Q4 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
- David Ryan Lewis, Analyst
- Larry Biegelsen, Analyst
- Richard Newitter, Analyst
- Rick Wise, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Surgical Q4 2018 Earnings Release call. As a reminder, today's call is being recorded.

I will now turn the call over to Senior Director of Finance and Investor Relations, Calvin Darling. Please go ahead sir.

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon and welcome to Intuitive Surgical's fourth 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 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 2, 2018, and 10-Q filed on October 22, 2018. 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 fourth 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 fourth 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 will turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Thank you, Calvin. Entering 2019, our business is showing strength. In 2018, over 1 million surgeries were performed using da Vinci systems, accompanied by approximately 1,500 peer-reviewed clinical journal articles. The total number of procedures performed since first launch exceeded 6 million and the total peer-reviewed clinical database contains over 16,000 articles. While these milestones represent a step forward, I believe that outstanding product design, robotics, advanced imaging, and informatics are just starting to take their place in surgery, and in acute interventions more broadly.

Surgery and acute interventions are sophisticated interactions among highly trained professionals. They have a common goal of delivering outstanding care to a patient in need. Starting with a careful understanding of operating and interventional environments, engineers and interaction designers collaborate closely with physicians to develop smart, connected devices with a goal of the quadruple aim.

First, decreasing complications; second, increasing patient satisfaction; third, increasing care team satisfaction; and fourth, improved efficiency and lowering of the total cost to treat. Considering our current da Vinci systems and the procedures and countries that are our focus today, we believe the applicable procedures exceed 5 million annually. As we consider our new concepts coming to market, including, but not limited to, our da Vinci Single Port System, our advanced imaging technologies, and our Ion flexible catheter system, the long-term total opportunity for our products to make a positive difference in physicians and their patients' lives is greater still.

Given the positive response of our customers and in pursuit of the substantial opportunity to improve surgery and intervention that lies ahead, we plan to accelerate some investments over the next several quarters. We'll review our guidance on spend later in the call. Given our prerelease this month, I'll be brief in summarizing our 2018 highlights.

Global procedure growth was strong, with approximately 19% growth in the fourth quarter and 18% for the full year. Growth in procedures was largely consistent through the year, 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 2018, though we expect slowing in these mature procedures going forward in some countries. In Japan, procedures grew over 40% in the second half of 2018 in response to additional reimbursements granted in Q2. Aggregate European procedure performance was generally in line with our expectations again this quarter, with particular strength in the UK and France. Calvin will review procedure trends in greater detail later in the call.

Our capital placement performance in 2018 was also strong, with growth in total placements rising 35% from 684 in 2017 to 926 in 2018. Net of trade-ins and retirements, our da Vinci installed base grew 13% over 2017. The mix of system placements between our flagship Xi system and our value X system generally aligned with our strategy regionally. As we discussed on our last earnings call, customers are interested in leasing and alternative capital placement models. The proportion of the systems placed under lease increased again in the quarter from 25% in Q3 of 2018 to 29% in Q4.

Financial highlights of our fourth quarter results are as follows. Revenue for the quarter was over $1 billion, up 17%. Pro forma gross profit margin was 71.8% compared to 72.4% in the fourth quarter last year. Instrument and accessory revenue increased to $539 million, up 18%. Total recurring revenue in the quarter was $722 million, representing 69% of total revenue. We generated a pro forma operating profit of $412 million in the quarter, up 7% from the fourth quarter of last year. And pro forma net income was $353 million, up 16%.

We launched the Intuitive Foundation with an initial contribution of $25 million in the quarter. The Intuitive Foundation's mission is to support clinical and technology research in acute interventions, as well as philanthropy in the communities which we serve and in which we live.

Financial highlights of the full year 2018 results are as follows. Revenue for the year was $3.7 billion, up 19%. Pro forma gross profit margin was 71.5% for the full year compared to 71.9% for 2017. Instrument and accessory revenue increased to $2 billion, up 20%. Total recurring revenue in the year was $2.6 billion, representing 71% of total revenue. We generated a pro forma operating profit of $1.5 billion in the year, up 17% from 2017. And pro forma net income was $1.3 billion, up 23%, with the difference in growth rate between operating profit and net income largely driven by the 2017 Tax Act and interest income earned.

Looking ahead, a review of clinical outcomes for complex surgery and acute interventions across large population still highlights a substantial need for improvement. We measure our efforts by their ability to positively impact the quadruple aim. Real progress requires more than minimally invasive tools and more than digital technologies. These technologies are necessary, but not sufficient. We believe intelligent surgery takes the integration of three elements.

First, a deep understanding of human interactions that inform holistic system design. Second, the development of high-quality smart and cloud-connected robotic imaging and instrument systems. And lastly, informatics and AI to deliver relevant validated insights. While we've made significant progress over our history, we believe continuous improvement is required and we've deployed our investments toward these aims.

