Q1 2018 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan, Analyst
- David Ryan Lewis, Analyst
- Isaac Ro, Analyst
- Larry Biegelsen, Analyst
- Richard Newitter, Analyst
- Rick Wise, Analyst
- Robert Hopkins, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Intuitive Surgical Q1 2018 Earnings Release Call. At this time, all lines are in a listen-only mode. Later, we'll conduct a question-and-answer session and I'll give instructions at that time. And as a reminder, today's conference is being recorded.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon, and welcome to Intuitive Surgical's first 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. Our

SEC filings can be found through our website or at the SEC's EDGAR database. Investors are cautioned not to place undue reliance on such forward-looking statement.

Please note that this conference call will be available for audio replay on our website at intuitivesurgical.com on the Audio Archives 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 first quarter financial results. Then, I will discuss procedures and clinical highlights and provide our updated financial outlook for 2018. And finally, we will host a question-and-answer session.

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

Gary S. Guthart {BIO 3429541 <GO>}

Good afternoon, and thank you for joining us on the call today.

Intuitive is dedicated to the mission of improving the availability and quality of minimally invasive surgery. We had a strong first quarter in pursuit of our mission with customer use of our systems at the top of our growth range, continuing momentum in new system placements and step-wise progress in the development of markets outside the United States. While we're pleased with our performance in the quarter the opportunity for improvement in surgery is substantial, and much work remains to be done.

Global procedure growth was approximately 15% in the first quarter of 2018. Underpinning this growth was increased use of da Vinci and general surgery in the United States, continued growth in urology in Europe and Asia, and multispecialty growth in China. General surgery growth was led by hernia repair and colon resection.

Mature procedures in the United States including prostatectomy and hysterectomy for malignant conditions grew above expected rates again in the quarter. European procedure growth was mixed by country, partially as a result of headwinds in the number of business days relative to Q1 2017.

Lastly, additional procedures were granted reimbursement by the Ministry of Health in Japan, effective April 1, 2018, at reimbursement rates equivalent to laparoscopy. Calvin will review procedure trends in greater detail later in the call.

Our capital placement performance in the first quarter of 2018 accelerated relative to 2017, with growth in total placements rising 39% from 133 to 185. Net of trade-ins and retirements, our da Vinci installed base grew by 13% over Q1 2017 from approximately 4,023 to approximately 4,528. Placement performance was strong globally, particularly in

the United States. Capital placements have been lumpy and we anticipate volatility in placements for the remainder of 2018.

Turning to operations, our performance in the first quarter met our expectations with good performance in product quality and cost reductions while average selling prices were stable. Investments to deepen our regional capabilities and to develop new technologies and services continue to be important in the first quarter. They will be so for the next several quarters as we progress through the launch of several products and build capability country-by-country. We are also investing to strengthen our corporate infrastructure and position us to benefit from increased scale.

Highlights of our first quarter operating results are as follows. Procedures grew approximately 15% over the first quarter of last year. We placed 185 da Vinci Surgical Systems, up from 133 in the first quarter of 2017. Our installed base grew 13% from a year ago. Revenue for the quarter was $848 million, up 25%. Pro forma gross profit margin was 71.6% compared to 72% in the first quarter of last year.

Instrument and accessory revenue increased to $460 million, up 21%. Total recurring revenue in the quarter was $623 million, representing 73% of total revenue. We generated a pro forma operating profit of $346 million in the quarter, up 30% from the first quarter of last year. And pro forma net income was $288 million, up 46%. Marshall will take you through our finances in greater detail shortly.

Our da Vinci Xi Surgical System is our most capable multi-port platform. We added our da Vinci X Surgical System in 2017, which offers fourth-generation imaging, robotics and instrumentation for focused quadrant surgeries at an attractive value. The da Vinci X Surgical System received regulatory clearance by PMDA in Japan this month and was showcased at a large surgical society meeting, JASIS, shortly thereafter. Combined with reimbursement approvals mentioned above, we're pleased with recent progress in Japan.

