Q1 2019 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan
- Craig Bijou
- David Lewis
- Imron Zafar
- JP McKim
- Larry Biegelsen
- Larry Keusch
- Richard Newitter
- Robert Hopkins
- Tycho Peterson

Presentation

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Surgical QI 2019 Earnings Release Call. At this time all participations are in a listen only mode. Later, we will conduct a Question & Answer session and instructions will be given at that time. (Operator Instructions) And as a reminder this conference is being recorded.

I'd now, like to turn the conference over to Calvin Darling, Senior Director of Finance, Investor Relations. Please go ahead.

Calvin Darling (BIO 17664656 <GO>)

Thank you. Good afternoon and welcome to Intuitive Surgical First Quarter Earnings Conference Call. With me today, we have Gary Guthart, our CEO, and Marshall Mohr, our Chief Financial Officer.

Before we begin, I would like to inform you that comments mentioned on today's call may be deemed to contain forward-looking statements. Actual results may differ materially

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from those expressed or implied as a result of certain risks and uncertainties. These risks and uncertainties are described in detail in the Company's Securities and Exchange Commission filings including our most recent Form 10-K filed on February 4, 2019.

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 first 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 first quarter financial results. Then, I will discuss procedures and clinical highlights and provide our updated financial outlook for 2019. And finally, we will host a question-and-answer session.

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

Gary S Guthart {BIO 3429541 <GO>}

This first quarter was a solid start to 2019 for Intuitive. Customer response to our products and services is healthy with continued growth in their use of da Vinci to deliver high quality minimally invasive surgery to a broad base of patients. As I've said in the past, 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.

We've a substantial opportunity and there is significant work to be done. Global procedure growth was strong at approximately 18% in the first quarter of 2019. Drivers of growth remain consistent with our trailing several quarters with growth in general surgery accounting for strength in the United States.

Growth in Japan continues to be healthy with strength in urology hysterectomy and colorectal procedures. Growth in China, met our expectations given constraints on capital placements. Placements of new systems in the quarter was strong with growth in total placements rising 27% from Q1 of 2018. Net of trade-ins and retirements, our da Vinci installed base again grew 13%, over Q1 2018 to approximately 5,110. The mix of system placements between our flagship Xi System and our value X System generally aligned with our strategy regionally. Trade-ins of earlier generation systems increased this quarter as customers pursue the features of our generation for systems and some hospitals seek to standardize.

As we discussed, on our previous earnings calls, customers are interested in leasing, including usage based models. The proportion of systems placed under operating leases increased again from 29% in Q4 2018 to 33% in Q1 of this year. The increase in trade-ins

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leasing and usage based models aligns with our strategy in supporting customers, and allows them greater flexibility to have the right systems in the right care delivery environments.

For the investor, it can make revenue modeling for systems harder to evaluate relative to prior quarters. As trade-ins impact our reported ASP and leasing defers revenue to future quarters. Marshall, will take you through greater detail later in the call.

Turning to expenses, we described our plans for increased investment in 2019 as we launch new platforms, strengthen our computational capabilities and invest in projects that support future scale and provide leverage opportunities, as we grow. Over the past year, we've seen our increased flexibility, with customers catalyze growth, which in turn enables us to invest in manufacturing efficiencies that lower our costs. Our spending fell near the top end of the range of projections, we shared with you last quarter, supported by procedure growth above the top end of our procedure guidance range.

Financial highlights of our first quarter are as follows, procedures grew approximately 18% for the first quarter of last year. We placed 235 da Vinci Surgical Systems out from 185 in the first quarter of 2018. Our installed base again grew 13% from a year ago. Revenue for the quarter was approximately \$974 million, up 15%. Pro forma gross profit margin was 71.2% compared to 71.6% in the first quarter last year. Instrument and Accessory revenue increased to \$552 million up 20%. Total recurring revenue in the quarter was \$747 million growing 20% over Q1 of 2018 and representing 77% of total revenue.

We generated a pro forma operating profit of \$362 million in the quarter, up 4% from the first quarter last year. And pro forma net income was \$312 million up 9%. As you know, we measure our efforts by their ability to positively impact the Quadruple Aim, better outcomes, better patient experience, better care team experience and lower total cost to treat per patient episode. 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 have deployed our investments toward these aims.

We design Instruments and Accessories to enable repeatable high-quality surgeries that are efficient and cost effective relating to total cost of treat. Our team is in the process of launching several sophisticated products in pursuit of the same. And customers are now adopting them broadly. Our 60-millimeter stapler is now in full launch and is used primarily in Abdominal surgeries.

Our second generation 45-millimeter stapler has recently received 510(k) clearance incorporating several of the learnings from our 80-millimeter line. Surgeon response has

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been strong and adoption of our stapling line is encouraging. We also launched, our third generation Vessel Sealer. Its adoption has likewise been strong.

Turning to systems, we are in our first phase launch of da Vinci SP We installed six systems in Q1, constrained in the, quarter by manufacturing availability and bringing our clinical installed base of SP to 21%. Roughly 800 procedures had been performed today. Recall we have two cleared indications for SP, urologic and transoral surgery. Surgeon and patient feedback have been positive for usability and patient experience in these early days of launch.

Going forward, we expect continued progress in strengthening our production performance to support SP launch at scale. As we've described in the past, we are also pursuing additional clinical indications for SP and have engaged regulatory agencies regarding their requirements. The combination of additional indications for SP and production readiness at scale will pace the speed of SP commercial deployment. And flexible diagnostics, our lon platform is focused on the need for definitive early diagnosis of suspicious lesions for lung cancer.

