

Q3 2018 Earnings Call

Company Participants

- Calvin Darling, Senior Director-Finance & Investor Relations
- Gary S. Guthart, President, Chief Executive Officer & Director
- Marshall L. Mohr, Executive Vice President & Chief Financial Officer

Other Participants

- Amit Hazan, Analyst
- Bob Hopkins, Analyst
- Brandon Henry, Analyst
- David Ryan Lewis, Analyst
- Isaac Ro, Analyst
- Lawrence Biegelsen, Analyst
- Lawrence Keusch, Analyst
- Richard Newitter, Analyst
- Tycho W. Peterson, Analyst
- Vijay Kumar, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Initiative (sic) [Intuitive] Surgical Third Quarter 2018 Earnings Release Conference call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. Instruction will be given at that time. [Operator Instructions] As a reminder, this conference is being recorded.

I'd now like to turn the conference over to our host, Mr. Calvin Darling, Senior Director of Financial and Investor Relations, Intuitive Surgical. Please go ahead.

Calvin Darling {BIO 17664656 <GO>}

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

Before we begin, I'd 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

FINAL

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 2, 2018, and 10-Q filed on July 20, 2018. Our SEC filings can be found through our website or at the SEC's EDGAR database. 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 Event section of 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. Gary will present the quarter's business and operational highlights. Marshall will provide a review of our third quarter financial results and I will discuss procedures and clinical highlights, and provide our updated financial outlook for 2018. And finally, we will host a question-and-answer session.

With that, I will turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Good afternoon, and thank you for joining us on the call today. The third quarter of 2018 was a strong one for Intuitive with continued clinical adoption of our products and positive steps in product launches. As we mentioned in the last quarter, we believe acceptance of da Vinci in general surgery in the United States, growth internationally, and appreciation of our Generation 4 platform underpins our recent performance. Our team introduced sophisticated new products into the market this quarter as we seek to advance our goals of improving the quality of surgery and decreasing its variability.

Global procedure growth was approximately 20% in the third quarter of 2018 compared with the third quarter of 2017, increasing modestly from our Q2 growth rate. Trends present in the first half of the year have continued with the United States showing particular strength in hernia repair, colorectal procedures and practice-related general surgery procedures, including cholecystectomy.

Mature procedure growth in the United States, including prostatectomy and hysterectomy, was solid again in the quarter. In Japan, procedures grew above 40% year-over-year while our team is onboarding customer-facing staff and optimizing training logistics to support market growth. European procedure performance was generally in-line with our expectations again this quarter with particular strength in the UK. Calvin will review procedure trends in greater detail later in the call.

Our capital placement performance in the third quarter was strong with growth in total placements over Q3 of 2017, rising 37% from 169 to 231 this quarter. Net of trade-ins and retirements, our da Vinci installed base grew 13% over Q3 2017. The mix of system

placements between our flagship Xi System and our value X System align with our strategy regionally. Capital placements have been historically lumpy, and we anticipate variability in placements going forward.

As we indicated on prior calls, we are seeing increased customer interest in alternative capital acquisition approaches, including leasing and usage-based models. This quarter, the proportion of new systems placed under lease increased over prior quarters. We believe that it is in both our customers' interest and Intuitive's to offer alternative financing models for qualified hospitals. We have expanded these programs accordingly.

On the investment front, we are building our organization and making investments to deepen both our technological and regional capabilities. Fixed-cost spending in the quarter was slightly lower than we planned, largely due to timing issues that we anticipate will catch up in future quarters. Use of our products has increased over the past year and we are in the early-stages of several important product launches. Speaking directionally, we are investing to drive technology strength and to build operating and supply capability in support of our future growth.

Financial highlights for our third quarter results are as follows. Revenue for the quarter was \$921 million, up 14%. Pro forma gross profit margin was 71.5% compared to 71.8% in the third quarter last year. Instrument and accessory revenue increased to \$486 million, up 21%. Total recurring revenue in the quarter was \$660 million, representing 72% of total revenue.

We generated a pro forma operating profit of \$391 million in the quarter, up 12% from the third quarter of last year. And pro forma net income was \$337 million, up 4% with the difference in growth rate between operating profit and net income largely driven by a one-time tax benefit in Q3 of 2017. Marshall will take you through our finances in greater detail shortly.

Delivery of substantive technology and service improvements are core to continued progress in surgery. We measure our innovations by their ability to positively impact outcomes in the hands of our customers, to be used efficiently while lowering the total cost of treatment per patient episode, and for their positive impact on the experience of surgical patients and the professionals who treat them. As we've said in the past, we design our products, systems, instruments and software to work together seamlessly as an ecosystem that enables a holistic approach to a surgical procedure.

We obtained FDA clearance for da Vinci SP Surgical System for urologic surgical procedures in Q2 this year, and we submitted our 510(k) application for transoral procedures for SP this quarter. We shipped three da Vinci SP Surgical Systems in the quarter, all in the United States. These first access sites will focus on clinical data generation and customer feedback.

Surgeon and team feedback from first cases has been extremely encouraging. That said, we are in the very early stages of a multi-year pathway for SP, and our focus is on satisfying

our early customers, expanding clinical indications, improving our processes and technologies, and further refining our supply chain.

Our team is progressing to plan on Ion, our flexible robotics platform, initially targeted to address the acute need and diagnosis of lung cancer, one of the most commonly diagnosed and most lethal forms of cancer in the world, and for which early detection is particularly important. As we announced last month, we submitted our 510(k) for its first indication. We showcased our Ion system at the CHEST Conference this month. Feedback from physicians relative to existing and recently-announced alternatives has been strongly supportive of our efforts. Our team is focused on working towards clearance and readying the product for its first phase of launch.