As we've discussed on prior calls, we plan to expand our Gen 4 family with a new capability in the form of da Vinci Sp. We submitted our 510(k) for our current Sp design in Q4 of 2017, and have received questions back from FDA. For preparing our response in overall, Sp is progressing to plan with the phased launch anticipated in 2018.

Also in the fourth quarter of 2017, we submitted our 510(k) application for our 60-millimeter surgical stapler for Gen 4 systems. We've received the first round of questions from FDA and are in the process of responding to their requests. Our Gen 4 systems have received growing use by surgeons globally and by general surgeons in particular. Including the 60-millimeter stapler, we're hard at work completing our advanced instrument offerings.

We continue to make progress on our flexible robotics platform, first targeted to address the acute need and diagnosis of lung cancer, one of the most commonly diagnosed forms of cancer in the world and for which early detection is important. Feedback from physicians evaluating our technology relative to existing and recently-announced alternatives has been strongly supportive of our efforts.

Our design and operations teams are working to incorporate their feedback, complete its production design and supply chain optimization and complete validations for regulatory submissions. We anticipate our 510(k) submission in 2018, and we have initiated the build of our commercial team, an outstanding and focused team of professionals.

I believe the opportunity for innovation and support of physicians in the flexible interventional space is substantial. That said, adoption will require clinical and economic validation, given the availability of multiple competing approaches in the market.

Lastly, our imaging teams continue to develop new ways to identify tissue, including progress in our molecular imaging program as well as improvements for our endoscopes and image-processing algorithms. We have been introducing improvements in our imaging hardware routinely, and expect to continue to do so in the remainder of 2018. We expect our lead molecular agent to enter Phase 2 trials in the second half of the year.

Stepping back and looking at the broader marketplace, our team's experience in robot-assisted surgery started decades ago, at research groups predating the formation of the company. Over this period, the rise of Mechatronics, powerful computing, improved sensing, microfabrication and molecular imaging has enabled new approaches to old problems.

Intuitive has been investing in innovation both incremental and revolutionary, with this in mind since our inception and with increased intensity for the past several years. This opportunity to improve surgery using advanced technologies is now being recognized broadly, particularly in the past several years and we anticipate the entry of additional systems by competitors into some regions of the world over the next several quarters.

To help our customers, Intuitive products and services are organized in generational families. Chair design principles, operating methods, user interfaces and product training allow surgical teams and hospitals to more quickly integrate new technologies and can deliver a significantly improved framework to training environments. As consolidation has progressed in health systems, standardization across surgical platforms can decrease variability and inefficiency from residency and fellowship programs to academic and community settings. Our fourth generation of surgical platforms offer our customers a fully enabled ecosystem of products and services in support of their programs.

In closing, during 2018, our focus remains in completing the tasks we set for ourselves: first, continued adoption of da Vinci in general surgery; second, continued development of European markets and access to customers in Asia; third, advancing our new platforms: imaging, advanced instruments, da Vinci Sp and our flexible catheter platform; and finally, support for additional clinical and economic validation by global region.

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

Marshall L. Mohr {BIO 5782298 <GO>}

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

First quarter 2018 revenue of $848 million grew 25% compared with first quarter 2017 revenue of $680 million and decreased 5% compared with the seasonally stronger fourth quarter revenue of $892 million. In the first quarter of 2017, we deferred approximately $23 million of revenue associated with the da Vinci X trade-out program that we offered certain first quarter customers. This revenue and related costs are recognized in the third and fourth quarters of 2017. Our comparison to 2017 results reflect the deferral as recorded.

We also have adopted the new revenue standard as required under GAAP and retroactively restated prior period results. We've updated the supplementary financial tables posted on our website to reflect this restatement. The adoption of the revenue standard had the effect of increasing first quarter 2017 total revenue by approximately $5 million and net income by approximately $1 million. The impact on the annual results for 2017 was insignificant, increasing total 2017 revenue by approximately $9 million and increasing net income by $11 million.

Revenue also benefited by approximately 2.5 percentage points from a weaker dollar. Excluding the impact of the revenue deferral and currency changes, revenue grew 18% relative to the restated 2017 first quarter.