Ion received FDA clearance in the first quarter. With 510(k) clearance, we have initiated our next phase focused on critical use, customer feedback and production optimization. First cases on the cleared system were performed at the end of Q1, and we plan a measured rollout this year. We do not anticipate material revenues from Ion in 2019.

In our cloud computing and informatics efforts, we routinely deliver programmatic insights to our customers, using our systems, which have been smart and connected for the past decade. They received FDA clearance for our IRIS augmented reality product in the first quarter and anticipate first clinical use in 2019, focused on several high volume da Vinci institutions that will lead clinical evaluation and analysis. We do not anticipate any revenue from IRIS in 2019.

In closing, our business fundamentals are strong. For the balance of the year, our focus remains in completing the tasks we set for ourselves. 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 intelligence surgery innovation. And finally, supporting additional clinical and economic validation in our focus procedures in countries.

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

Marshall L Mohr {BIO 5782298 <GO>}

Good afternoon. I'll describe the highlights of our performance on a non-GAAP, or proforma basis. I will also summarize our GAAP performance later in my remarks. A reconciliation between our pro forma and GAAP results is posted on our website. Key business metrics for the first quarter, were as follows. First quarter 2019 procedures increased 18 -- approximately 18% compared with the first quarter 2018 and decreased approximately 1% compared with last quarter.

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Procedure growth continues to be driven by general surgery in U.S., and urology worldwide. Calvin will review details of procedure growth later in this call. First quarter system placements of 235 systems increased 27%, compared with 185 systems last year and decrease from the 290 system placements in our seasonally stronger fourth quarter. We expanded our installed base of da Vinci systems by 13% to approximately 5,110 systems, which is consistent with the fourth quarter and slightly higher than the 12.6% increase last year. Utilization of current clinical systems in the field measured by procedures per system grew in the mid-single digits.

Our revenue overview is as follows. First quarter 2019 revenue was \$974 million and increase of 15%, compared with 848 million for the first quarter of 2018, and a decrease of 7%, compared with a seasonally stronger fourth quarter revenue of \$1.47 billion. Instrument and accessory revenue of \$552 million increased 20%, compared with last year which is higher than procedure growth primarily reflecting increased use of our advanced instruments in customer buying patterns. Instrument and accessory revenue realized per procedure was approximately \$1,960, an increase of 2% compared with the first quarter of 2018 and an increase of 4% compared with last quarter.

Systems revenue for the first quarter 2019 was \$248 million, an increase of 6% compared with the first quarter of 2018, and a decrease of 27% compared with last quarter. The variation between 6% systems revenue growth and the 27% system placements growth reflects greater proportion of operating leases, a greater proportion of system trade-ins, a greater proportion of X Systems, a higher mix of distributor placements and volume based discounts provided to customers purchasing multiple systems. We completed 78 operating lease transactions, representing 33% total placements compared with 43% or 23% of total placements in the first quarter of 2018, and 84%, 29% of total placements last quarter.

As of March 31, we have 423 operating leases outstanding and realized approximately \$20 million of revenue related to these arrangements in the quarter, compared with \$10 million last year, and \$16 million last quarter. Operating leases create a future source of recurring revenue and reduce the volatility of system revenue. While the increased number of operating systems placed in the quarter, dampen short-term revenue growth for the quarter in which they are placed.

Operating leases include usage-based financing that we provide to certain experienced hospitals We believe that our leasing alternatives aligned with customer objectives and have enabled faster market adoption. Relative to systems purchased over the lease period, we earn a small premium reflecting the time, value and money, and in the case of usage-based arrangements the risk that those systems may not achieve anticipated usage levels.

The proportion of these types of arrangements could increase long-term. It will be lumpy quarter-to-quarter. 36% of the current quarter system placements involved trade-ins, reflecting customer desire to access or standardize on our fourth generation technology. This is an increase in the proportion of trade-ins compared to 31% in the first quarter of 2018, and 28% last quarter.

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Trade-in activity can be lumpy and difficult to predict. 67% of the systems placed in the quarter, were da Vinci Xis. 25% were da Vinci X systems compared with 73% da Vinci Xis, and 18% da Vinci X's last quarter. Six of the systems placed for SP systems. Our roll out of the SP surgical system is measured, putting systems in the hands of experienced da Vinci users while we optimize training pathways in our supply chain.

As mentioned by Gary, SP production was constrained in the first quarter. Globally, our average selling price which excludes the impact of operating leases and lease buyouts, was approximately \$1.31 million compared with \$1.49 million last year, and \$1.46 million last quarter. The changes compared with prior periods primarily reflect a greater portion of trade-in transactions. Volume based incentives providing customers purchasing multiple systems, a greater proportion of X systems and higher proportion of distributor sales.

Outside of the U.S. results were as follows. OUS procedures grew approximately 21%, compared with the first quarter of 2018 and increased 6% compared with last quarter. First quarter revenue outside of the U.S. of \$282 million increased 3%, compared with the first quarter of 2018 and decreased 8% compared with last quarter. The 3% year-over-year revenue growth primarily reflects a greater proportion of X systems, a higher mix of distributor arrangements and a greater proportion of operating leases.

Outside the U.S., we placed 81 systems in the first quarter compared with 73 in the first quarter 2018 in 115 systems last quarter. Current quarter system placements included 49 into Europe, 13 into Japan, 8 into Brazil and three into China. 36% or 44% of the systems placed in the first quarter were X systems compared with 19% last year and 30% last quarter. 11 of the system placements were operating leases compared, with one last year and 15 last quarter.