We also initiated our early launch of our SureForm 60 millimeter Stapler for use with our fourth-generation systems this summer. Customer feedback has been encouraging at these early sites with hundreds of procedures performed today. The SureForm 60 brings to surgeons class-leading articulation and precision with computer measured and controlled staple firing. Collectively, our SureForm 60 millimeter Stapler joints are force bipolar grasper, and Vessel Sealer Extend advanced interweaving instrument to provide an optimized set of tools for general surgeons, particularly in hernia, bariatric, and colorectal procedures.

Our Vessel Sealer Extend launched in Q2 this year and our force bipolar instrument launched in Q3. Feedback on these instruments has been outstanding. We anticipate expanding the rollout of SureForm 60 in 2019, broadening the set of tools available to general surgeons in our fourth-generation platform.

For the balance of 2018, our focus remains in completing the tasks we set for ourselves. First, continued adoption of da Vinci in general surgery. Second, continued development of European markets and access to customers in Asia. Third, advancing our new platforms, imaging, advanced instruments, da Vinci SP, and our Ion platform. And finally, support for additional clinical and economic validation by global region.

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

Marshall L. Mohr {BIO 5782298 <GO>}

Good morning. I'll describe the highlights of our performance on a GAAP and non-GAAP or pro forma basis. Our results are also posted to our website.

Third quarter 2018 revenue of \$921 million grew 14% compared with third quarter 2017 revenue of \$808 million and increased 1% compared to the second quarter of \$909 million. Third quarter 2017 revenue included \$21 million that had previously been deferred in connection with a customer trade-out program that the company had offered to certain first quarter 2017 customers. Excluding the \$21 million, revenue grew 17%.

Third quarter 2018 procedures increased approximately 20% compared with the third quarter of 2017 and were relatively flat compared with last quarter. Procedure growth

FINAL

Bloomberg Transcript

continues to be driven by general surgery in the U.S. and urology worldwide. Calvin will review details of procedure growth later in this call.

Instrument and accessory revenue of \$486 million increased 21% compared with last year, which is higher than procedure growth, reflecting increased usage of our advanced instruments. Instrument and accessory revenue realized per procedure was approximately \$1,900, an increase of 1% compared with the third quarter of 2017, and an increase of approximately 3% compared with last quarter. These increases primarily reflect increased advanced instrument usage and customer buying patterns.

Systems revenue of \$275 million increased 5% compared with the third quarter of 2017, primarily reflecting higher system placements and higher lease-related revenue, partially offset by the recognition of \$21 million of previously deferred systems revenue in the third quarter of 2017, a high number of system placements under operating lease arrangements and slightly lower ASPs. We placed 231 systems in the third quarter 2018 compared with 169 systems in the third quarter of 2017, and 220 systems last quarter. 58 operating lease transactions, representing 25% of total placements were completed in the current quarter, compared with 20 or 12% of total placements in the third quarter of 2017 and 44 or 20% of total placements last quarter.

We provide financing alternatives to hospitals that are well-positioned in their markets, including some usage-based options, as we believe these alternatives align with customer objectives enabling faster market expansion. As of September 30, we had 279 operating lease and usage-based arrangements outstanding with a net present value of their future revenue stream being approximately \$250 million. We expect a proportion of these types of arrangements to increase long term.

28% of the current quarter system placements involve trade-ins, reflecting customer desire to access or standardize on our fourth generation technology. This is an increase compared with 26% in the third quarter of 2017 and lower than the 34% trade-in rate realized last quarter. Trade-in activity could be lumpy and difficult to predict.

68% of the systems placed in the quarter were da Vinci Xis and 28% were da Vinci X systems compared with 72% da Vinci Xis and 21% da Vinci Xs last quarter. Many of the X systems were placed with cost-sensitive customers in Europe and with customers in Japan where we obtained X approval this past May. Three of the systems placed in the U.S. were SP systems.

Our installed base of da Vinci systems increased 13% year-over-year and our average system utilization grew in the mid-single-digit range. Globally, our average selling price, which excludes the impact of operating leases, lease buyouts, and revenue deferrals was approximately \$1.45 million compared with \$1.47 million last year and \$1.42 million last quarter. The changes compared with prior periods primarily reflects the mix of X systems and trade-in transactions.

Outside of the U.S., results were as follows. Third quarter revenue outside of the U.S. was \$244 million, increased 15% compared with the third quarter of 2017 and decreased 8%

FINAL

compared with last quarter. Compared with the prior year, instruments and accessories revenue increased \$30 million or 34% and systems revenue decreased \$5 million or 6%. The increase in instrument and accessory revenue relative to the prior year was primarily driven by procedure growth and customer buying patterns. The decrease in systems revenue was driven by an increase in the number of operating leases, lower ASPs reflecting product mix, and the impact of trade-in transactions. The decrease in O-U.S. revenue relative to the previous quarter reflects seasonality and was driven by a decrease in the number of systems placed, a higher number of system lease transactions, and lower procedures, partially offset by customer I&A buying patterns.

O-U.S. procedures grew approximately 23% compared with the third quarter of 2017 and decreased 1% compared with second quarter. Outside the U.S., we placed 75 systems in the third quarter compared with 62 in the third quarter of 2017 and 82 last quarter. Current quarter system placements included 30 into Europe and 30 into Japan, 36 of the 75 systems placed in the third quarter were X systems. Placements outside of the U.S. will continue to be lumpy as some of the O-U.S. markets are in early stages of adoption, some markets are highly seasonal, reflecting budget cycles or vacation patterns, and sales into some markets are constrained by government regulations.

