45 per share for the third quarter of 2018 and GAAP net income of $318 million or $2.67 per share for last quarter. The adjustments between pro forma and GAAP net income are outlined and quantified on our website and include excess tax benefits associated with employee stock awards, employee equity and IP charges, amortization of intangibles, and acquisition-related items and legal settlements.

We ended the quarter with cash and investments of $5.4 billion compared with $5.1 billion at June 30, 2019. The cash generated from operations was offset by stock repurchases, acquisition of Schoelly Fiberoptic's 3D robotic endoscope business and investments in working capital and infrastructure during the quarter.

We've repurchased approximately 141,000 shares for $70 million at an average price of $493 per share. In the quarter, we grew inventory by approximately $67 million to $580 million, representing approximately 150 days of inventory. We continue to build inventory to address the growth in the business as well as mitigate risks of disruption that could arise from trade supply or other matters.

In summary, our results for the quarter were solid. While we will provide you with detailed 2020 guidance in January, I want to highlight certain business dynamics that may impact

your models. As I noted earlier, we will continue to invest in the business, growing operating expenses as we see it, the substantial opportunity to expand the benefits of minimally-invasive surgery. We also believe the percentage of leasing and alternative financing arrangements will increase over time.

In addition, we believe the number of trade-in transactions will level off in the short term and then decline over time. It is also likely we will see increased price negotiations and elongated negotiation timeline as competition get closer to launching new products. These dynamics could result in profit fluctuations. However, we will continue to manage the business for the long term as we believe that the fundamentals of the business are strong.

And, with that, I'd like to turn it over to Calvin, who will go over procedure performance and our outlook for 2019.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall third quarter procedure growth was nearly 20% compared to 20% during the third quarter of 2018 and 17% last quarter. Our Q3 procedure growth was driven by 18% growth in US procedures and 23% growth in OUS markets. Third quarter 2019 procedure growth benefited from one additional working day compared to last year. Through the three quarters, working days are now roughly consistent between this year and last.

Our Q3 2019 year-to-date procedure growth was 18%, equal to 18% growth through three quarters of last year. In the US, Q3 procedure growth was largely driven by continued strength in general surgery, with substantive contributions from gynecologic and urologic procedures. In US general surgery, third quarter growth in leading procedures, hernia repair and colorectal remains solid at days adjusted growth rates consistent with last quarter.

Cholecystectomy growth continued to accelerate in the third quarter and now represents a significant driver of incremental procedures. While we remain cautious regarding the size of the addressable chole market for robotics, our recent data is encouraging. Growth in cholecystectomy represents a healthy mix of new and continuing surgeons, shows very little churn and sees increasing Firefly utilization. Bariatric procedures, while still not an area of broad emphasis, again accelerated modestly in Q3.

Q3 US gynecology procedure growth was largely consistent with the first half of 2019 and last year in the mid-single-digit range, with hysterectomy for cancer volumes accelerating modestly in the quarter. We had surprisingly strong growth in US urology and dVP procedures in the third quarter. dVP growth was just over 10% for the quarter after having moderated to low single digits in Q2. As a highly penetrated mature procedure category, we believe that our US prostatectomy volume should track to the broader prostate surgery market.

Third quarter OUS procedure volume grew approximately 23% compared with 23% for the third quarter of 2018 and 20% last quarter. Third quarter 2019 OUS procedure growth was driven by continued growth in dVP procedures and earlier stage growth in kidney cancer procedures, general surgery and gynecology.

In China, as in Q2, procedure growth accelerated modestly as new systems installed under the latest system quota began to provide additional capacity for incremental growth. The Q3 China procedure growth rate remained below the overall OUS metric.

In Japan, procedure growth was again strong at roughly 40%, reflecting growth in procedures granted reimbursement status in April 2018 and continued later-stage growth in urology procedures. Our emphasis in Japan remains on surgeon and team training and building proctoring networks.

Overall, European procedure growth was largely consistent with prior periods with variation by country. German results were particularly strong, while results in the UK were below our plans.

Now, turning to the clinical side of our business. Each quarter on these calls we highlight certain recently published studies that we deem to be notable. However, to gain a more complete understanding of the body of evidence, we encourage all stakeholders to thoroughly review the extensive detail of scientific studies that have been published over the years.