We're bringing together several efforts in pursuit of our mission. We are early in our Phase I launch of da Vinci SP. We installed 15 systems in 2018 and a few hundred procedures have been performed to-date. Surgeon and patient feedback have been positive for usability and patient experience in these early days of launch. We submitted our 510(k) for our second indication, Transoral Robotic Surgery, in Q4 of 2018 and are responding to FDA questions on the second indication.

We're also working through supply chain optimization as we begin to ramp production for SP, in anticipation of additional clearances and broader launch. Our first step into flexible diagnostics, Ion, is nearing Phase I launch. We submitted our 510(k) in 2018 and have responded to FDA questions this month. We anticipate a Phase I limited launch of Ion in 2019 focused on the need for definitive early diagnosis of suspicious lesions for lung cancer.

In instruments and accessories, we plan to broaden the launch of our SureForm 60-millimeter stapler for da Vinci in the first half of 2019. The 60-millimeter stapler is used primarily in abdominal surgeries, including bariatric surgery. Surgeon response has been encouraging and our team has performed well in establishing its supply chain.

Over the past several years, we have been increasing our cloud computing and informatics capabilities. Today, we routinely deliver programmatic insights to customers using our systems, which have been smart and connected for the past decade. We believe there are opportunities to further enhance these capabilities. Our advanced imaging programs and augmented reality programs are making progress. We anticipate first clinical use of our augmented reality program in 2019.

As described in our prerelease, we've also been increasing investments in building our business operations in countries important to our future. Our efforts in China will accelerate in 2019 with the da Vinci distribution arm of Fosun Pharma, Chindex, joining our joint venture this quarter. Combined with the release of the next system quota and the clearance of da Vinci Xi in China, we will be accelerating investments to establish our base to serve China over the long term.

In 2018, we also acquired our da Vinci business in India and Taiwan, and anticipate strengthening our investments and presence over the next several quarters. We described the multiyear nature of these investments in our JPMorgan talk, using Intuitive Japan as an example. Market development in country is an arduous multiyear process. It involves building a strong management team and company culture, establishing strong working relationships with the surgical societies, policymakers, regulators, and key customers, as well as building training and proctoring capability along with the local clinical evidence base.

As we bring these efforts together, we plan to accelerate our spend rate above our historical norms for the next several quarters. As described above, the increase in spend is driven primarily by funding and growth of our joint venture in China, the ramp of our informatics efforts, infrastructure to support our procedure growth, including manufacturing lines and facilities, and the launch of our new platforms. We pace the rate of investment not just by the opportunity for growth, which we believe is substantial, but by our ability to integrate talented staff and execute against our objectives.

In closing, as we start 2019, our focus will be on; first, supporting adoption of da Vinci in general surgery and in key procedures in global markets; second, launching our SP and Ion platforms; third, driving intelligent surgery innovation; and finally, supporting additional clinical and economic validation in our focus procedures and countries.

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

Marshall L. Mohr {BIO 5782298 <GO>}

Good afternoon. I'll describe the highlights of our performance on a non-GAAP pro forma basis. I will also summarize our GAAP performance later in my script. A reconciliation between our pro forma and GAAP results is posted on our website.

Consistent with our preliminary press release on January 9, fourth quarter 2018 revenue was $1.047 billion, an increase of 17% compared with $892 million for the fourth quarter of 2017 and an increase of 14% compared with third quarter revenue of $921 million. Fourth quarter 2018 procedures increased approximately 19% compared with the fourth quarter of 2017, and increased approximately 11% compared with last quarter. Procedure growth 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 $539 million increased 18% with last year, which is lower than procedure growth, reflecting approximately 6 million of I&A repurchased from distributors in China and Taiwan in conjunction with transactions to go direct in both geographies and customer buying patterns, partially offset by increased usage of our advanced instruments. Instrument and accessory revenue realized per procedure was approximately $1,890, a decrease of 1% compared with the fourth quarter of 2017 and relatively unchanged compared with last quarter. Excluding the buyback of inventory from China and Taiwan, instrument and accessory revenue per procedure was similar to last year.

Systems revenue of $341 million increased 20% compared with the fourth quarter of 2017, primarily reflecting higher placements and higher lease-related revenue. We placed 290 systems in the fourth quarter of 2018 compared with 216 systems in the fourth quarter of 2017 and 231 systems last quarter. 84 operating lease transactions, representing 29% of total placements, were completed in the current quarter compared with 40, or 19% of total placements, in the fourth quarter of 2017 and 58, or 25% of total placements, last quarter. Operating leases include some usage-based financing that we provide certain large hospitals. We believe that these usage-based financing alternatives align with customer objectives enabling faster market expansion.

As of December 31, we have 350 operating leases outstanding and we realized approximately $16 million of revenue related to these arrangements in the quarter. The proportion of these types of arrangements could increase in the long-term and will be lumpy quarter-to-quarter. 28% of the current quarter system placements involve trade-ins, reflecting customer desire to access or standardize on our fourth-generation technology. This is approximately the same proportion as last quarter and last year.