Placements outside 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 limitations.

Moving on to gross margin and operating expenses. Pro forma gross margin for the first quarter of 2019 was 71.2% compared with 71.6% for the first quarter of 2018, and 71.8% last quarter.

The decrease compared with the first quarter of 2018 and last quarter primarily reflects lower system ASPs and higher mix of advanced instruments. Partially offset by improvements in manufacturing efficiency. Future margins will fluctuate based on the mix of our new products, the mix of systems and instrument and accessory revenue, system ASPs and our ability to further reduce product costs and improve manufacturing efficiency.

Pro forma operating expenses increased 27% compared with the first quarter of 2018, and decreased 2% compared with last quarter. Fourth quarter 2018, operating expenses included a \$25 million contribution to the newly-formed Intuitive Foundation. Excluding the contribution to the foundation, pro forma operating expenses increased 5% compared with last quarter. In order of magnitude of increase, first quarter expenses

reflect costs associated with expansion of our OUS markets, spending on our informatics capabilities and investment in our infrastructure in order to scale the business.

Our pro-forma effective tax rate for the first quarter was 19.8% compared with our expectations of 19% to 20%. Our tax rates will fluctuate with changes in the mix of US and OUS income, changes in taxation made by local authorities, and with the impact of one-time items. Our first quarter 2019, pro forma net income was \$312 million or \$2.61 per share compared with \$288 million or \$2.44 per share for the first quarter of 2018 and \$353 million or \$2.96 per share for the fourth quarter 2018.

I'll now summarize our GAAP results. GAAP net income was \$307 million or \$2.56 per share for the first quarter of 2019, compared with GAAP net income of \$288 million or \$2.44 per share for the first quarter of 2018. And GAAP net income of \$293 million or \$2.45 per share for the fourth quarter of 2018.

The adjustments between pro forma and GAAP net income, are outline and quantified on our website, and include excess tax benefits associated with employee stock awards, employee equity and IP charges in legal settlements. We ended the quarter with cash and investments of \$5.1 billion compared with \$4.8 billion at December 31, 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 \$60 million to \$468 million, representing approximately 140 days of inventory.

We continue to build inventory to address the growth in the business as well as mitigate risks of disruption that could arise from trade, supplier or other matters. With the growth in the business and our focus on efficiency and scale, we expects Capital expenditures will increase to over \$250 million in 2019. In January, our Board of Directors increased our stock buyback authorization to two billion. We did not repurchase any shares in the quarter.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall first quarter procedure growth was 18% compared to 15% during the first quarter of 2018 and 19% last quarter. Our Q1 procedure growth was driven by 17% growth in US procedures, and 21% growth in OUS markets. In the U.S., Q1 procedure results were generally consistent with recent trends. Q1 growth was again driven by growth in U.S. general surgery, thoracic and benign gynecology procedures.

In general surgery, first quarter of hernia repair and colorectal procedure growth remains strong, while growth in other general surgery procedures such as cholecystectomy, bariatric and liver and pancreatic cases also contributed to growth. First quarter U.S. Gynecology continued to grow in the mid-single digits, driven by benign hysterectomy procedures. Our data continues to indicate an increasing proportion of overall gynecology procedures are being performed by gynecologic oncologists.

In addition, our recently launched Vessel Sealer Extend instrument is increasingly being adopted by gynecologists. US Urology, first quarter growth moderated a bit in Q1 driven by prostatectomy, which moved closer to the underlying incident rate for prostate cancer. As a mature procedure category, we believe that our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market. In other US procedures adoption of lobectomies and other thoracic procedures was again solid in the first quarter.

First quarter OUS procedure volume grew approximately 21% compared with 18% for the first quarter 2018 and 24% last quarter. First quarter 2019 OUS procedure growth was driven by continued growth in dVP procedures, and earlier stage growth in kidney cancer procedures, general surgery and gynecology. Two weeks ago, we attended the Society of American Gastrointestinal and Endoscopic Surgeons or SAGES conference in Baltimore. SAGES is one of the largest general surgery meetings this year attended by many of the world's leading general surgeons. We were encouraged by the emerging consensus view regarding the value of robotic-assisted approaches in general surgery procedures.

Our booth was highly visited by surgeons interested in hands on access to the full breadth of our generation four platform, including the da Vinci Xi, da Vinci X and Da Vinci SP systems on the floor. In our advanced instrumentation including the SureForm surgical stapler.

The SAGES conference emphasizes clinical evidence and I will share with you one of the e-posters presented at the event analyzing real-world evidence. 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.

At this year's SAGES, Dr. Elizabeth Raskin from Loma Linda University presented research titled, reducing variability in outcomes. Conversion rate analysis in minimally invasive sigmoidectomy. The study used to premier healthcare database, selecting data from institutions performing at least 100 laparoscopic assisted or robotic-assisted sigmoidectomy cases between 2013 and 2015. Data for 8,821 patients from 75 hospitals were analyzed. The median conversion rate for minimally invasive surgery to open surgery across the entire sample was 10.85%. The data was split between higher conversion rate hospitals above the median and lower conversion rate hospitals below the medium.

Among patients from the higher conversion rate hospitals, the conversion rate for lap procedures was 18.41% compared to 11.33% robotic-assisted. Among patients from the lower conversion rate hospitals, the conversion rate for lap assisted cases was 7.33%, compared to 2.89% for the robotic cases.