Adoption of Intuitive systems for surgery is fundamentally based upon the clinical utility they provide for surgeons and positive procedure outcomes they enable for patients. We are now in the early stages of introducing the da Vinci SP to the market, and over 50 clinical articles have been published involving the SP thus far.

Last month, some of the first clinical research related to the da Vinci SP usage in transoral surgery was published by JAMA Otolaryngology-Head & Neck Surgery section. The research titled A Next-Generation Single-Port Robotic Surgical System for Transoral Robotic Surgery results from prospective non-randomized clinical trials was authored by Dr. F. Christopher Holsinger from Stanford, et al. The objective of the study was to evaluate the da Vinci SP in head and neck surgery prospectively through concurrent non-randomized clinical trials.

The study included a total of 47 patients across four institutions, three in the US and one in Hong Kong. All 47 patients had tumors of the oropharynx and underwent surgery with the da Vinci SP. 40 patients had malignant tumors, while seven were benign. All 47 patients, 8 women and 39 men with a mean age of 61, safely underwent transoral resection with the da Vinci SP without conversion to open surgery, laser surgery or multi-port robotic surgery. There were no intraoperative complications or device-related serious adverse events. Mean estimated intraoperative blood loss per procedure was 15.4 milliliters, with no patients, no patients received a transfusion. Within 30 days, 45 of the 47 patients were eating by mouth and without the need for percutaneous endoscopic gastrostomy tube.

The authors concluded, "The use of the device appears to be feasible, safe and effective for transoral robotic surgery of oropharyngeal tumors."

I will now turn to our financial outlook for 2019, starting with procedures. Last quarter, we forecast 2019 procedure growth of 16% to 17%. We are now increasing our forecast and expect full year 2019 procedure growth of 17% to 18%.

Turning to gross profit. On our last call, we forecast our 2019 full year pro forma gross profit margin to be within 70% and 71% of net revenue. We are now slightly increasing our forecast and expect full year gross profit margin to be between 71% and 71.5% of net revenue. Our actual gross profit margin will vary quarter-to-quarter depending largely on product, regional and trade-in mix, and the impact of new product introductions.

Turning to operating expenses. On our last call, we forecast to grow full year pro forma 2019 operating expenses between 24% and 28% above 2018 levels. We are now retiring the top end of the range and expect our full year pro forma operating expense growth to be between 24% and 27%.

On our last call, we forecast our non-cash stock compensation expense to range between $320 million and $340 million in 2019. We're now refining this estimate to the top half of the range between $330 million and $340 million.

We expect other income, which is comprised mostly of interest income, to total between $125 million and $130 million in 2019 compared to $130 million to $135 million forecast on our last call.

With regard to income tax, apart from certain non-discrete items impacting Q3, we have a consistent view of our tax rate. We estimate our Q4 pro forma tax rate to be between 19% and 20% of pre-tax income.

That concludes our prepared comments. We will now open the call to your questions.

Questions And Answers

Operator

(Operator Instructions) And our first question comes from the line of David Lewis with Morgan Stanley. Please go ahead. Your line is open.

Q - David Lewis {BIO 15161699 <GO>}

Good afternoon. Just a couple of questions for me. Gary, just starting off on procedure acceleration. Even adjusting for selling, there's still a couple of hundred basis points, maybe 200 basis points to 300 basis points of momentum acceleration into the third quarter. I wonder if you could talk about some of the drivers there? You talked about the gen surg capacity issues last quarter. Sounds that they've been resolved, but was that the

principal driver of the momentum improvement? Or could you just kind of point out other factors that drove this relative momentum acceleration into the third quarter? And then I have a quick follow-up.

A - Gary S. Guthart {BIO 3429541 <GO>}

So, in general, general surgery was positive for us. I would not say that we have resolved all the constraint issues that we have been -- we had talked about last quarter, we moved in the right direction. So I think productivity for the US sales force was something we talked about last quarter. I think we took a modest step in the right way. We'll keep working on that. Likewise, convenient access to systems. So general surgery was strong for us, but I think there is more opportunity there over the long term. We had -- and Calvin had touched on it, we were positively surprised in the urology part of the business and we're digging in a little bit to figure out where that positive surprises come from. Calvin, I don't know if you want to add to that.