Trade-in activity can be lumpy and difficult to predict. 73% of the systems placed in the quarter were da Vinci Xis and 18% were da Vinci X systems compared with 68% da Vinci Xis and 28% da Vinci Xs last quarter. 12 of the systems placed 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 $1.46 million compared with $1.47 million last year and $1.45 million last quarter. The changes compared with prior periods primarily reflect the mix of systems.

Outside of the U.S., results were as follows. Fourth quarter revenue outside of the U.S. of $307 million increased 24% compared with the fourth quarter of 2017 and increased 25% compared with last quarter. OUS procedures grew approximately 24% compared with the fourth quarter of 2017 and increased 10% compared with the third quarter. Outside the U.S., we placed 115 systems in the fourth quarter compared with 86 in the fourth quarter of 2017 and 75 systems last quarter.

Current quarter system placements included 55 into Europe, 31 into Japan, and 9 into Brazil. 35 of the 115 systems placed in the fourth quarter were X systems and 15 were operating leases. Placements outside of the U.S. will continue to be lumpy, as some of the OUS 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 gross margin and operating expenses. The pro forma gross margin for the fourth quarter of 2018 was 71.8% compared with 72.4% for the fourth quarter of 2017 and 71.5% last quarter. The decrease compared with the fourth quarter of 2017 primarily reflects product mix and costs associated with new products. 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 costs and improve manufacturing efficiency.

Pro forma operating expenses increased 31% compared with the fourth quarter 2017 and increased 27% compared with last quarter. Fourth quarter 2018 operating expenses included a $25 million contribution to the newly formed Intuitive Foundation. The Foundation is a charitable organization aimed at improving patient outcomes. It will donate to qualified non-profit academic organizations directed at surgeon training and education, including fellowships, advanced clinical research, and advanced robotics research.

The $25 million will enable the Foundation to make meaningful contributions over the next several years. Our pattern of future contributions will vary based on various factors, including the financial performance of the company and opportunities for the Foundation to make meaningful contributions within its mission.

Excluding the contribution to the Foundation, pro forma operating expenses increased 21% compared with the fourth quarter of 2017. The increase in fourth quarter expenses reflect, one, increased costs that fluctuate directly with revenue, including sales and corporate incentive compensation; two, costs we elected to accelerate, including spend on infrastructure in order to scale the business; and three, investments to drive our future opportunity, including costs associated with going direct in China, Taiwan, India, and cost of prototypes.

We believe that we are early in our journey to expand minimally invasive surgery and feel the fundamentals in the business are strong. So we are accelerating our investment in selected areas, while continuing to invest in key product areas, including SP, Ion, vision, and advanced instruments. We will accelerate spending on our informatics capabilities; expansion of our OUS markets, including China, India, and Taiwan; and investments that enable us to scale the business, including expansion of in automation of manufacturing. We believe these are important investments.

That said, we intend to control spending and head count growth to that which we could manage will. This leads us to a broad estimate of operating expense increase of 20% to 28% in 2019. Some spending naturally fluctuates with revenue and procedures, like sales, production expenses, and corporate incentive compensation.

Other spending is longer-term in nature and positions us for future growth. For example SP, Ion, and imaging. We would target to spend the lower end of the 20% to 28% range with the bottom-end of procedure growth guidance. We are investing with an eye towards long term for the company and the market, and as such, don't intend to modulate long-term investments in response to transient conditions.

Our pro forma effective tax rate for the fourth quarter was 20% compared with our expectations of 19% to 20%. Our tax rates will fluctuate with changes in the mix of U.S. and OUS income, changes in taxation made by local authorities, and with the impact of onetime items. Our fourth quarter 2018 pro forma net income was $353 million, or $2.96 per share, compared with $305 million, or $2.60 per share, for the fourth quarter of 2017 and $337 million, or $2.83 per share, for the third quarter of 2018. Excluding the Intuitive Foundation contribution, pro forma net income was $373 million, or $3.13 per share.

I will now summarize our GAAP results. GAAP net income was $293 million, or $2.45 per share, for the fourth quarter of 2018 compared with GAAP net loss of $32 million, or $0.28 per share, for the fourth quarter of 2017, and GAAP net income of $293 million, or $2.45 per share, for the third quarter of 2018. The GAAP net loss for the fourth quarter of 2017 reflects the impact of the Tax Act, while the fourth quarter of 2018 includes the $25 million contribution to the Intuitive Foundation. 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.

We ended the quarter with cash and investments of $4.8 billion compared with $4.6 billion at September 30, 2018. The increase generally reflects cash generated from operations, partially offset by investments in working capital and infrastructure. In the quarter, we grew inventory by approximately $40 million to $409 million, representing approximately four months 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, supplier, and other matters. With the growth in the business and our focus on efficiency and scale, we expect our capital expenditures will increase to over $250 million in 2019. 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 2019.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall fourth quarter procedure growth was 19% compared to 17% during the fourth quarter of 2017 and 20% last quarter. Our Q4 procedure growth was driven by 18% growth in U.S. procedures and 24% growth in OUS markets. Overall procedure growth for the full year 2018 was approximately 18% compared to 16% in 2017, comprised of 17% growth in the U.S. and 22% growth in OUS markets.