First quarter 2018 procedures increased approximately 15% compared with first quarter of 2017 and were flat with last quarter. Procedure growth continued 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 $460 million increased 21% compared with last year, which is higher than procedure growth primarily reflecting increased usage of our advanced instruments and customer buying patterns. Instrument and accessory revenue realized per procedure was approximately $1,930, an increase of 5% compared with last year primarily reflecting advanced instrument usage, customer buying patterns and the impact of a weaker U.S. dollar.

Systems revenue of $235 million increased 46% compared with the first quarter of 2017 primarily reflecting higher system placements, the revenue deferral of $23 million in the first quarter of 2017, and a weaker U.S. dollar particularly offset, partially offset by an increase in the number of operating leases. We placed 185 systems in the first quarter of 2018 compared with 133 systems in the first quarter of 2017 and 216 systems last quarter.

43 operating lease transactions, representing 23% of total placements, were completed in the current quarter compared with 16% of total placements in the first quarter of 2017 and 19% last quarter. While the number of leases is difficult to predict in the short-term, we expect the proportion of these types of arrangements to increase long-term.

31% of the current quarter system placements involve trade-ins reflecting customer desire to access or standardize on our fourth generation technology. This is an increase in the proportion of trade-ins compared to 21% in the first quarter 2017 and 26% last quarter; however, trade-in activity is lumpy and difficult to predict.

76% of systems placed in the quarter were da Vinci Xis and 16% were da Vinci X Systems compared with 67% da Vinci Xis and 24% da Vinci Xs last quarter. Our installed base of da Vinci Systems ended the quarter at 4,528 systems, up 13% year-over-year and average system utilization grew in the low single-digit range.

Globally, our average selling price which excludes the impact of operating leases, lease buyouts and revenue deferrals was approximately $1.49 million, which is slightly higher than the $1.47 million in the fourth quarter. The increase reflects a higher mix of Xi Systems, a weaker U.S. dollar, partially offset by geographic mix.

Outside of the U.S., results were as follows. First quarter revenue outside of the U.S. of $275 million increased 49%, compared with the first quarter of 2017 and increased 11% compared with last quarter. The increase compared to the prior year reflects increased systems revenue of $55 million or nearly 100% growth, an increased instruments and accessories revenue of $30 million or 32% growth. Systems revenue was driven by an increase in the number of systems placed, a lower number of operating leases, favorable product and geography mix and a weaker dollar. Instrument and accessory revenue was primarily driven by procedure growth, a weaker dollar and customer buying patterns.

OUS procedures grew approximately 18% compared with the first quarter of 2017. OUS procedures were somewhat negatively impacted by the timing of holidays in 2018 compared to 2017. Outside of the U.S., we placed 73 systems in the first quarter compared with 56 in the first quarter 2017 and 86 in the seasonally strong fourth quarter.

Current quarter system placements included 45 in the Europe, 9 in Japan. 63% of the systems placed were da Vinci Xis compared with 54% in the first quarter of 2017 and 48% 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 in some markets are constrained by government regulation.

Moving on to the remainder of the P&L. The pro forma gross margin for the first quarter was 71.6% compared with 72% for the first quarter of 2017 and 72.4% last quarter. The decrease relative to the fourth quarter primarily reflects higher fixed costs spread over lower volumes. The decrease compared with the prior year primarily reflects product mix.

Future margins will fluctuate based on the mix of our newer products, mix of systems and accessory revenue, system ASPs and our ability to further reduce product cost and improve manufacturing efficiency.

Pro forma operating expenses increased 17% compared with the first quarter of 2017 and were flat compared with last quarter. Our spending is consistent with our plan reflecting

investments in da Vinci Sp, catheter-based robotics, image and advanced instrumentation and expansion of our OUS markets. These investments involve multiyear commitments.

Our pro forma effective tax rate for the first quarter was 20.1% compared with our expectations of 20% to 22%. 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 one-time items.