After adjusting for variables, the lap patients in the higher conversion rate hospitals had 75% more risk of converting to open approach. In the lower conversion group, laparoscopic approach was found to be 2.5 times more likely to be converted to open compared to the robotic-assisted approach. While we're encouraged by the lower da Vinci conversion rates, relative to laparoscopy, this study highlights that there is still

significant remaining opportunity for surgeons to drive conversion rates meaningfully lower, which has the potential to improve outcomes and patient experience.

Furthermore, as evidenced by the large gap between the higher and lower conversion rate hospitals, there remain significant opportunity to reduce the variability of outcomes across care teams.

I will now turn to our financial outlook for 2019. Starting with procedures, on our last call, we forecast full year 2019 procedure growth, within a range of 13% to 17%. We are now refining our estimate to the upper half of that range and estimate full year 2019 procedure growth of 15% to 17%. With respect to revenue, as we've mentioned previously, in mature markets capital sales are ultimately driven by procedure growth, catalyzing hospitals to establish or expand robotic system capacity.

Capital sales revenue can vary substantially from period-to-period based upon many factors, including U.S. Healthcare policy, hospital capital spending cycles, reimbursement and government quotas, product cycles, economic cycles and competitive factors. Indeed, the impact of leasing, trade-in, and product mix are reflected in our systems revenue results for Q1. While these factors are aligned with our strategy and positive business levers, the revenue result was lower than historical norms relative to the number of systems placed.

Looking forward, we expect continued variation by quarter, and we expect to continue to see meaningful proportions of capital placements involving trade-ins and, or we structured those operating leases.

Turning to gross profit, we continue to 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 are expanding our investments in 2019. Given our results in the first quarter, we expect to grow pro forma 2019 operating expenses between 24% and 28% above 2018 levels compared to the 20% to 28% range forecast on our last call. We expect our non-cash stock compensation expense to range between \$320 million and \$340 million in 2019 compared with \$310 million to \$340 million forecast on our last call.

We continue to 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, we continue to estimate our 2019 pro forma income tax rate to be between 19% and 20% of pre-tax income.

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

Questions And Answers

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Operator

(Question And Answer)

(Operator Instructions). Our first question will come from Tycho Peterson at JP Morgan. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, thanks. You know, maybe I will start with bariatric. Obviously, a lot of excitement coming out of stages on the opportunity around bariatric. Gary, can you maybe just talk about the ramp and any infraction you're seeing between gastric bypass leads reviews. And you know, if we think about 180,000-ish procedures in the U.S., what you think the adoption curve looks like over the next couple of years?

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

Well, thank you. For starters on bariatrics, we're excited about the long-term opportunity. And as you described, there's interest in all of the procedure subcategories you've laid out all in a minute, turn over to Calvin and speak a little bit about sizing. Where we are in terms of commercial focus? The commercial team is largely focused now on hernia and colorectal procedures. We see some early interest in bariatrics and will support that early interest, but well we'd like to make sure we satisfy the hernia markets and the colorectal markets we're in today, and then we'll pivot over time to support bariatrics more broadly. Calvin, you might speak to.

A - Calvin Darling {BIO 17664656 <GO>}

No, Tycho, you are right. I mean \$180,000 is about right in aggregate, but there is a lot of different types of procedures within that category from sleeve gastrectomy. So, the full bypass is to the redo procedures you mentioned, where I think there is some clear benefits to robotic approach for those complex surgeries. You know at this point in time, we've seen some very nice early stage adoption. Obviously based upon the patient benefits but also there is some pretty significant surge in benefit as well from an economic standpoint, so it's a nice foundation that's building and at this point as Gary mentioned, we haven't focused the team entirely there.

Q - Tycho Peterson {BIO 4279327 <GO>}

Great. And then on China, Gary, you characterized the market is still being constrained that you only had three systems this quarter. Can you talk about your latest thinking on the quarter impact, and when you think things start to pick up there a little bit?

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

Marshall, why don't you take us through that?

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

Sure. So just a replay, the quota is 154 systems for robotic systems. That is a quota that is available to anybody that has approval to sell robotic systems. So, if there were to be another company that came along that got approval through CFDA, they would also be able to share in that quota.

The quota has been distributed to provinces. The provinces are responsible for identifying the specific hospitals and then to -- the hospitals then have to launch a tendering process. All of that takes time, and the tendering processes can take quite a bit of time. And in fact, if you replay back to when we got the 2015 or the 2013 quota, it took till near the end of 2015 when we saw a majority of those systems get done. So what we had told you before was that you should plan on fewer systems early and more systems later. And in fact, the three systems that were done this quarter were not done within their quota. So, we have not seen any systems from the quota yet.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then just last one on Ion. You know, now that you're out on the market, how do we think about the kind of data collection window here and what time frame we could start to see the publications. Could we see some by the back half of the year? And then can you maybe talk to your supply chain optimization efforts and where you are in that?

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

Sure, I think, we'll be gathering two sets of data. Some are position preference and workflow data, and the other is outcomes over time. I imagine you'll see various interim publications toward the end of the year. It will take some time to get the full set written in review that may come after '19, but I think you'll see updates from key customers as we go through the year.

In terms of manufacturing optimization, so far so good. A lot of this is really just starting to create the manufacturing process and lines to build things out at a little bit bigger scale, and incorporate learnings and update tolerances and other kinds of validation work. So far so good. I think the team is doing a nice job there.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay, thank you.

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

Thank you.

Operator

Thank you. And next we go Bob Hopkins with Bank of America. Please go ahead.