Moving on to the remainder of the P&L. The pro forma gross margin for the third quarter of 2018 was 71.5% compared with 71.8% for the third quarter of 2017 and 71.1% last quarter. The decrease compared with the third quarter of 2017 primarily reflects lower system ASPs, partially offset by higher mix of I&A. The increase compared with last quarter primarily reflects higher system ASPs and higher production levels.

Future margins will fluctuate based on the mix of our newer products, the mix of systems, instrument and accessory revenue, system ASPs, and our ability to further reduce product costs and improve manufacturing efficiency. Pro forma operating expenses increased 16% compared with the third quarter of 2017 and increased 4% compared with last quarter. Overall, our spending was below our annual guidance, reflecting the timing of expenditures. We expect to continue to invest in key technologies and O-U.S. market expansion, and expect spending to increase next quarter and into 2019.

Our pro forma effective tax rate for the third quarter was 18.5% compared with our expectations of 19.5% to 20.5%. Our tax rates will fluctuate with the changes in the mix of U.S. and O-U.S. income, changes in taxation made by local authorities, and with the impact of one-time items. Our third quarter 2017 pro forma tax rate of 9.7% reflected \$68 million of tax benefits associated with the expiration of statutes of limitations.

Our third quarter 2018 net income was \$337 million or \$2.83 per share compared with \$325 million or \$2.78 per share for the third quarter of 2017, and \$327 million or \$2.76 per share for the second quarter of 2018. Our third quarter 2017 net income benefited from the \$21 million of deferred revenue net of costs and the \$68 million of tax benefits associated with the expiration of statutes of limitations, or a total of \$0.68 per share.

I will now summarize our GAAP results. GAAP net income was \$293 million or \$2.45 per share for the third quarter of 2018 compared with GAAP net income of \$299 million or

FINAL

\$2.56 per share for the third quarter of 2017, and GAAP net income of \$255 million or \$2.15 per share for the second quarter of 2018. 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 and legal settlements.

Note that the IRS has not issued final tax regulations associated with recent U.S. tax legislation. Therefore, impacts of the U.S. Tax Cuts and Jobs Act reflected in our results and our projection of future tax rates represent our best estimates of the impact of the U.S. Tax Cuts and Jobs Act and could change as tax regulations are finalized and further interpreted.

We ended the quarter with cash and investments of \$4.6 billion compared with \$4.3 billion at June 30, 2018. The increase generally reflects cash generated from operations. We did not repurchase any shares in the quarter and have approximately \$718 million remaining under the board buyback authorization.

And with that, I'd like to turn it over to Calvin, who will go over procedure performance and our outlook for 2018.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall third quarter procedure growth was 20% compared to 15% during the third quarter of 2017 and 18% last quarter. Our Q3 procedure growth was driven by 19% growth in U.S. procedures and 23% growth in OUS markets. In the U.S., procedure performance across general surgery, gynecology and urology all exceeded our expectations with Q3 year-over-year growth rate increasing modestly across these largest categories as they did in the second quarter.

Q3 procedure performance was again driven by growth in general surgery led by hernia repair and colorectal procedures. Hernia repair, both ventral and inguinal, continued to contribute the most incremental cases in the quarter. Cholecystectomy, bariatric and other practice-based general surgery procedures all had strong growth in the third quarter.

In U.S. gynecology, third quarter 2018 year-over-year growth increased to mid-single-digits driven by higher benign hysterectomy volumes. In the third quarter, we continued to see favorable surgical consolidation trends as our da Vinci Surgery data indicates that practicing da Vinci surgeons perform more da Vinci hysterectomies, and an increasing proportion of U.S. gynecology procedures are being performed by higher volume physicians that specialize in complex benign and cancer surgery.

Q3 U.S. urology procedures had growth rates consistent with 2017 and year-to-date 2018 driven by prostatectomy volumes. As a mature procedure category, we believe our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market, which has benefited from recent macro trends. In other U.S. procedures, adoption of

lobectomies and other thoracic procedures was again solid during the third quarter. Our overall U.S. procedure growth rate likely benefited from a weaker Q3 2017 comparison.

Q3 OUS procedure growth trends were largely consistent with Q2. Third quarter OUS procedure volume grew approximately 23% compared to 23% for the third quarter of 2017 and 22% last quarter. Third quarter 2018 OUS procedure growth was driven by continued growth in dVP procedures and earlier-stage growth in kidney cancer procedures, general surgery and gynecology.

Procedure growth in Japan again accelerated as procedures were performed within the set of 12 additional procedures approved for reimbursement effective April 1. Procedure growth in China, again moderated in Q3, as da Vinci System capacity expansion is constrained by system quota requirements, the most recent of which expired at the end of 2015. In Europe, procedure results vary by country with continued strength in the UK.

Adoption of our products is ultimately based upon differentiated patient outcomes and procedure economics compared to alternative therapies. Intuitive supports the generation of high-quality clinical evidence through collaborative research initiatives. We work with clinicians, hospitals and medical and surgical societies to study da Vinci clinical outcomes while maintaining a patients first mindset.

Intuitive is currently supporting comparative multicenter studies for several key procedures including hernia repair, lobectomy, and right colectomy. In hernia repair, we are supporting a prospective multicenter comparative study evaluating outcomes associated with open, laparoscopic and robotic-assisted inguinal and incisional hernia repairs in up to 900 subjects. This study is designed to collect outcomes related to pain, quality of life, and recurrence for up to three-years post-procedure, capturing patient-reported outcomes through direct electronic or phone follow up.

We are supporting a prospective comparative study for right colectomy comparing outcomes associated with extracorporeal and intracorporeal anastomotic techniques in up to 300 subjects, collecting information related to patient quality of life parameters, including but not limited to, gastrointestinal quality of life and incidence of incisional hernia rates. Intracorporeal anastomosis by the robotic approach may be amenable to more surgeon skillsets than the laparoscopic counterpart. Indeed, the degree of difficulty of the sutured laparoscopic anastomosis has limited wide application of this approach.