In the U.S., Q4 and full year procedure results were consistent with recent trends. Q4 growth was again driven by growth in U.S. general surgery and thoracic procedures, augmented by continued contributions from growth in mature gynecologic and urologic procedures. For the full year, approximately 753,000 procedures were performed in the U.S. For the full year 2018 U.S. general surgery procedures increased approximately 32% to 325,000 procedures. Hernia repair, both ventral and inguinal, continued to contribute the most incremental cases in the quarter and year, with colorectal procedures continuing to show strong growth.

Growth in practice-based procedures, including cholecystectomy and bariatric surgery, increased as the year progressed. In U.S. gynecology, full year 2018 year-over-year growth increased to mid-single digits, driven by higher benign hysterectomy volumes. Fourth quarter 2018 U.S. gynecology procedure growth was slightly above the full year growth rate, likely reflecting increasing seasonality in these benign procedures, partially offset by modest headwinds in hysterectomy for cancer, a mature category where da Vinci Surgery is standard-of-care.

In the fourth quarter, we continued to see favorable surgical consolidation trends, as our da Vinci Surgery data indicate that practicing da Vinci surgeons performed more da Vinci

Hysterectomies and an increasing proportion of U.S. gynecology procedures are being performed by higher volume physicians.

Full year 2018 U.S. urology procedures grew approximately 8%. Q4 2018 growth was at a rate largely consistent with the full year results, driven by prostatectomy volumes. As a mature procedure category, we believe that 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 fourth quarter.

Full year 2018 OUS procedures grew 22%, consistent overall with 23% growth in 2017. Q4 OUS procedure growth trends were mostly in line with the full year results. Fourth quarter OUS procedure volume grew approximately 24% compared to 21% for the fourth quarter of 2017 and 23% last quarter. Fourth 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. Q4 procedure growth in Japan was consistent with Q3 at a rate over 40%, as procedures were performed within the set of 12 additional procedures approved for reimbursement effective April 1. Procedure growth in China again moderated in Q4, as da Vinci system capacity expansion was constrained by system quota requirements.

As Gary mentioned, over 1,500 peer-reviewed clinical articles regarding da Vinci Surgery were published in 2018 and over 16,000 have been published to-date. 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.

In December 2018, a manuscript was published by the Journal of Gastric Cancer titled Clinical Advantages of Robotic Gastrectomy for Clinical Stage I/II Gastric Cancer: A Multi-Institutional Prospective Single-Arm Study. This study was one of the largest multi-center prospective studies for gastric cancer, which included 330 patients across 15 institutions in Japan. This study was designed to show the safety, effectiveness, and economic efficiency of da Vinci Surgery for gastric cancer and was in support of the MHLW's Senshin Iryo B process, which led to the recent addition of gastrectomy to reimburse status in Japan.

The main hypothesis of the study was to demonstrate a reduction in morbidity associated with robotic surgery compared to laparoscopy. The hypothesis was confirmed, as the results showed a reduction in the morbidity rate to 2.45% for robotic procedures compared to 6.4% for the historical lap control group.

Patient characteristics and surgical outcomes were compared between the prospective arm, the robotic group, and the historical control, the laparoscopic group. Preoperative differences were noted in both groups, as the robotic group contained more patients of younger age, but also contained more complex patients with higher comorbid conditions. The robotic arm had lower clinical staging, while no differences were noted in pathological staging between the groups.

In the directional analysis, the robotic-assisted cohort was noted to have significantly lower intraoperative blood loss; shorter duration of hospital stay, 9 days versus 13 days, with comparable operative time. The office of the study concluded that the significant reduction in morbidity might help demonstrate reduced total cost of care of da Vinci Surgery to be likely the same amount as for laparoscopy.

In conclusion, the robotic group reduced the morbidity rate when compared to the findings of the lap group. Robotic surgery might be safe, feasible, and effective for gastric cancer.

I will now turn to our financial outlook for 2019. Starting with procedures, as described in our announcement earlier this month, 2018 total da Vinci procedures grew approximately 18% to roughly 1.037 million procedures performed worldwide. As communicated previously, during 2019 we anticipate full year procedure growth within a range of 13% to 17%. We expect 2019 procedure growth to continue to be driven by U.S. general surgery and procedures outside of the United States, where we are still in the early stages of adoption. We expect similar seasonal timing of procedures in 2019 as we have experienced in previous years, with Q1 being the seasonally weakest quarter, as patient deductibles are reset.

With respect to revenue, as we have mentioned previously, capital sales are ultimately driven by procedure growth, catalyzing hospitals to establish or expand robotic system capacity. Capital sales can vary substantially from period-to-period based upon many factors, including U.S. healthcare policy, hospital capital spending cycles, reimbursement in government quotas, product cycles, economic cycles, and competitive factors. Within this framework, we'd expect 2019 capital placement seasonality to generally follow historical patterns by quarter.