A - Calvin Darling {BIO 17664656 <GO>}

No, that's it. I mean it was -- as we saw, it's kind of settled in the low single digits last quarter and just over 10% this quarter and then we are working with our field team and customers to better understand the dynamics behind that.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Very helpful. And maybe just a quick two-part question on broader CapEx. And, Gary, the gross system placements this quarter, I know trade-ins and retirements looked heavier, but gross system placements in the US looked a little lighter. Is there anything you've seen from a change in the capital environment in the US that you're willing to call out? And then related to that, Marshall your commentary on next year competitive dynamics, maybe could you share with us what you've seen from some of these new systems that have now been displayed in the US and Europe? Any comments you're willing to provide there? And how your commercial strategy may change next year as you learn more about these systems? Thanks so much.

A - Gary S. Guthart {BIO 3429541 <GO>}

On the first front, I don't know that we're at perfect read on the CapEx environment more broadly. We do think that procedure growth is in the US, the dominant driver of additional systems over time, system capability, but also clinical installed base access. So I think we saw in this quarter met our expectations. I think the second question around spending looking into next year, I'll let Marshall take.

A - Marshall L. Mohr {BIO 5782298 <GO>}

Yeah. So you were asking specifically about the dynamics around potential competitors in my comment about the impacts that might have in terms of elongated negotiations or negotiations with customers. We know that when the competitors' products comes out, that will be an impact. When it comes out or when it will have an impact is less certain. And so, we're just trying to make sure that you understand that as those dynamics occur that you're not surprised.

A - Calvin Darling {BIO 17664656 <GO>}

Next question, please.

Operator

And next we turn to line of Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good afternoon, and thanks for taking the question. Just maybe one follow-up to Marshall on the operating margin and the OpEx spending that you talked about for next year. I mean, in the past you've talked about not expecting constant deleveraging over time, but how should we think about margin pressure in 2020 relative to 2019 as you invest for top line growth and you potentially have new competition coming in, and I had one follow-up.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. I think that you've heard from us, and you've heard from others is that there is a substantial opportunity in front of us in terms of minimally-invasive -- the minimally-invasive market and so we think about those opportunities. We think about the technology as they are necessary to take advantage of those to improve patient outcomes and we think about the global expansion. And so that's where we're spending our money. We'll give you more precise guidance on what spending will do when we get to the January call. So I'm not going to really comment at this point about magnitude of leverage or not -- deleverage or whatever, but we will continue to spend on expansion.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

That's helpful. And then to stay on the 2020 theme, Calvin, on the guidance the implied Q4, it's about somewhere about 15% at the midpoint for procedure growth. Should we be thinking about more of the high-end here, Calvin? And maybe, if you could, talk about the puts and takes for next year. You have some good growth drivers from general surgery and international. Should we be thinking about kind of stability in procedure growth? Thanks for taking the questions.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. I think as you look at Q4 and then further out into 2020, the growth drivers, as you say, Larry, are general surgery in the United States as well as growth outside the United States and I think that's likely to continue to be the drivers. At the high-end of the guidance range, I think we're seeing consistency with where we are on a year-to-date basis. But, again, in the third quarter, we saw benefit for some of the mature category. So I think at the lower-end, you can contemplate some moderation there.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Thanks, guys.

Operator

And next we turn to the line of Bob Hopkins with Bank of America.

Q - Robert Hopkins {BIO 2150525 <GO>}

Thanks, and good afternoon. I just wanted to ask a couple of quick questions on the comments you guys made on SP in the prepared remarks. It sounds like the regulatory pathway is moving around a little bit. Gary, is that a function of something specific with your process or is it just a tougher regulatory environment, generally, with the FDA with these new robotic platforms?

A - Gary S. Guthart {BIO 3429541 <GO>}

Yeah. I think it's probably the latter. As you look at both our products that are moving into new clinical domains and also a little more broadly across the med device industry, it looks like the environment is becoming a more data centric. However, the data requirements are increasing.

Q - Robert Hopkins {BIO 2150525 <GO>}

And then just also just wondering if you could characterize kind of the demand for SP generally and what your comments imply about kind of next year's growth opportunity in SP? Should we be thinking it's fairly limited until you get colorectal or do you see enough underlying demand that 2020 could keep some -- some nice sales of that product?

A - Calvin Darling {BIO 17664656 <GO>}

We won't forecast it for you on this call. I think, in general, there is an opportunity for the indications that we have and more indications are better. The clinical data that we're seeing and that's building in the database reinforces my support for the product line long-term. And I think there is also a set of indications beyond the colorectal that will be interesting to us. That said, we'll work with regulatory bodies to meet the requirements and that may take some time. That will pace us. So near term as we get closer to 2020 and get into it, we'll talk a little more about it.