In this year where lung cancer is the leading cause of cancer death among men and women in the United States, a gradual decline is noted in the percentage of lung cancer surgery performed by an open approach, from 43% in 2015 to 31% in 2017. The literature supporting the use of minimally-invasive approach both VATS and robot-assisted for lobectomy is incrementally growing with the majority of them attributed to the treatment of early stage lung cancer.

Intuitive is conducting a retrospective, comparative, multicenter lobectomy study evaluating both the short-term and long-term outcomes across both early stage and

locally-advanced lung cancer, in up to 5,000 patients. You can find a full description of all of these studies on the Clinical Evidence page of our new website.

I will now turn to our financial outlook for 2018. Starting with procedures. On our last call, we forecast full-year 2018 procedure growth within a range of 14.5% to 16.5%. We're now increasing our forecast and estimate full-year 2018 procedure growth of 17% to 18%.

In regards to Q4 system placements, consistent with historical patterns, we anticipate seasonally strong fourth quarter system placements. However, we do expect some moderation from the 30%-plus growth in system placements we've realized in recent quarters. Furthermore, we expect that the proportion of systems placed via operating leases in Q4 will increase further from the 25% in Q3.

Turning to gross profit. On our last call, we forecast our 2018 pro forma gross profit margin to be within a range of between 70% and 71.5% of net revenue. We're now retiring the lower-end of the range and expect pro forma gross profit margin to be between 70.5% and 71.5% of net revenue. Our actual gross profit margin will vary quarter-to-quarter depending largely upon product, regional, and trade-in mix, and the impact of new product introductions.

Turning to operating expenses. Last quarter, we guided 2018 operating expense growth of between 16% and 18%. We are now adjusting this range lower and expect to grow 2018 operating expenses within a range of between 15.5% and 17% above 2017 levels.

We are adjusting upwards our estimate for noncash stock compensation expense to a range of between \$255 million and \$260 million in 2018 compared to \$245 million to \$255 million forecast on our last call. We continued to expect other income, which is comprised mostly of interest income, to total between \$70 million and \$75 million in 2018.

With regard to income tax, on our last call, we forecast our 2018 pro forma income tax rates to be between 19.5% and 20.5% of pre-tax income. We are now shifting our estimates slightly lower to a range between 19% and 20% of pre-tax income.

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

Q&A

Operator

Thank you. We have a question from the line of Bob Hopkins with Bank of America. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Hello. Thank you, and good afternoon. I actually wanted to start, if okay, with a question on capital allocation. Obviously, the business trends are very strong right now. I think you

mentioned that you've got \$4.6 billion in cash and the authority to buy back stock. Maybe, if okay, if you wouldn't just mind, commenting on why you're not buying back stock right now. And does that suggest the potential for some M&A opportunities out there? Thank you.

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

Hi, Bob. It's Marshall. We've not modified our capital deployment priorities, and so they're consistent with what we said before. First, the organic investment in substantial growth opportunities that are available to us; second, acquiring technologies and talent that will ensure that we can accelerate our growth; and then third, using efficient long-term focus vehicles to return cash to shareholders, and in that regard, we have done stock buybacks. You've seen us do them periodically. We do them opportunistically based on our assessment of the market. I think the market will continue to be volatile as it has been recently, and as this provides opportunities to purchase at the right price, you'll see us do something.

Operator

Thank you. And we have a question from the line of David Lewis with Morgan Stanley. Please go ahead.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Good afternoon. Gary, a couple questions for me. I guess the first is Marshall touched on this, but obviously leases suppressed revenue in the quarter, but net placement numbers in the U.S. were the best we've seen as well as system utilization, both those numbers are the best we've seen in years. And 20% procedure growth obviously reflects another quarter, I think the third straight quarter of momentum acceleration. So I guess if you keep up these U.S. box and procedure trends, can you just walk us through some of the drivers that you're seeing specifically in the U.S. for these dynamics?

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

I think the procedure demand is of course the top line. And as we called out in the script, the sustained strength in some of the mature categories in urology and gynecology as well as general surgery really rising has been strong, and I think the box placements that are in response to that increased procedure demand. From our perspective, we're happy to see utilization go up. We really view capital placements in mature markets as a way to enable the procedure market, and so you're seeing that. Leases are then kind of a fall-out of that philosophy or hospitals that have good positions in their markets and are well-run. Then we think giving them access where and when they needed it at terms that work for them and work for us helps facilitate the market and we've been willing to do that.

Operator

Thank you. And our next question will come from the line of Amit Hazan with Citi. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Hello. Thanks. Well, looks like we're getting about one question each here.

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

Yeah, we'll give David a chance to jump back in queue a little bit later, go ahead. Sorry about that.

Q - Amit Hazan {BIO 6327168 <GO>}

No problem. I'll ask mine on Japan. That was obviously some improved numbers in Japan, strong procedures and installations. And so I'm just curious if that's surprising to you, if that's the reimbursement. And if you could just give us some more color on how you're seeing that market react and develop close to new reimbursements. And whether the sustainability of that growth that we're seeing now looks more realistic to you after this quarter. Thanks.

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

We're pleased with progress in Japan. The kind of the settle down growth rates are going to be a little bit hard to predict. Right now, demand looks really good. And I think it's really the pipeline of activities from demand to clinical cases and up and running programs that's the right limiting step. Some of that is training capacity and logistics. Some of it is field support on our side. Some of it is the depth of the surgeon proctoring network. Not all of the procedures that were reimbursed will adopt at the same rates nor will we pursue them all at the same rate. And so there's a little bit of shakeout here as the priorities firm up. So far so good, but I really think there's a few quarters to go before this settles into kind of a more predictable cadence.