During the fourth quarter of 2018, 84 of the 290, or 29%, of the systems shipped were under operating leases. We expect that the proportion of systems placed via operating leases will vary from quarter-to-quarter and could trend up in the future.

Turning to gross profit. Our full year 2018 pro forma gross profit margin was 71.5%. In 2019, we expect our pro forma gross profit margin to be within a range of between 70% and 71% 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. As Gary and Marshall outlined, we will be following through on and expanding our investments in 2019. We expect to grow pro forma 2019 operating expenses between 20% and 28% above 2018 levels. We expect our noncash stock compensation expense to range between $310 million and $340 million in 2019 compared to $261 million in 2018. We expect other income, which is comprised mostly of interest income, to total between $120 million and $130 million in 2019. With regard to income tax, consistent with our 2018 results, we estimate our 2019 pro forma income 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.

Q&A

Operator

Thank you. And our first question will be from the line of David Lewis, Morgan Stanley. Please go ahead.

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

Good morning. Maybe I'll start financial, and then work to Gary for strategic. So just Marshall and maybe a little bit for Gary as well. Just thinking about the spending breakdown for 2019, two questions, then I'll just do one follow-up. On financial pieces, Marshall, any sense of R&D relative to SG&A? We're sort of assuming you continue to grow R&D at a similar rate to 2018 and the material step-up in spending relative to our model is more SG&A. And maybe just sort of walk us through a couple of the components there in R&D and SG&A that are driving the majority of the spend. And then I had a quick follow-up for Gary.

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

Yeah. I think the step-up in spend is maybe slightly weighted towards SG&A, but pretty even across the categories. The elements of SG&A are, as I discussed, the expansion OUS and the investments we're making in China, India, and Taiwan. Those are commercial organizations and that appears in SG&A. Of course, SG&A will grow a lot of the costs that fluctuate with revenue, such as sales compensation and incentive compensations flow through SG&A. However, in the R&D area, we will continue to invest in SP, Ion, and vision, and advanced instruments. And then as I said, we'll be accelerating some of our investments in digital capabilities or informatics.

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

Okay, very helpful, Marshall. And, Gary, there's been some media reports about one of your competitors drawing instruments from a much larger company, and I'd say barriers to entry is perhaps the most common incoming question we get from investors. So, I wonder if you could help us articulate what is the Intuitive moat as you see it. Or are investors asking the wrong question and they should be more focused on TAM expansion? Thanks so much.

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

So I think a little bit of both that are going on, I think, in the competitive world. On the first side, how our customer is going to choose, I think customers appreciate choice and will expect it from us and from others, and I think they'll evaluate competitive offerings. For us, we focus a lot on understanding what the workflow environment is, understanding the total cost, not just the constituent price of the system or price of the instruments and accessories. It's really total cost to use the product.

Stability, usability, supply chain stability, all of those things, I think, are valued when people are putting a fair amount of their surgical volume onto a platform. And I think it will take some time for folks to fully absorb and understand that. And I think also there's some nice effects about surgeons training surgeons. There's a large installed base of surgeons. They interact with each other through surgical societies. They proctor each other, and I think that that allows a compound cycle of learning that's been effective.

To the question of what does it do as some of the other larger competitors declare their desire to enter, I do think it validates for the broader market the things we believed for many years and have been investing towards for many years. So, I think it's a signal to everybody that these technologies and approaches are going to be important to the future.

That said, there are smart people in all these organizations and outside of our company, and we'll see. We have evaluated many of the competitive concepts that we see out there, often making them for ourselves and evaluating them over the years. We really make our decisions based on what we think the customer needs and as a forward look and as a result, I think we may be wrong about some of our decisions, but we've tried to be well informed about our decisions.

Operator

And our next question is from the line of Bob Hopkins, Bank of America. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Thanks very much for taking the questions and I have sort of two similar lines of questioning here. First, just to follow-up a little bit on the comments on spend in 2019. For 2018, there was a 17% increase; for 2019, you're talking about, at the midpoint, a 24% increase. I mean, that's roughly $75 million. I was wondering if you could kind of lay out how much of that is the investment in China and Taiwan in going direct. And then also how would you just sort of characterize that incremental $75 million in the growth rate you're experiencing this year? Is this more of kind of one-time increase in the growth of expenses, or could this be sort of a growth rate that we would experience for another couple of years? Thank you.

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

So, I think, Bob, these are multiyear investments and, as Gary referred to in his script, if you go back and you look at, sort of, what we said we did in Japan, the investments were made early on, but you continue to make those investments over time to get to a point of where you might see a real return from them. And in the case of Japan, we've been investing in Japan for 10 years and we're now seeing the fruits of that investment in terms of a 12-procedure reimbursement. So, I wouldn't characterize these as a one-time event. I think we'll continue to invest in some of those things for quite some time.

As far as how – you came up with $75 million, how you would proportion the pieces? I think I pretty much laid it out for David. There is a chunk of spending associated with the expansion OUS in China, India, and Taiwan. You'll see that primarily in the SG&A line. But there is an equal set of investments being made in terms of informatics, as well as investments to scale the business, investments in expansion and automation of the manufacturing group. So...