Q - Robert Hopkins (BIO 2150525 <GO>)

Thanks for taking the questions. Just two for me. First, Marshall to start out. I just want to get your latest thinking on operating leases. Obviously, it's accelerated up to 32% of

placements. I guess, the way I'd ask a question is, would you be surprised if that moved up to 50% or do you think we're getting close to a top-tier with a third in placements?

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

Yes. We introduced leasing and other alternatives, financing alternatives, a few years ago. And we did that in the face of what we thought would the customer demand, and in fact we think it's played out quite well. And that we have been able to allow customers to expand more quickly their installed base. I think, -- so it's really a customer driven demand. Having said that, if it were my choice, I'd find that the leases and the alternatives that we're providing customers are favorable to us and that it creates a recurring revenue stream eliminate some of the volatility at system placement revenue. And I think in the long-term it will enhance any type of upgrade cycle that might come along.

So, it's hard for me to predict exactly how far it will go, but again, if it were my choice, I'd like to see it go further.

Q - Robert Hopkins {BIO 2150525 <GO>}

But it doesn't -- it seems like it's going to go higher from here. I mean, it clearly seems like there's no momentum in that. And I don't think it's that big of a deal. I'm just curious as your thoughts as to where we might be headed.

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

Yeah, I've given you my thought.

Q - Robert Hopkins {BIO 2150525 <GO>}

Got it.

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

Well, it's hard to predict what the anchor point is, likely a little more from here

Q - Robert Hopkins {BIO 2150525 <GO>}

Okay. And then one last question. Gary, you guys -- or for Marshall, you spent at the highend of the guidance this quarter. And it was particularly the R&D spend I think was up 38% now annual rising at roughly \$400 million. I was wondering, if you could just go into a little more detail on where that incremental R&D spending is going. And I know we talked about it last quarter, but any incremental details on where that big uptick in R&D spending is going would be helpful? Thank you.

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

Yeah, it's a fair question. So first just total spending in context, the bigger component of the increase was actually expanding our field teams outside the U.S. So on a percentage basis, R&D grew on an absolute basis, it was actually investments in commercial teams and field teams in Asia that drove the biggest side.

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With breaking down the R&D to answer you're actually expanding our field teams

question. In kind of priority order, computational capability and informatics both in the product and back in the office is the largest uptick followed by Ion, followed by advanced instrument investments, followed by imaging investments. Those are the ones that are responsible for growth down that pathway. And we think we're on our front foot there and making progress where we are we are, and we're putting those investments out to support our future growth, but that's the rough priority order.

Q - Robert Hopkins {BIO 2150525 <GO>}

Perfect. Thanks very much.

Operator

Thank you. And next we have David Lewis with Morgan Stanley. Please go ahead.

Q - David Lewis {BIO 15161699 <GO>}

Great. Good afternoon. Just a couple questions for me. And Marshall, I wanted to come back to this dynamic of systems mix more broadly, and you gave a lot more detail on systems mix this quarter, than we've heard in the last several quarters. Calvin highlighted this in guidance. So I think, it's going to create this notion of something (inaudible) change cyclically, this is just a weird quarter or structurally there's different dynamics we should be considering for '19 and beyond.

So can you just talk in more detail, you talked about trade-ins, x-distributors, volume-based discounting. So it does seem like mixed dynamic shifted more maturely this quarter than perhaps in the last two to three quarters. I wonder if you could just highlight what changed and what's driving some of those changes?

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

Sure, so to be clear, there was a shift, you are right. That we've seen an increase in the trade-ins, the percentage of trade-ins, and as I said earlier, it was 36% compared to 28% a year ago. And you know, what we're seeing is just customers wanting to avail themselves to the fourth-generation technology, and standardize to have multiple systems and standardize their portfolio.

And then we've seen more multi-system deals and some of that has to do with, what Gary was just talking about. Their desire to expand their base and as they are doing that, they would rather deal with one set of I&A, one set of training protocol and so forth, and so they standardize on the platform. So the two were somewhat intertwined.

We also saw a greater proportion of X systems, and that's been a kind of a volatile statistic. Actually if you go back in time since we introduced X, it's jumped around a little bit. But indeed, we introduced X with the intention of being able to deliver a lower cost product to geographies where reimbursements are lower.

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And in fact, in Europe, we saw 45% of the system sold were accessed which is exactly the market we targeted it for. So these are all things that we think are positive trends and leasing as well, as I spoke to earlier. But the confluence of them all this quarter did drive systems revenue to only grow 6% and also ASPs be a little lower. If you were looking out into the future for the rest of this year, you know it's more likely given the trend in tradeins and trend in multi-system arrangements, that will be closer to, let's say the ASPs, we saw this quarter then we saw for the whole of last year. If you go back to last year, you know we're pretty much around \$1.45 million on a consistent basis last year. And so that's where I think we are and where we're going.

Q - David Lewis {BIO 15161699 <GO>}

I don't want to put words in your mouth, Marshall, but it sounds like with this trade-in dynamics has been going on for six to eight quarters, that's sort of been there. The X mix number can move around quarter-by-quarter. So it sounds like the only incremental new piece of information is some of these larger system orders. Is that a fair characterization of what's probably the incremental new piece information?

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

True. Yes.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Very, very helpful. Just two more for me, and I'll jump back in queue. One Gary, you mentioned some SP manufacturing constraints here in the first quarter. Are those resolved and sort of what's the pace to resolve them? And then maybe for Calvin, just there's been a lot of channel dynamics around women's health. Well, broadly women's health general surgery breast as of your gynecological FDA letters. Any impact in the underlying procedure base targeted on either those two letters or channel disruption? Thanks so much. Those are the two questions.