And if you have a follow up, go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Sure. Yeah. So I'm going to maybe ask about hiring pace. So from the numbers that you guys reported, it's obviously really strong, it's up to 5,200 head count now, that's about a 700 increase so far this year. So maybe just some color on where the heavy areas are in which those heads are being allocated? And then, how you're thinking about that head count growth as we think about the next year or two? Thanks.

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

Good question. Some of the head count growth is - roughly tracks to the procedure momentum that we're seeing. So, there's field support that's required, there's the production side of instruments and accessories, and there's training resources that go into product training. And so those things are kind of ratable. And we get a little leverage out of them, but we want to make sure that we support our customer really well. So, that's where you see the bulk of the hiring. And as procedure growth goes, we expect a little leverage there, but not a ton. There are also new platforms coming, we talked about in the script, SP and Ion. And those are deep technology efforts, supply chain efforts, and so some of the heads have gone into the support of that set of activities as we go. That may

well be the rate-limiting step for growth of the company is really the onboarding capability of really good people. So, we watch it really carefully and care about it.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks, guys.

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

Thanks, Amit.

Operator

Okay. Thank you. And our next question will come from Tycho Peterson with JPMorgan. Please go ahead.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Thanks. I'll ask a couple on some of the emerging procedures. On bariatric, I'm just wondering if you can comment on some of the market development efforts now that you've got the SureForm stapler out there. And how should we think about sleeve gastrectomies versus bypass versus maybe other procedures? And then, separately, I noticed you both, Calvin and Gary, talked about chole, I'm wondering if that's coming back a little bit relative to what we've seen in the past?

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

Yeah. On the bariatric front, long term, we're really enthusiastic about it. In the near term, we're optimizing a few things. We are optimizing the product portfolio in terms of some of the instruments that I mentioned in the script, so the Vessel Sealer Extend and the SureForm 60. We're still in our first phase launch, which is building capacity in the supply side as well as working through customer preference feedback. That will start to expand into 2019. And it'll be a measured launch, in part to make sure that our supply capabilities match demand and in part to make sure that our sales force is well balanced in terms of supporting general surgery customers in hernia, which is growing nicely; in colorectal, which is growing nicely, so that we have a balanced approach to the general surgery market. So, I wouldn't overbuild the near-term on it. I think in the long term, it looks quite good.

With regard to resolution on kind of the clinical approach question you asked underneath sleeve versus bypass, a little too soon for us to work through it. Clearly, there's a mix in the market. How that mix applies to robotics, I think that's a question for future quarters.

On cholecystectomy, just touching that, we have seen strength in multi-port chole, a decline in Single-Site cholecystectomy more than made up for by strength in multi-port. For us, it's hard to know how much of that is a part of new general surgeons coming in versus how much of it is surgeons adopting or changing their practice pattern for patients that they think are well suited to robotics. There's clearly a mix of both. And separating

FINAL

Bloomberg Transcript

those two in terms of intent is very hard. So we mention it because the growth numbers have been substantive. The sustainability of that growth we're not ready to call yet.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Okay. And then if I could just ask one more clarification, can you comment on the difference between a usage-based model and an operating lease for those systems that are kind of undertaking one of those?

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

Sure. Marshall?

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

Sure. Operating leases, frankly, we structure these things to meet customer needs. And operating leases come in various flavors, including that we will do your traditional four-year lease with a bargain buyout at the end. We also do short-term rentals that get them over budget cycles, and again, so we're ultimately pretty flexible on the leasing programs. The usage-based programs really are based on time and usage over a period. And we've done that with a few hospitals, as we said, that are well-positioned in the market and are serious robotic users.

A - Calvin Darling {BIO 17664656 <GO>}

And in terms of our reporting, Tycho, we are including these alternative structures in with the operating leases, right? So, they're all included in the overall operating lease number. Just think of it as another form of operating lease.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Okay. Thank you.

Operator

Thank you. And our next question will come from the line of Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. Two for me, I'll just ask them upfront. Gary, on the Q2 call, you said hernia is moving to a different phase, and it's worth thinking through that phase. Can you elaborate that, maybe talk about some themes you're seeing in hernia? And then, separately, obviously, with the CHEST Meeting and AATS, the two robotic bronchoscopy platforms got more Wall Street attention. Gary, the differences seem to be between the two systems, the camera capability and the size of the working channel. How would you compare and contrast the two systems with respect to those differences? Thanks for taking the questions.

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

Okay. I think the conversation we had last quarter, it was kind of a question of what inning are we in, in hernia. And I think we're still in the first half of the game, but out of the first couple of innings. And why do I say that? I think you're starting to see a fair amount of data that's being collected in things like registries that's able to show clinical benefit. And we're seeing a fair amount of reorders from existing customers that does not appear that a lot of it is just trialing. It looks like it's - for those who have adopted their commitment to it appears to be pretty good.

How deeply that goes into the total market in terms of what the total number of hernias out there is, we still are struggling a little bit to understand what fraction of the total available market of hernias will settle into robotic-assisted surgery in terms of size of the herniation and bilateral versus unilateral inguinal hernia repair and so on. Some of the segments of the underlying market are not yet resolved and so that's uncertain. We'll see it as we go-forward. But the data so far in the surgeons taking this has been good. So that's what we were seeing last quarter, I think that holds up this quarter.