Q - Robert Hopkins {BIO 2150525 <GO>}

Thanks so much.

Operator

And we have a question from the line of Tycho Peterson with JP Morgan. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, thanks. I want to go back to some of the procedure commentary, the cholecystectomy recovery, can you comment on what you think might be driving that? And then to your comments on the dVP step up, any early view on what might be behind that? Is that patients dropping out of watchful waiting? Or is there another dynamic there?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. On the chole side, Tycho, talked about the acceleration being driven by a healthy mix of the new surgeons and existing surgeon is not a lot of churn and increasing Firefly utilization. So that feels a lot different than, say, our earlier experience with single site set of tools or it was more of a cosmesis-oriented value proposition.

And what's interesting is, while in the past chole may have been a popular training procedure and it's still can be that, now it's not necessarily the first procedure, it's a lot more often that it's a, say, a hernia repair that's the first procedure and as general surgeons are applying robotics across their practices chole is obviously a big part of what they do.

So they are -- the reasons for optimism, given what we see in the data, but we continue to monitor and analyze the growth trends closely and remain conservative about the overall opportunity.

Q - Tycho Peterson {BIO 4279327 <GO>}

On prostatectomy?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. Prostatectomy, I think, we've pretty much stated on that. We were surprised and we're kind of digging into what the root causes may be.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then on SP, it sounds like you work through the endoscope issues in relatively short order. Should we think about any sort of catch-up effect in the fourth quarter in terms of installations? And then any comments you want to make on the IDE trial, how big you think that might have to be?

A - Calvin Darling {BIO 17664656 <GO>}

On the (multiple speakers) Yeah. On the SP endoscope, we have release supply and -- but we still have some work to do and we will work through it really for SP endoscopy at scale. So we can support the scale we're at today, but as we get bigger and what our long-term plans are, I want to see improvements in that product line. So we will see -- we're not ready to describe what the outline for the trial yet are. Indeed, its finalizes an IDE then it will get published in a public database and you'll be able to look it up and we'll point you to it.

Q - Tycho Peterson {BIO 4279327 <GO>}

All right. And then, lastly, any comments you can make on ASPs? I think, last quarter, there was a view that they would maybe step down, but, obviously, they didn't. So I'm just curious how we should be thinking about system ASPs going forward?

A - Marshall L. Mohr {BIO 5782298 <GO>}

Yeah. I think it's pretty specific in my remarks actually. For ASPs, this quarter, we just saw a really favorable mix just like last quarter in terms of Xis versus Xs and Sis. We also saw a really favorable mix in terms of distributor -- lower distributor and higher direct sales. As far as what you should expect going forward, I think what I said was for the remainder of this year, you should look at ASPs more similar to the mix between Q1 and Q2. And that's where we see it coming out and that will reflect a higher mix of distribution sales in Q4, which is typical if you go back and look at our history.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. Thank you.

Operator

And next we turn to the line of J.P. McKim with Piper Jaffray. Please go ahead.

Q - J.P. McKim {BIO 18054566 <GO>}

Hi. Good afternoon. Thanks for taking the question. I just wanted to touch on just the uplift in instrument ASPs. Can you talk about maybe the, A, the sustainability there and just what's really driving? Is it more advanced procedures or just more advanced instruments with the staplers and vessel sealers?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. Hi, J.P. It's Calvin. Yeah, we saw this -- in this quarter revenue per procedure was approximately $1,980 and that's the highest we've seen in quite some time. Marshall mentioned in his comments that we did see a benefit relative to the last quarter just due to timing of orders, but obviously higher usage of the advanced stapling and vessel sealings also contributed to the growth.

Going forward, clearly, the favorable timing of the orders should offset, but there is a number of factors that are going to kind of impact that trend going in different directions, including the anticipated continued growth in the advanced instrument usage offset by an increasing proportion of lower complexity cases, like cholecystectomy that we've talked about. So I&A revenue per procedure is going to have variability quarter-to-quarter and I don't have a long-term direction to give you.