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

Okay. On the SP side, the manufacturing constraint was a mechanical thing having to do with frictions and rails and the way these things both together. I think, the team has got it, I think we'll meet our SP shipment client for the year. So I think they're knocking it out, just a timing issue there.

With regard I'll start on the broader one. With regard to FDA environment as it relates to medical devices and women's health, clearly they're signaling more conservative approach and are speaking about it broadly across the industry. With regard to Intuitive, that may change some future data requirements and it may introduce some uncertainty in timelines for indications of kind of things we're interested in over time. With regard to what it looks like in the installed base and things like cyclical perplexity. Calvin, I'll turn it back to you.

A - Calvin Darling {BIO 17664656 <GO>}

Sloomberg Transcript

Company Name: Intuitive Surgical Inc Company Ticker: ISRG US Equity

Date: 2019-04-18

Yeah. As it relates to the -- there actually -- the FDA action relates to the use of mesh intended for transvaginal repair or pelvic organ prolapse. There are actually various methods of medical management for pelvic organ prolapse including observation, history management and surgery. And da Vinci cyclical perplexity is a minimally invasive method of abdominal surgery, so not transvaginal. And so since our procedure is abdominal we don't think that the -- this action is going to negatively impact our cyclical perplexity volumes last year. We did something like 15,000 to 20,000 cases in that category and we're about 40% of the market.

Q - David Lewis {BIO 15161699 <GO>}

Thanks so much.

Operator

And our next question is from Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon, thanks for taking the question. One for Gary, one from Marshall. I'll start with the one for Gary. Intuitive has launched a new system every, call it, six to seven years. Do you expect to maintain that cadence? I think, it's been about five years since you launched Xi. What can you tell us about how you're thinking about enhancing Xi? Should we expect a low-cost system perhaps for the ASC setting? And I have one follow-up.

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

Yes. With regard to innovation cadence, we continue to be committed to innovation on exact cadences. We won't predict timelines because it's uncertain based on what kind of technologies we're developing and based on the regulatory environment. But you can be assured that we are committed to bringing to market things that help our customers solve their problems.

With regard to the specific question of economics and price points, you can see our historically, X and Xi and what we've done there but just frankly we routinely assess and balance customer needs, the features that they're interested in to achieve their aims and the price points and we explore and invent broadly. We don't disclose what our specific plans are, or timing for competitive reasons.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Understood. And Marshall, based on your guidance for procedure growth and OpEx growth. In 2019, you're operating margin will likely decline. So how do you want investors to think about your operating margin beyond 2019 especially in 2020, when we could start to see new competition? Thanks for taking the question.

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

Sure. We haven't provided guidance beyond this year, and I think what we said at the beginning of this year was you would see a decline in our operating margins, given the

level of increased spending that we were going to embark on. Calvin gave you the guidance for increased operating spending, as you know, it did not change from our previous guidance. So, I think that's all I really have to say about that.

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

Yeah. I'd add something. I think as we look out the opportunity for improvement in acute interventions in surgery with the kinds of things we do, robotics, informatics, imaging, advanced imaging, we think it's substantial. And as a result we take a long-term view. We think these are multi-year developments and multi-year investments but ultimately, the size of that opportunity is quite large. And as a result we try not to tune it perfectly quarter-by-quarter or year-by-year, but really look over the very long-term.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for taking my questions, guys.

Operator

Next we will go to Amit Hazan with Citigroup. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Hey, thanks for taking the question now. I mean -- let me start with procedures for the quarter. Just big picture it looked to us like a state of comp adjusted slowdown in growth in the U.S. and OUS And I'm just wondering I want to make sure we're not missing anything but is there anything to call out that was off trend? I heard you say prostate, we got that one but if there's any other headwinds that you saw in the quarter on year-over-year basis, that would have kind of driven a slight slowdown. Is there anything there at all?

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

No, I think we're the comments pretty much reflective that we were on trend in most of the major growth drivers in general surgery, a continuation of what we've seen before. And you can look at the Q1 comp, but then another thing to look at is work days. So we had one fewer operating day in the first quarter, just due to timing of weekends is partially offset by Easter. So I think you overcame that a little bit too. So I don't think there's anything more to add to that.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay, great. And then secondly, I want to ask about the da Vinci Sis. So we spent some time with a few of your customers this quarter. And they basically told us that you guys are -- have sent them a letter that you're sun-setting the da Vinci Si and its instruments by 2024. And so I just want to see if we could first of all get a confirmation of that. And also, some context for how many Sis are still out there and how you'd expect it to play out in terms of the replacement cycle?

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

Date: 2019-04-18

Yeah. I'll let Calvin speak to the number of Sis that are out there, indeed we did put a letter out. The letter really talked about discontinuation of stapling in certain energy instruments, specifically. And that those would be coming to an end in 2020. We also indicated that we would discontinue annual service pricing in 2025. Having said that, we're committed to supporting Si. We'll continue to deliver instruments and accessories even beyond the end date of 2024. And we will even provide services beyond 2024, just not in the form of annual service, but rather, in the form of time and materials.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, in terms of the installed base, we just turned the -- crossed the line here this quarter. The slight majority are now da Vinci Xi systems. But still, nearly half are Si and previous models. And we talked a lot about trade-in cycle and the impact in a number of trade-ins, so there's still a significant number of Si and previous out there.

Q - Amit Hazan {BIO 6327168 <GO>}

Alright, thank you very much.

Operator

Next, we have JP McKim with Piper Jaffray. Please go ahead.