Turning to our Ion platform as it relates to other products in the market. We made some decisions early on that were really driven around what we viewed as the clinical problem in pulmonology, which was early detection of distal meaning on the periphery of the lung and on the further distant branches within the lung of suspicious lesions that are give or take a centimeter in size. And to do that, you needed really good sensing, which we did. That was through our shape-sensing technology and some of the first partnering and then acquisition and development of Luna sensor. And then it was depended strongly on the size of the catheter. So we make that decision based on understanding the physiology of the lung, understanding where those nodules were, and hoping to understand what interventional pulmonologists and thoracic surgeons really needed. That's what drove our architecture.

We feel good about it. It is possible technologically feasible to make a bigger catheter. Making a bigger one is easier than making a smaller one, putting a permanent camera in if we needed to do that was all something that could be done, and we chose not to. We chose to make it small, and time will tell whether that was the right decision. I feel good about it.

Last point I'd make about the lung space is that this is a space that has been looking at early diagnosis of lung cancer for some time, and for which several commercial teams have gone in and promoted products. Several of which are disappointing. So I don't think it's a market that will move on what's said. I think it's a market that will move based on true capability and clinical evidence, and that's where our focus is. We feel good about where we are and we show what we think we can and then I think that will determine success for us.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Thanks for taking the questions.

Operator

Thank you. Our next question will come from Brandon Henry with RBC Capital Markets. Please go ahead.

Q - Brandon Henry {BIO 18858621 <GO>}

Yeah, thanks for taking my question. Can you discuss any challenges you expect to face with the Ion roll out, and who will be selling these systems to pulmonologists? Will it be a separate sales force or the existing Intuitive sales force? And then I just have a follow up.

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

I would anticipate the kinds of challenges that are related to the sort of complex product launches that we specialize in. So I think the early launches will be a couple of things. It will be engaging with sites that have a long-term commitment to clinical progress, data collection, that's associated with that clinical progress. Stabilizing supply chains for these kinds of technologies is non-trivial. It's hard and it's important. And so we will do that for Ion for sure. And your stable supply chain allows you to support a larger customer base and also gets your costs in-line. And so that is routinely an exercise we need to do, and then building your technology training pipelines and the product training networks that are required to really expand launch. So those things are all in front of us in terms of Ion. That's the challenge. The good news is that we have a history of engaging those challenges. And I think we'll work it through.

Did I miss the second part of the question?

Q - Brandon Henry {BIO 18858621 <GO>}

Who's the sales force, will it be the existing sales force or do we have to build-out a completely new sales force and just how will that look?

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

Yeah. We have a small specialty team within our existing force right now that's deeply trained in this space and linked to our other key account leadership and management. So they are deep where they need to be and connected where they need to be.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. And then as a follow up separately, could you provide an update on some of the opportunities to enhance Intuitive's vision and informatics portfolio. And specifically, could you touch on the recent InTouch Health agreement and where the company is at with its augmented reality technology? Thanks.

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

Sure. As we've said before, for the last several years, we've increased our investments in imaging. I think imaging is important. I think it can really help change outcomes, and we do that routinely. We do it in the image sensors, in the endoscopes, we do it in the software that we use to process those images, and the way we tune images we do it in our displays and our user interface. We are investing in molecules to expand our Firefly

platform as you know. Molecules are just a way to increase the signal-to-noise for surgeons to detect structures they care about whether they are things that they want to take out or things they want to leave in and not disturb.

Informatics works hand-in-hand with that, certainly, in OR informatics. So we have built cloud capabilities over the years, as you know, we've been the Internet of Things for surgical robots for a decade now. Over 90% of our systems are internet-connected. So we have Big Data capabilities that we've built and we'll continue to build. That allows us to do offline informatic processing. And increasingly, we could use machine learning techniques and other things to do real-time capabilities. And of course, over time, that will give us the opportunity to do mixed reality or augmented reality features.

How fast they come and where are the first markets are, we're not prepared to discuss yet. I think it's interesting and a long-term pathway. And so that's a step in that direction. We've known InTouch and have worked with them together for many years. And this was just the deepening of that relationship and the ability for us to build some real strength internally to Intuitive as we accelerate our cloud capability.

Q - Brandon Henry {BIO 18858621 <GO>}

All right. Thank you.

Operator

And our next question will come from Bob Hopkins with Bank of America. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Oh, thanks for letting me sneak back in. I just wanted to ask a question on lon and flex cath for lung. Gary, how long will it take following the approval of the product to generate the kind of efficacy data that you need to really drive broad adoption of the therapy?

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

Good question. I don't really know the answer right now. I think we'll get some early data that will be out of a few sites that'll be quarters, not years. And they're multicenter studies that integrate that up and go through peer review cycle, of course will be years, not quarters. So I think you'll see, as we have in the past, increasing cadence of publication, just depending a little bit on what the complexity of the clinical trials is.

Q - Bob Hopkins {BIO 2150525 <GO>}

And then if demand for SP is really high, do you have the capacity to meet that demand? I mean I know you want to go slow and focus on the long-term, but if demand is high, can you meet it?

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

FINAL

Yeah, I think the focus up front is two things. One, is to work on expanded indications. As you know, SP is a platform technology from our point of view. We have the first set of indications in urology, we've submitted for the second set in transoral robotic surgery. We think there are other indications that'll be important. So the first thing is to really make sure we're putting systems out that will help us develop those indications over time. So that is important to us.

Second thing is that SP is amongst the most sophisticated products. I've never been personally associated with, certainly that Intuitive has brought to market. And making sure that we really understand and well-characterize what our technologies are and we have a really good stable supply chain before we go broad is really important to us. My enthusiasm over the long-term and the customers' enthusiasm for its capabilities is very good. But I think we'll be measured in this next set of quarters as indications come and as our confidence builds, then of course we can always accelerate supply chain capacity, but we're going to take it in steps.

Q - Bob Hopkins {BIO 2150525 <GO>}

Great. Thank you very much.