Q - J.P. McKim {BIO 18054566 <GO>}

Okay. That's helpful. And then maybe just on -- you've got the CHEST Conference coming up this weekend, maybe what can we or should we expect from you guys in terms of Ion? Any single side data? And then maybe what investors should be looking for in terms of the right way to sort of compare systems or what -- what really is going to drive adoption and surgeon interest?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. So the conference, I think, what you're going to see is a lot of what we've talked about on this call. We're going to talk about just qualitatively, I think, some of the early

experiences in the field. We'll be doing a lot of test drives and talking about the system and its capabilities. I don't think there is no new data that I think is going to be groundbreaking at the event.

A - Gary S. Guthart {BIO 3429541 <GO>}

In general, I think you'll see from both sides relatively early data. I think the larger market in Ion and in -- and robotic-assisted bronchoscopy will be data-oriented and broader settings looking at safety and efficacy. And as that develops, I think we're feeling pretty good. There have been systems in the market in the past, as you know, and I think a fair number of accounts will wait to see what the data says. So there is the future benefit kind of conversations that happened in the early market, I think a lot of the market will wait to see what that expresses like in clinical use. Thank you.

Q - J.P. McKim {BIO 18054566 <GO>}

Thank you.

Operator

And our next question comes from the line of Richard Newitter with SVB Leerink. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thanks for taking my questions. Wanted to just follow up on chole. So I know that I believe chole is a faster procedure relative to some of the more complex areas where the robotic gets used. So I'm just curious, the extent to which you think this acceleration trying to staying power, could that help alleviate some of the capacity and training issues that you've outlined in the past with respect to the mix of the types of procedures getting done?

A - Calvin Darling {BIO 17664656 <GO>}

I think it can change the -- certainly the utilization rate for systems in the field. It's still -- it can still create access challenges as different people buy for time. But as you just described if they are faster through it. With regard to training, I think that high volume procedures allow surgeons to move through their early experiences more quickly and that has a generally positive net effect.

Q - Richard Newitter {BIO 16908179 <GO>}

Great. And I was hoping -- thanks for the color on the China procedure growth metrics relative to the overall OUS. I was just curious as you have more systems getting placed each quarter, how many quarters you think it might take to get approaching the international average. And I think it would be helpful just to know where was the growth rate trending in the last two quarters? Thanks -- relative to this quarter.

A - Calvin Darling {BIO 17664656 <GO>}

Right. So the overall OUS growth rate is roughly 23% and in the last two quarters, we've seen some modest acceleration. We are probably approaching that right now. So a successful scenario in the next quarter or two we may crossover.

Q - Richard Newitter {BIO 16908179 <GO>}

Thank you.

Operator

And next we turn to the line of Imron Zafar with Deutsche Bank. Please go ahead.

Q - Imron Zafar {BIO 7558242 <GO>}

Hi. Good afternoon. Thanks a lot for taking my question. Gary, you highlighted in your prepared remarks the stapling franchise. Can you talk a little bit more about, I guess, the 60-millimeter in particular and the impact you're seeing in terms of specific procedures where you're seeing the uptake, is it colorectal versus gastric sleeve? And then, also, how much cannibalization are you seeing of the 45-millimeter in cases like bowel resection, et cetera?

A - Gary S. Guthart {BIO 3429541 <GO>}

60 is mostly used in the lower abdomen. So you definitely have stomach and in colorectal. There is modest exchange for the 45s where a 60 will do, it's pure fires [ph]. But, in general, I think that mix and surgeon selection in that space is pretty well understood from prior experience with laparoscopy. And we're not overly stressed about it.

Q - Imron Zafar {BIO 7558242 <GO>}

Okay. And then in Japan, I know last quarter you talked about some sequential slow down, but the metrics you gave today, the 40% plus procedure growth and healthy placements, I think 27, can you just talk about the contributors to procedure growth there? Is it still urology, non-dVP urology or general surgery, mostly? And then are you expecting more procedure reimbursement approvals in April 2020?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. So, as we mentioned on the call, the growth -- move back to 40% where we had been prior to last quarter. Last quarter, I think, we largely felt the effect of a number of holidays or a fewer work days in the quarter than this quarter where that recovered. So that was the main thing. We are seeing increasing numbers of the 12 procedures that were granted reimbursement status in April of 2018, as well as continuing to see adoption of the urology procedures.

A - Marshall L. Mohr {BIO 5782298 <GO>}

Yeah. We don't think that the -- of the 12 that all adopted equal rate and we'll see some start to break out from the pack, whether it's in colorectal or thoracic relative to some of

the others. With regard to reimbursement opportunities going forward, it's something we track and we discuss with surgical societies for their support as needed. We'll see nothing to communicate with you at this time.