Q - Bob Hopkins {BIO 2150525 <GO>}

Okay, I appreciate that. And then one for Gary. Just a question on competition. I'll frame it just a little bit differently. J&J and Medtronic, both continue to suggest that sometime late in 2020 they'll bring some sort of technology to the market in robotic form. They both suggest that they're going to have lower-cost systems. They haven't given us much details. But in my view, both have sort of implied that their systems will be geared towards converting lap-focused surgeons to robotic platform. So, my question to you is, I realize you don't comment much on your pipeline, but I was just curious if you could comment. Do you see potential value in advancing lap through robotics, and is this a priority for Intuitive today?

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

I do believe that some advanced MIS surgeons are becoming increasingly open to views of robotic surgery and intelligent surgery. Today in the market we see bariatric surgeons interested in our technologies, and that's a domain that is high laparoscopic penetration. So I believe there's opportunity there.

I would separate the idea of capital being the only thing to think about as an opportunity to pursue that growing idea in advanced laparoscopy. And what I would say is that, I think physicians are going to balance multiple criteria. They're going to look at total cost to treat, so the capital, the cost to service that capital, instruments and accessories, the outcomes that they get from it, efficiencies, and human labor time in the OR, and they're going to balance that. And I think all of those are up for discussion when you think about trade-offs between advanced laparoscopy and intelligent surgery. We think there's an opportunity there. We will pursue that opportunity.

When I hear folks kind of over-rotate to just capital costs on systems, I kind of think about how excited are people to jump aboard a just good enough commercial airliner. For sure, if you're flying commercial airline, you want the lowest total cost per passenger mile, but you can get that a lot of different ways and cheapening the capital may be not the best way. We evaluate all of those elements. We've thought about them deeply and we've made investments to pursue what we think is the right leadership position there.

Q - Bob Hopkins {BIO 2150525 <GO>}

Terrific. Thank you.

Operator

Our next question is from the line of Tycho Peterson, JPMorgan. Please go ahead.

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

Thanks. I want to maybe just pick up where you left off on some of these new initiatives. You talked about the first clinical use case for augmented reality this year. Can you talk a little bit about how you think about commercializing that? Where you see the key application areas? And then similarly, on the informatics investments, can you talk a little bit about what you're hoping to accomplish there?

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

Sure. Those two are related, but we'll start with augmented reality or mixed reality, and that's something we have been working on for some time and the world has been interested in. The idea here is to use multiple sources of information, preoperative CT scans or MRI scans, intraoperative, other imaging, like ultrasound or fluorescence imaging, molecular imaging, and combine them in ways that allow the surgeon or physician to see things differently. It is embedded and inherent in Ion already, some of that core capability is required.

We're also bringing some of that core capability to our da Vinci systems. In the beginning it'll be around preoperative imaging and some intraoperative imaging mixed together for the surgeon in real-time. First, I'd expect first clinical uses this year and the beginnings of the study that go around that. I don't think it'll be a meaningful revenue contributor in the near term, but I think it's one of the things that can really change outcomes, efficiency in the procedure and outcomes. Now, it remains to be proven, but we're excited about it.

That's one leg of our thoughts around informatics and you've heard us talk about this over the years, from strengthening our cloud computing capabilities. We internet connected our systems a decade ago to a partnership and then an increased and closer investment with InTouch Health around routing of data quickly and low latency and real-time. Two, internal capabilities around managing data lakes and providing for customers offline processing that allows them to compare their programs and take advantage of some advances in machine learning.

Those are the types of elements that we're bringing to bear. It's nice, we have a foothold, we have some brilliant scientists who are advancing and leading that cause. And we think we have discrete deliverable steps that we can do and then validate that will start bringing real value to the market.

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

And then, I guess, a follow-up on Ion, a couple of questions here. Any risk of timeline slipping with the government shutdown now that you've submitted the 510(k)? And then should we expect additional clinical data to come out this year? And it sounds like from the gross margin commentary you're not expecting any real negative impact on gross margins with the rollout. Can you confirm that?

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

Well, let me speak to the first two, and I'll let Marshall speak to that last one on margin. There's always a risk that things slow down. We are in engaged contact with FDA, and so far we're feeling pretty good about it. But I can't speak to what the long-term implications will be in terms of shutdown dynamics.

In terms of clinical data, there'll be – if things proceed the way we hope, we'll start collecting additional data as that comes out. In terms of when that gets published, I think it will depend on the timing of the clearance and the speed with which some of the installs happen. We think that the demand pipeline for Ion looks really good. The scientific response to FDA's questions, we feel good about. And the engineering team and supply chain team bringing those early systems up, looks really good too. So I'm really pleased with the internal team's performance and the setup of activities. With regard to margin impact, Marshall?

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

Yeah. Ion will be rolled out in a measured fashion to create a good foundation, and so the consequences of both on the revenue and the gross margin line will be very small.