Operator

Thank you. And our next question will come from David Lewis with Morgan Stanley.

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

Hi, David. Welcome back.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Good afternoon. The suspense was killing me. So I don't know that my question will live up to the suspense.

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

(00:48:27).

Q - David Ryan Lewis {BIO 15161699 <GO>}

I know, this is terrible. But Calvin had mentioned in the prepared remarks the systems moderation in the fourth quarter. Just is there anything fundamental behind that other than just harder comps and obviously the increased implications of higher leases?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, I think it's really - I mentioned comparisons in the prepared remarks. We actually kind of crossed over that 30% growth in placements threshold last Q4, and so now, this is the first quarter we're comparing against that kind of comparison. And so it's just a little tougher but like I said we still expect a seasonally strong fourth quarter.

Q - David Ryan Lewis {BIO 15161699 <GO>}

And, Gary, just you've had a lot of questions on this call on SP and Ion. I wonder just a lot of investors are focused on these platforms. From a commercial perspective, if I compare SP and Ion, which one is going to require greater channel development, and how would you compare the near and long-term opportunity for system placements and revenue across these two systems? Thanks so much, guys.

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

As I think about it, SP is more familiar customer base. I think it has really interesting core clinical capability, which is the ability to work in small spaces and parallel access. And I have been pleased with surgeon response, which has been now that I have the raw capability like this, there's some different approaches that may be available to us and they're interested developing the data that helps that. But I think that our visibility on that is probably a little better, because we know the customer base quite well.

As you look at Ion, I think Ion first is a diagnostic initial application that will have a little bit different set of dynamics for us as a company over time. I think the platform itself will have long legs. If you think about the ability to navigate tortuous pathways and inspect things using pre-operative images, which is kind of the core technology underneath, there are a lot of things that in the body could be interesting there. But it'll take some time to develop it. And given that those were a different set of procedures that are different call points for us, that will take more development for us and frankly for the competitors in the space as that develops out. So that's a more nascent market. I think very interesting and long-term possibility.

You kind of asked how big are the total available markets for these two different things, and how do we think about future market capacity. Those are highly uncertain. We of course have models on them. We look at them, but as you know with us for years here, that capability ultimately determines the total opportunity in the market. And as capability is established with these things we'll know better and as we get more experience with them we'll start to share with you our thoughts as the uncertainty starts to come down a little bit.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Great. Thanks so much.

Operator

Thank you. Our next question will come from the line of Larry Keusch with Raymond James. Please go ahead.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Yeah, hi. Good afternoon. Gary, just wanted to see if there are any observations or learning from China over the last three months since the 2Q call?

FINAL

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

Generally, no big change. As we've said before, we think demand in China for our products is real and we're excited about it, and we think the long-term opportunity there is great. We think the macro trade environment is pressured. And we think that that pressure does not help us. And so, incrementally, a little more headwinds on the micro side. On the ground side, we continue to make incremental progress and we keep working within the environment we have to work.

Q - Lawrence Keusch {BIO 1504587 <GO>}

So I take it not a whole lot more visibility on just the process and the quarter itself?

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

Correct.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay. And then secondly, I know you obviously choose your words carefully in the prepared comments. And I think in the part around the 60 millimeter stapler, you indicated that the sort of initial feedback was encouraging. And I guess, as I listened to that, I was wondering if that is meaning that, look, this is getting out there and people are starting to use it, and it'll take some time to build the capabilities to get out there to drive more demand. Or does encouraging mean that perhaps you're seeing some things where you may actually need to tweak it a little bit before it's really ready for, if you will, primetime in 2019?

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

In terms of customer response has been quite good. The things that we're pacing - if you ask - another way to ask your question is what's pacing launch? And there are really two things that are pacing us. One is, staplers are sophisticated devices to make and you want to make sure that as you expand your supply capacity that you're doing it at a very high-quality level, and so we're doing that. The second one is that we don't want to overwhelm our sales force with enormous amounts of new and different products simultaneously. We want to give them time to be deep and be able to address customer interest and demand as it happens. Those are really the two pacing items.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay. Perfect. Thanks very much.

Operator

And we have a question from the line of Richard Newitter with Leerink Partners. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thank you. Just in light of the operating expense growth coming in a little bit lighter than kind of what you were forecasting is little (54:09) operating leverage this year clearly. I was wondering if you could offer some thoughts on maybe some of those projects you said were getting deferred or it's a timing issue, and maybe some color on how we should be thinking about operating leverage potential in 2019 with respect to spending.

A - Gary S. Guthart {BIO 342954} <GO>}

Sure. My preference would have been that we had spent our full allotment now rather than underspent. On the other hand, I'd rather spend it wisely than spend it because I have it. Most of the spending has to do with human capital, bringing on staff and we're doing well. But there's kind of a natural rate for bringing on staff, and we'll do it where we are bringing on outstanding people and integrating them well. It's not so much a specific product or project that is impacted and it's not so much a prototype dollars just rolled from one spot to another. There's a little bit of that, but that isn't the dominant effect. The dominant effect is really modulating the growth of head count and that has to do with pipelines for bringing in talent.

You asked a little bit of what does that imply for 2019. And as we said in our prepared remarks, we're seeing a good procedure momentum in the marketplace and good demand. And we want to make sure that we're able to meet that demand with high quality. We are not setting ourselves up to try to drive leverage in the 2019 model. Now, we haven't finished all of that and we'll do our spending models for 2019 at the end of the next call. But directionally speaking, we want to make sure we can satisfy market demand here.