Q - Imron Zafar {BIO 7558242 <GO>}

Thank you very much.

Operator

Next, we turn to line of Craig Bijou with Cantor Fitzgerald. Please go ahead.

Q - Craig Bijou {BIO 18909856 <GO>}

Thanks for taking the questions. Just a couple of quick follow-ups. Gary, on SP, I think you mentioned that you might be looking at other indications. So I guess I just wanted to get a sense for given the IDE that will be required for colorectal, could we see another indication come in before seeing colorectal?

A - Gary S. Guthart {BIO 3429541 <GO>}

I can give you no reason to be optimistic for that.

Q - Craig Bijou {BIO 18909856 <GO>}

Okay. Fair enough. And then, Marshall, just your comments on the med device tax. I just wanted to -- you said that you expected to come in and I just wanted to get -- is that just you being conservative or assuming that it will come in in 2020 or is there anything else behind that comment?

A - Marshall L. Mohr {BIO 5782298 <GO>}

At this phase -- at this point, that is what is supposed to happen. I know there is lobbying efforts to try to change that, but -- so we're just telling you the way it is.

Q - Craig Bijou {BIO 18909856 <GO>}

Also fair enough. Thanks for taking the questions, guys.

A - Calvin Darling {BIO 17664656 <GO>}

Thank you.

Operator

And we have a question from the line of Jason Mills with Canaccord Genuity. Please go ahead.

Q - Jason Mills {BIO 5220951 <GO>}

Hi. Thank you for taking the question. Wanted to follow up, Calvin, on the revenue per procedure. You've given us that data fairly consistently. So (technical difficulty) things that have to change quite significantly across several of our procedures for that trend line to change over, let's say, the next three years. So it's been on a nice fairly decent upward slope. What would you say, I guess, over the longer term with respect to that trend line given you have so much data, but it is a dynamic business, it would seem like it could continue to trend upward with some volatility quarter-to-quarter, but upward over a longer period of time. Maybe tell me what I'm missing, if that's incorrect?

A - Calvin Darling {BIO 17664656 <GO>}

No, it has been increasing in low single digits the last couple of years, anyway. And I tried to mention that that we do expect to see a continued contribution from the advanced instruments as a tailwind to the metric, but that's being offset by a number of factors I mentioned increasing proportion of lower complexity cases and fact is people are just becoming all the more efficient as time goes on as well, wasting less, doing less with more and we help them to do that with some of the analytics we provide. So -- yeah, those are the offsets and so, yeah, you have the gives and the takes. So, at this point, I'm not ready to say whether the trend is going to continue up or be flat or trend down.

Q - Jason Mills {BIO 5220951 <GO>}

Okay. Fair enough. And, obviously, the big reveal one of the competitors recently, the number that they continue to harp on was 2% robotic surgery relative to procedures done, whether it'd be general laparoscopic. I was wondering if you could provide us, Gary, comment on that number from your perspective, obviously much more broad. If you could comment on the number or just give any general commentary as it relates to robotic surgery penetration, I know you talked qualitatively about it being early innings, but just specifically to that quantitative figure I'd like your thoughts. And then specific to Japan as it relates to the penetration of robotic surgery would seem to be lower than that like your commentary with respect to that geography specifically, if you don't mind. Thank you.

A - Gary S. Guthart {BIO 3429541 <GO>}

Let's zoom out for a second and then we can zoom back in. I think the opportunity for computer-aided and robotically-assisted surgery and acute intervention more broadly is clearly substantial and clearly durable. And that's going to draw in new entrants, which it's doing. I think those new entrants will help accelerate broader adoption more generally, and customers will appreciate that choice. And I think they will look at that.

Our strategy over this period has really to been understand our customers deeply and understand the quadruple aim. It's really hard to do the total accounting of what the total available market will be and what I'd ask you to look at is, over time what does it look like in the next couple of years, what does it look like in the next four, what does it look like in the next 10?

I think some of our competitors as they speak about these opportunities are looking out pretty far and okay, that's a forecast. Hard to have an exact crystal ball, but clearly even

speaking with our most candid critics, the idea that computer aids and robotics are going to make an impact more broadly in surgery is pretty well accepted. So I think we're in early innings.

Japan, I think likewise. We -- a little bit different healthcare system, the single-payer system that runs through MHLW or the predominantly single-payer system means that their requirements and negotiations using data with the government early are much more important and getting those right open the market over time and that's what we've been working on. So clearly that's an early set of opportunities for us as well.