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

Okay. And then if I could just ask one last one on the cadence of placements in China you're expecting, now that you've had a little bit of time to digest the quota, anything to think about in the first half of the year here?

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

Yeah. So the quota, just to recap for everybody, 154 systems. Keep in mind that 154 systems is for surgical robots. If there were to be competitors that got their product approved in China, they would share in that quota. So it's not just a quota for us. The quota has been released; however, there are tendering processes that the hospitals have to go through. Let me remind you, the last time we got a quota in 2013, most of the systems were shipped near the end of 2015, so it took a while. What I would say – and finally, the other implication is that there is a 25% tariff on the robots that the Chinese have imposed. We think that there is high interest in robotics in China, so I don't know how that 25% will affect their desire to buy. What I would say is that the pattern of placements will be few in the first half and more near the end of the quota period, which is 2020.

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

Okay. Thank you.

Operator

Our next question is from the line of Larry Biegelsen, Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. One on SP and one strategic question for you, Gary. So, on SP, I heard the commentary upfront about a few hundred procedures.

Any themes you would highlight? And remind us again of when we can expect the full launch.

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

With regard to early themes, the feedback has been that usability on the new platform has got a little – slightly different set of operating principles has been a positive surprise. Also the physician excitement about its ability to reach into small places and some of the flexibility it exhibits relative to set-up and access has been a really positive surprise for us, which has been great. So, that's been good.

I think pacing – demand looks really good. We are for sure supply-constrained relative to demand. And the pacing there will really be around a couple things. One is, we want to get our supply chain partners ready for real volumes, so we knocked down some of those issues that may – take them a while to produce things, we want to solve some of the manufacturing bottlenecks. The second thing is we want some of the additional indications that give our customers a little more flexibility with how they can use the product.

So, that will pace it. We don't have a timeline yet for you on those two things. Both of them have a little bit of uncertainty in them. The FDA review of submissions being one and working down some of the technical bottlenecks is the other. I don't see any insurmountable technical challenges. I think it's just work. But so far so good and we're feeling like they are meeting the plan we set.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful. And, Gary, as you know, we're seeing procedures in the U.S. moving to the outpatient and ASC settings. Do you believe your current Gen 4 offering and leasing option provide adequate terms for expansion into this environment? Thanks for taking the questions.

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

Yeah, thank you. You think about freestanding centers, there's kind of two dimensions on which you think about freestanding surgery centers. One of them are hospital-owned outpatient departments. We are already well-used and appreciated in those settings. So, the physical structure is kind of the same. It's just how the ownership and operations are organized.

Freestanding centers that are owned by group practices, not hospital-owned, have a little bit different reimbursement and economics. We actually do see some of them starting to express interest and adopt robotics. I think that, as we were saying earlier in the call, which procedures go there depends both on the reimbursement of the procedure and the efficiencies with which products get used. And I think that for the right settings, Gen 4 can be quite strong.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thank you.

Operator

Our next question is from the line of Amit Hazan, Citigroup. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Hey, good afternoon. Let me just start with system or unit growth question first. Totally understanding the macro comments you made about that. But if I look at the data, look at the numbers, second year of accelerating growth, lots of drivers kind of seeming to be accelerating at the same time, trade-ins, operating leases, new products, procedure growth accelerating. So, lots happening that's accelerating. And I've got very little, really nothing to tell me that growth trends are going to change that much. So, help me out and tell me outside of the macro issues, why would unit growth trends change much in 2019?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. I mean, regarding procedures, like we said in the prepared comments, it's really the procedure growth that drives demand for capital placements. You mentioned a number of other factors, things like trade-ins, leasing programs, new product introductions, things like that can have an effect on the results either, but we talk about these things possibly fluctuating quarter-to-quarter. And it comes down to just laying out your model and your frame of thought and working backwards from the installed base and working at the installations. But there's a lot of – the factors you described are what's in the world.

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

And mature procedures will moderate growth, for sure. And we also know that in some cases – for example, there was a publication of a couple of articles about cervical cancer in New England Journal, and that can change procedure growth rates too and create a headwind. So there's a little bit of puts and takes here. In general, we're feeling like the business is strong and there's strong momentum, but there are some things that will moderate as well.

Q - Amit Hazan {BIO 6327168 <GO>}

And if I could follow-up on the operating lease side. In the U.S. in particular, where obviously, I think, it's up about 30% of units sold. In 2018, I think it was 20% of units sold in 2017. So we're starting to see kind of a trend line. And I do get what you're saying with volatility, but the question, I think, for us, especially as we start to model or try to model your system revenue number accurately for the year is how to think about that trend for 2019 and even 2020. It seems like you're focusing more on it. You're offering more programs and that trend line could continue, so we could kind of be towards the mid-30s to 40% range in the U.S. in 2019. Are there other things that I should be considering for why that wouldn't happen?

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

Well, it's been a successful program. I mean, it's been a way for us to offer hospitals an opportunity to expand their capacities without the initial capital investment. So it's been very successful. I'm not sure the numbers completely jive with what you said. We were at 25% of placements in Q3 and 29% in Q4 were under operating leases. So you saw that step-up quite a bit in the last couple quarters. And so our comments are like, okay, we're here now, it's likely to fluctuate quarter-to-quarter from where we ended the year, and then over the long term it could increase.