Q - Richard Newitter {BIO 16908179} <GO>}

Okay. And just following up on one comment you made earlier. You said China, as expected, without increased capacity, is moderating; the growth in China continues to moderate. Just curious if you can characterize kind of the pace of moderation in growth that you're seeing there, relative to kind of what you'd have expected. Is it not slowing as fast as you would have thought or is it in line with your expectations? Maybe just a little color there so we can think about kind of how much of a headwind that might present going forward.

A - Calvin Darling {BIO 17664656} <GO>}

We continue to make progress on utilization on the systems that are in China. Last quarter, we talked about the China growth rate in procedures being fairly in line with the overall O-U.S. growth rate in the low-20s. We're at a stage now where the moderation is at a moderate pace, if you will, and so you're gradually moving down from there.

Q - Richard Newitter {BIO 16908179} <GO>}

Okay. Thanks.

Operator

Thank you. And our next question will come from the line of Isaac Ro with Goldman Sachs. Please go ahead.

Q - Isaac Ro {BIO 15121543 <GO>}

Good afternoon. Thank you. Two questions, one on equipment and one on investment in the business. On the first one, I was curious with the Xi upgrade cycle, if you could maybe qualify where you think we are in that process, the extent to which you have still a fair amount of opportunity. And then, secondly, on the expense side, Gary, you mentioned a little bit about the opportunities for training, and I think of that as a bit of a competitive advantage for you guys. And so, if you could maybe contrast how you think training for your platform will evolve not only for new applications, but also globally as you expand to other countries where medical practice is different. I'd be interested in sort of some of the things you're doing on the training side. Thank you.

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

Sure. On the Xi upgrade cycle kind of or the generation 4 upgrade cycle, just roughly speaking, I don't know how many Xis are out in the world, but give or take.

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

2,500.

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

So, I don't know exactly what I'd say what it is when (00:57:54) we're done, but there's an installed base of Xis that - over 2,000 that's an opportunity for us as we go forward. I think the implication behind your training question is exactly right. Building training capability is heavy lifting. It's a combination of human capital, people who are good at training and what that looks like, a set of processes to build that are valid and you have validated. And then proctoring networks, and proctoring networks are your customers, our customers who are deeply experienced and have teaching capability and willing to teach others. And so, we developed those things. We have built a set of tools internally that allowed us to gain some efficiency in being able to spread that capability into new markets. And so that helps us. And we think that doing that well and doing that efficiently is something that is worth the investment, and we have done so.

What is its long-term competitive advantage? I don't know exactly, but I believe it's important for our customer and, therefore, important for the company. Perhaps just one last question, and then we'll close here.

Operator

Thank you. Okay. So our last question will come from Vijay Kumar with Evercore. Please go ahead.

Q - Vijay Kumar {BIO 17881836 <GO>}

Hey, guys. Thanks for squeezing me in, and congrats on the really impressive procedure number. So maybe, Gary or Marshall, just starting on the procedure number, the guidance says 18%, right. So when you think about next year a number of factors at play, but just how do you think the procedure number is going to look like? Should we be thinking of a really strong number? You made some comments on hernia. We're still at the very early stages of this hernia pickup. You have a couple of new products coming in. So I'm just curious on how that number should trade-in. Just given, lease, it looks like the percentage of lease is going to increase next year, right. So when we're thinking about modeling revenues for next year if you could just explain the procedure, how we should think about it? I think that would be extremely helpful. Thank you.

A - Gary S. Guthart {BIO 342954} <GO>}

Yeah. Hi, Vijay, it's Calvin. Obviously, we'll give our specific procedure guidance on our next call in January, but we do anticipate the drivers of procedure growth in 2019 to be fairly consistent with what we saw this year in 2018 and last year in 2017, namely U.S. general surgery, U.S. thoracic surgery and OUS procedures broadly speaking driving the lion's share of growth. U.S. general surgeries now our largest specialty yet as we were describing we're in still fairly early stages for hernia repair, both ventral and inguinal, colorectal procedures as well and even earlier-stages for some of the broader practice-based procedures.

On the OUS side, we're investing in growth in a larger European countries, Japan, China, Korea, OUS driving growth. And when we talk about what can lead to some of the variability and the potential range of growth, it would be obviously the pace and breadth of that U.S. general surgery growth, U.S. mature procedure tends, any change in the China systems quota, positive or negative, and then in Japan, the pace of adoption on the 12 new reimbursed procedures.

All right. Well, thanks, Calvin. Thanks, Vijay. That was our last question. As we've said previously, while we focus on financial metrics such as revenues, profits and cash flow during these conference calls, our organizational focus remains on increasing value, by enabling surgeons to improve surgical outcomes and reduce surgical trauma. We've built our company to take surgery beyond the limits of the human hand. And I assure you, we remain committed to driving the vital few things that truly make a difference.

This concludes today's call. Thank you for your participating and support on this extraordinary journey to improve surgery, and we look forward to talking to you again in three months.

Operator

Thank you. And, ladies and gentlemen, that does conclude our conference call for today. Thank you for your participation, and for using the AT&T Executive TeleConference Service. You may now disconnect.

FINAL

This transcript may not be 100 percent accurate and may contain misspellings and other inaccuracies. This transcript is provided "as is", without express or implied warranties of any kind. Bloomberg retains all rights to this transcript and provides it solely for your personal, non-commercial use. Bloomberg, its suppliers and third-party agents shall have no liability for errors in this transcript or for lost profits, losses, or direct, indirect, incidental, consequential, special or punitive damages in connection with the furnishing, performance or use of such transcript. Neither the information nor any opinion expressed in this transcript constitutes a solicitation of the purchase or sale of securities or commodities. Any opinion expressed in the transcript does not necessarily reflect the views of Bloomberg LP. © COPYRIGHT 2021, BLOOMBERG LP. All rights reserved. Any reproduction, redistribution or retransmission is expressly prohibited.

Bloomberg Transcript