Q - JP McKim {BIO 18054566 <GO>}

Hi, good afternoon. Thanks for taking my question. I wanted to ask one on SP, I think you said there was around 800 procedures performed in that platform to date. Maybe if you could just talk about whether those were procedures that would have been done robotically previously, or if it is expanding the market a little bit. And then maybe your thought on other indications this year and some rough timing around when those could happen?

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

Thanks for the question. The bulk of the procedures so far were in urology, would likely have been done robotically anyway. Indication -- the additional indication we got in transoral robotic surgery was relatively recent. That will grow in time that will likely be a small expansion relative to what's being done robotically. The next likely procedure for us to pursue is a colorectal indication that will not occur in 2019. We will do a lot of the work, but I do not participate an additional clearance in '19 for colorectal, but it's likely next on deck, that we expect to be more expansive than substituting.

Q - JP McKim {BIO 18054566 <GO>}

That's helpful. And then there's clearly a push to get everything under the fourth generation, just in terms of the program you talked about earlier. But maybe if you could talk about strategically how important that is for you as a company either just to standardize manufacturing more or ahead of competition to get more and more customers standardized on this fourth-generation platform.

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

Our primary motivation is that the fourth gen is well optimized to the kinds of things our customers do. So our first motivation is we think it's beneficial for them particularly things like advanced instruments and stapling and so on, we're at more mature products and those kind of advanced instruments. And in that sense, you see the trade-in numbers go up and some of the ASP conversations, we think. We want to be aligned with our customers to both standardize and get the right access to the right technologies in the right place. We think that helps them, we think that helps us, and if we're helping both sides, we think that's good for our competitive position over time.

Q - JP McKim {BIO 18054566 <GO>}

Thank you.

Operator

We go now to Larry Keusch with Raymond James. Please go ahead.

Q - Larry Keusch {BIO 1504587 <GO>}

Hi, thanks. Good evening. Gary, just one relative to hernia. You obviously indicated that you still have the sales organization very much focused in the general surgical area on hernia and colorectal and you're not ready yet to quite get going on bariatric yet with meaningful field support. So just on hernia itself since that remains a focal point, can you help us think a little bit sort of what inning we're in at this point as you look at U.S.? And I guess the follow-on question is, what will it take to really start to drive general surgical procedures in Europe, because again still being dominated by urology?

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

Yeah, I think in the hernia market, I think we're in the end of the early innings is kind of where I'd put it. I think starting to enter more mainstream use. How far it goes depends a little bit on clinical condition. As you know, not every hernia is the same not every patient is the same, in terms of comorbidities. So assessing total size of the market and applicability is always a bit of an estimate. But I don't think we're half way done yet, and that's why we have our sales force focused the way it is.

Second half of the question, I'm sorry? Europe and urology, so on European side we're starting to see some early interest in general surgery and visceral surgery. Certainly on the more complex procedure side we see interest in procedures that are done, where the underlying causes cancer also has interest.

There may be an opportunity in benign general surgery as well. The economics maybe slightly different and that may require a slightly different adjustment from the company that made sure we satisfy that market. Early on, we have work to do to finish urology. We're not done yet. And then, we're looking at the next indications in the more complex side as the next step.

Q - Larry Keusch {BIO 1504587 <GO>}

Okay, perfect. And then one -- quick one from Marshall, just on the operating leases. I know it's still early in the experience in terms of ramping those up. They did ramp relatively consistently through last year, I guess, the 2Q was down a little bit, but it is -- should we think about any seasonality just in the operating lease percentages given what you know today?

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

No, I don't think we've seen enough of a pattern to know whether there's any kind of seasonality to it. I suppose that there's the possibility that there's some seasonality associated with hospital budgeting cycles and so forth. But again, we haven't seen any particular patterns we'd point out at this point.

Q - Larry Keusch {BIO 1504587 <GO>}

Okay. Perfect. Thanks guys.

Operator

And next in gueue we have Richard Newitter at SVB Leerink. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thanks for taking the questions. I have two. First one for you, Gary, just on I appreciate that maybe you're not as focused with the commercial focus to move into bariatrics with hernia and colorectal, the priorities now. But with the introduction of the 60-millimeter stapler, have you noticed any kind of inflection in the demand curve, at least, with respect to interest in bariatrics? And are we nearing that point where you would start to allocate the resources there? And then I have a follow-up.

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

Remember, in terms of sequencing to activate a market, there is optimizing the product set to get them there, there's helping build partnering networks, and the capacity for training and team training. So, there's some pre-work, and then there's the building of the sales force competencies and support, customer base. So, we're engaged in the pre-work. First from the products and now into building the pathways and engaging those who will lead, so we're excited about it.

I think there's real interest and there's real long-term opportunity, and it's really just a question of timing. In terms of results, I wouldn't call anything out, one way or another showing strength or weakness. I think we're really in a building capacity phase before we expect more out of the commercial team.

Q - Richard Newitter {BIO 16908179 <GO>}

Okay, thanks. And the just as we think about a higher proportion of systems getting placed under these flexible financing arrangements minimum volume committed --

commit arrangements, I'm just curious, a straight operating lease model one would have thought, hey, some of these systems maybe are more susceptible or the customers are more susceptible to a trialing phenomenon as competitors come into the market.

But the more I hear you talk about these and the multi-system sales in these volume commitments. I'm wondering, does that just raises the switching costs, as we think of a higher percentage of systems getting placed in there?