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

We believe that operating leases are a good thing. We would, having the choice, place a system under an operating lease rather than sell the system. It reduces the fluctuation. Like you said, it stabilizes sort of the revenue stream, if you will. And also, in terms of, if there were an upgrade cycle, what we've seen in studies is that the upgrade cycle is quicker when there is leases versus purchased product. So we think it's positive in a number of ways. However, it's up to customers. We really leave it to customers to decide what is best for them and we will fulfill that. And so it's hard for us to predict exactly where the customer will go and to what level we'll windup with leases versus purchased.

Q - Amit Hazan {BIO 6327168 <GO>}

Fair enough, guys. Thank you.

Operator

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

Q - Rick Wise {BIO 1490589 <GO>}

Good afternoon, Gary. Maybe turning back to the acquisition of your da Vinci business in India and Taiwan again. I heard you clearly these are long-term investments. It'll take a long time to play out. I'd be curious to hear more about your thoughts about the relative size of the opportunities in India and Taiwan. Sort of you mentioned Japan as a proxy a little bit, but do India and Taiwan matchup with China and Japan in terms of magnitude? I mean, I assume you must think the opportunity there is significant. Just maybe help us think about that and frame it for us.

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

Clearly, the strategic motivation behind India and Taiwan are a little bit different. With regard to Taiwan, in terms of actual size (00:55:27), it's not going to be a huge part of the business. However, it's an influential market. The distributor there that we were working with was well-built and we think that it's a group that does good surgery and has good influence in the region. I think it's important to serve that customer base well, but it's not a massive financial impact by any means, nor do we expect it to be.

India has, I think, a fair amount of runway. Where it is today and where it might be in a decade can be quite different. And so, here the idea is it will take some time to build our capabilities in India, but we also think it's an economy that's been growing. There's a strength in the surgical community in India both there and globally. And so, it's an important long-term market for us. We think that financially, of course, it can become a significant part of Intuitive's business over the years.

And the point of illustrating some of the Japanese example is that building a real presence and building the organization and the trust within the healthcare community in those markets take time. So if you want to get there in a decade, then you better start. And that's really what's driven us in those two markets.

Q - Rick Wise {BIO 1490589 <GO>}

Okay. Just as a follow-up on a different topic. You highlighted, obviously, some puts and takes in terms of procedure growth and you mentioned specifically slowing mature procedure growth in some countries. Maybe just expand on that? Is this just you've penetrated the market and flowing, or is there something else going on? Maybe just give us a little more color there. Thanks so much.

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

In several countries we are a substantial share of the surgical market, think of United States prostatectomy or parts of nephrectomy in the United States or hysterectomies for certain conditions. And as a result, we see that part really growing at the demographic trends rather than a changing share of approach trends. And that's true in the U.S.. It's true in some countries in Europe with regard to prostatectomy and some urologic procedures. And Japan, we're already quite highly penetrated in prostatectomy and increasingly so in nephrectomy. So that was – what's some of the detail or examples of what underlies the more general comment.

Q - Rick Wise {BIO 1490589 <GO>}

Thank you.

A - Calvin Darling {BIO 17664656 <GO>}

Just one more questioner, please.

Operator

And that question is from the line of Richard Newitter. Please go ahead, sir.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thank you. I wanted to start off on the percentage of operating leases and flexible financing arrangements. That's clearly increasing as a percent of the total placements. Could you characterize for us what the utilization rate differences are on the systems that are getting placed under those types of contracts versus the rest of the installed base? I would imagine it's higher, but can you quantify it at all?

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

We do quantify it. We monitor closely and there is not a market difference between what the utilization rates are on leases versus purchased product.

Q - Richard Newitter {BIO 16908179 <GO>}

Okay, thanks. And then just on follow-up to last question, Rick's question. As you think about the low-end and the high-end of your 2019 procedure growth range, is the slowing mature procedure growth commentary kind of meant to be throughout the entire range, or is that contemplated at the low-end instead of the high-end?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. Some level of moderation, particularly in the U.S., is part of the trend and, obviously, more moderation at the lower end and less moderation at the higher end. But the range will be largely – the range itself is largely reflective – the biggest factor is going to be the breadth and pace of growth in U.S. general surgery, our largest category now, than the mature procedures and some other factors regarding growth in China, timing of placements of new systems, and the pace of adoption of reimbursed procedures in Japan.

Q - Richard Newitter {BIO 16908179 <GO>}

Thank you.

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

Well, thank you. Thank you for the questions. That was our last one. 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 that we remain committed to driving about a few things that truly make a difference. This concludes today's call. We thank you for your participation and support on this extraordinary journey to improve surgery, and we look forward to talking to you again in three months.

Operator

Thank you. Ladies and gentlemen, that does conclude your conference and we do thank you for joining. You may now disconnect. Have a good day.