Our methodology when we think about total available market is to be conservative in the early days, show that we can bring real value and then revise as we see greater depth other companies take a different statistical approach to that.

Q - Jason Mills {BIO 5220951 <GO>}

Thank you so much.

Operator

And next we turn to the line of Vijay Kumar with Evercore ISI. Please go ahead.

Q - Vijay Kumar {BIO 17881836 <GO>}

Hey, guys. Thanks for taking my questions. Maybe just tacking on that last question, Gary. If you just look at the medium-term outlook, right, just given where we are in the CapEx cycle, given the amount of product cycles that you guys have on a number of different platforms where -- I know, historically, you looked at utilization rates as being -- on the system utilization rates, the growth in system utilization as being a leading indicator for systems. Is this now -- given the acceleration we're seeing in procedures, is that a leading indicator for our systems? Like, you just give us a sense for what drives that systems next year? Because obviously you have competition. I'm just curious given why we're seeing base procedures accelerating, is that an indicator for how we should be modeling systems?

A - Gary S. Guthart {BIO 3429541 <GO>}

Well, I'll just draw a broader picture and let Calvin speak to a little bit of the modeling. In the broader sense, we know that in a mature market that has experience with robotic surgery, that procedure demand will drive the underlying system demand. And there's two ways that they go about it, one is capacity and they can get additional capacity by more efficient utilization of their systems. We have designed our systems with that in mind. We work closely with them and in various arrangements to help them get improved efficiency that will have to buy an X system, if they don't want to.

The other thing is feature content. Does the product have the feature content that's required to do the procedures they want to do? And so we work with them on those things.

Clearly competitors will enter the market and make claims. And, I guess, what I would say for both customers and for our shareholders, due diligence is really important. It's really easy to make claims on trade show floors and it's pretty hard to back them up in real life. And our experience in the world has been that there is a lot of noise in the beginning as those claims are made and then it takes a couple or three years in the actual clinical market and clinical use to see what the broad market thinks about that.

That will have an impact for us in the next few years. I don't know if it's next year or the year after and I think that's what Marshall's commentary was. Signaling is that customers will evaluate and will take their time and that may change capital acquisition cycle timelines or otherwise and they change the nature of negotiations for us, but we are planning and thinking for the long term and we're focused on enablement of the quadruple aim and we'll be here for our customers as we go through that.

Calvin, anything you want to help with on modeling.

A - Calvin Darling {BIO 17664656 <GO>}

No, I mean, clearly procedures are the catalyst for driving the demand for systems. When we look at our models, we would expect to see a continuation of the trend of increasing utilization over time.

A - Gary S. Guthart {BIO 3429541 <GO>}

Vijay, if you have a short follow-up, this is your chance. One last one.

Q - Vijay Kumar {BIO 17881836 <GO>}

One quick follow-up, Gary, I mean headcount is up 30%, up from 5,000 to -- will cross 7,000. I mean, that's an impressive phenomenal number. I'm just curious now where that is going? Thank you.

A - Gary S. Guthart {BIO 3429541 <GO>}

Yeah. We try to balance our growth in our investments by both the opportunity and we think the opportunity is enormous and durable and then we balance it by what we think we can achieve and do well and that really is what caps our growth and our spend. Absorbing, training, selecting, developing staff during rapid growth is really the challenge and that's what we are focused on.

As we get into 2020, 2021 and we'll share with you in future quarters what our plans are, but we try to balance those two things, being agile and pursuing the opportunity at the same time making sure we're not over extended and losing our ability to execute and be efficient.

So, thank you, that was our last question.

In closing, we believe there is a substantial and durable opportunity to fundamentally improve surgery and acute intervention. Our teams continue to work closely with hospitals, physicians and care teams in pursuit of what our customers have termed the quadruple aim; better more predictable patient outcomes, better experiences for patients, better experiences for their care teams, and, ultimately, a lower total cost of treatment.

We believe value creation in surgery and acute care is foundationally human that flows from respect for and understanding of patients and care teams, their needs and their environment.

Thank you for your support on this extraordinary journey to improve surgery. We look forward to talking with you again in three months.

Operator

Ladies and gentlemen, that does conclude our conference for today. Thank you for your participation, and for using AT&T Executive Teleconference Service. You may now disconnect.