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

Well. First of all, when you say volume commitments, they are not volume commitments. They are targets that we establish, but we don't have a volume commitment per se. Second, I think there are costs to switch of course, that go beyond the system itself. Training surgeons and staff, as well as protocols on how you set up the -- how you set up the OR, and how you manage the product, and how you use the product and so. I think those are barriers as well, as far switching costs associated with the system itself. You do run a risk with some of the variations, we're putting out there in financing that it may be easier for a customer, to switch out. But we think that broadening the base now and getting the commitment of the surgeons and getting them trained. So that we increase the barrier on that front is a better route to go.

Q - Richard Newitter {BIO 16908179 <GO>}

Okay. Thanks for the clarification.

Operator

Thank you. And next we have Craig Bijou with Cantor Fitzgerald. Please go ahead.

Q - Craig Bijou {BIO 18909856 <GO>}

Hi guys. Thanks for taking the questions. I wanted to ask on Japan, and I appreciate the comment that procedural growth was still strong. But I wanted to see, is it -- are you still seeing some of the growth, that you saw in the last couple of quarters? Just how should we think about where exactly, or I guess, how strong that growth is with the new procedures?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. We're full year now right? We got clearance for those 12 new procedures April 1st of 2018. And even after full year it's still fairly early and so we're focused on things like we were talking about the training support, proctoring network, building a solid foundation of surgeons, the OR teams and really emphasizing the clinical outcomes. We talked about back in Q3 of '18 procedure growth moving above the 40% line in Japan that continued in Q4. And in fact, here in Q1 of 2019, it kind of held on to that kind of rate of growth.

Q - Craig Bijou {BIO 18909856 <GO>}

And maybe just a follow up on Japan. I know, you added 13 systems in the quarter, but maybe just help us get a sense for what the demand -- or I guess, system demand is I

know that -- I believe that utilization of the Japan systems was one of your lower geographic regions. So just maybe a little color there.

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

Yeah. I think what we've said before and we're still on that same page is that, the systems are utilized poorly at this point and there is the opportunity to increase the number of procedures that can be done on them. However, the 12 procedures that were improved last year are not necessarily all done at the same hospitals. So you've seen us sell systems because there are hospitals that do those procedures that were not doing prostatectomies or nephrectomies and now want to do robotic surgery.

So, it's hard for us to gauge exactly how much more -- how many more systems we can sell given the opportunity in front of us. The number of procedures being performed that had previously been approved which was prostatectomy and nephrectomy was around 25,000 to 30,000 and these additional 12 procedures was 200,000 although they were highly laparoscopically penetrated, and so it's also difficult to know how many of those will actually adopt or switch.

Q - Craig Bijou {BIO 18909856 <GO>}

Okay. Thanks for the color.

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

Just one more questioner please, operator?

Operator

Absolutely. Our final question will come from Imron Zafar with Deutsche Bank. Please go ahead.

Q - Imron Zafar {BIO 7558242 <GO>}

Hi, good afternoon. Thanks for taking my questions. First on U.S. General surgery. I'm curious, if you could give us some insight on how much of the growth you're seeing is coming from higher penetration within your existing users versus new general surgeons embracing robotics?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. You just look at what we're selling. The large majority of capital was -- are going into existing customers. They were expanding their programs and we're working with them as thoughtfully, as we can with analytics and insights and expanding programs to build them out in the hospitals. So a large part of the remaining opportunity and procedures that are currently adopting are in the hospitals or hospital networks that we've established relationships. Yes, we still have some greenfield opportunities to be sure, but in terms of proportion it's heavy on existing.

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

Quick question may have been asked from the point of surgeon themselves, more from a surgeon or newly trained surgeons and it's clearly a balanced mix of both.

Q - Imron Zafar {BIO 7558242 <GO>}

Okay. Thank you. And then, can you just talk about the long-term opportunity for a mastectomy? I know you have a clinical study ongoing or is getting under way. And is it fair to assume that that's more of an SP opportunity rather than the multi-port?

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

No, not ready to characterize anything yet. And we know that there are some folks who are interested in it who are starting to work through what studies might look like, but we are not yet prepared to talk about what the long-term looks like there.

Q - Imron Zafar {BIO 7558242 <GO>}

Okay. And then one -- just one last quick one for Marshall. There's been a pretty sizable increase in your headcount, since the third quarter I think it's up like 800 something. I assume some of that is just headcount accretion from some of your distributor acquisitions late last year, but can you just talk about what geographies those hires are targeting?

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

Yeah, the two greatest increases, one is what you characterize, which is that we took on distributor headcounts. So specifically, over the last year we've added over 300 heads associated with our growth in Asia-Pacific. And the second area is really manufacturing headcount. And we bring manufacturing headcount into on a temporary basis at first, and then we hire them in boluses. And in fact, we hired a bolus of them in the last six months.

Q - Imron Zafar {BIO 7558242 <GO>}

Great. Thanks so much.

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

Well, thank you. That was our last question. In closing, we believe there's a substantial and durable opportunity to fundamentally improve surgery and acute interventions. Our teams continue to work closely with hospitals, physicians and care teams in pursuit of what our customers have termed the quadruple aim, better, more predicable patient outcomes, better experiences for patients that are experiences for care teams, and ultimately as lower total cost of care.

We believe that accomplishing the same takes the integration of three elements. First, a deep understanding of human interactions across the continuum of care second, smart and connected systems imaging and instruments that augment care teams. And third the ability to measure impact through analytical insights and translation of these insights into action that drives positive change. We believe value creation in surgery and acute care is

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foundationally human. It flows from respect for and understanding of patients and care teams, their needs and their environment.

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

Operator

That does conclude our conference for today. Thank you for your participation, and for using AT&T TeleConference. You may now disconnect.

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