Our first quarter 2018 pro forma net income was $288 million or $2.44 per share compared with $197 million or $1.71 per share for the first quarter of 2017 and $305 million or $2.60 per share for the fourth quarter of 2017. First quarter 2017 GAAP and pro forma net income per diluted share excluded $0.09 per share from the deferral of $23 million of revenue net of costs and income tax.

I will now summarize our GAAP results. GAAP net income was $288 million or $2.44 per share for the first quarter of 2018 compared with GAAP net income of $181 million or $1.57 per share for the first quarter of 2017 and a GAAP net loss of $32 million or $0.28 per share for the fourth quarter of 2017.

The adjustments between pro forma and GAAP net income are outlined and quantified in our website and include fourth quarter charges related to the U.S. Tax Cuts and Jobs Act, excess tax benefits associated with employee stock awards, employee equity and IP charges and legal settlements.

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

We ended the quarter with cash and investments of $4.1 billion compared with $3.8 billion at December 31, 2017. The increase reflects cash generated from operations of $280 million. We did not repurchase any shares in the quarter, and have approximately $718 million remaining under the board buyback authorization.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall first quarter procedure growth was 15% compared to 18% during the first quarter of 2017 and 17% last quarter. Our year-over-year Q1 procedure growth was driven by 14% growth in U.S. procedures and 18% growth in OUS markets.

In the U.S., overall Q1 procedure performance by specialty closely aligned with patterns present in 2017. In U.S. general surgery, first quarter 2018 growth was consistent with 2017.

Q1 growth was again driven by hernia repair, which continued to provide the most incremental cases and continued da Vinci adoption in colorectal procedures. Early-stage adoption in bariatric procedures and growth across the breadth of the general surgery category also contributed to growth.

In U.S. gynecology, first quarter 2018 growth was consistent with 2017 trends as procedures grew modestly year-over-year, with growth led by hysterectomy. We believe gynecologic procedure consolidation continues to drive modest growth as an increasing proportion of U.S. gynecology procedures are being performed by physicians that specialize in complex benign and cancer surgery, who tend to be users of da Vinci Systems.

Q1 U.S. urology procedures had growth rates consistent with 2017 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 first quarter. Utilization of our da Vinci Xi Systems and surgical staplers, which help to optimize robotic thoracic procedures has been increasing.

First quarter OUS procedure volume grew approximately 18% compared with 23% for the full year of 2017. First 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. The Q1 2018 OUS procedure growth rate was lower than the previous year in part due to fewer operating days in Q1 2018 from the timing of holidays, including Easter.

Procedure growth in China moderated meaningfully in the quarter in part because da Vinci System capacity expansion is constrained by the system quota requirements, the most recent of which expired at the end of 2015. We believe core demand for robotic surgery in China is meaningful.

In Japan, Q1 procedure growth in prostatectomy and partial nephrectomy moderated as these procedures have achieved high levels of adoption. As Gary indicated, effective April 1, 2018, 12 additional procedures have been approved for reimbursement in Japan, with reimbursement equivalent to laparoscopic surgery.

The applicable opportunity for da Vinci adoption within the set of procedures is difficult to estimate at this time due to the uncertainty of the perceived value of da Vinci relative to alternative surgical approaches. With nearly 300 systems installed in Japan, the level and pace of system expansion in Japan over the next year is difficult to predict, but it will likely be modest.

Last week, we participated in the Annual Society of American Gastrointestinal and Endoscopic Surgeons, or SAGES meeting in Seattle. General surgery is our largest and fastest growing specialty, surgical specialty in the U.S. And this event represents one of

the largest gatherings of general surgery practitioners and thought leaders. As more general surgeons adopt robotics in their practices, at this year's conference, we continued to see increased numbers of robotic surgery presentations, clinical papers and podium speakers.

Included in the clinical data presented at SAGES were results from a study recently accepted for publication in the Hernia Journal (sic) [Journal Hernia] titled Open Versus Robotic-Assisted Transabdominal Preperitoneal Inguinal Hernia Repair, a multicenter matched analysis of clinical outcomes.

Data from this study was presented by lead author, Dr. Reza Gammagasi (sic) [Gamagami], from New Lenox, Illinois. This study is one of the largest multicenter evaluations of outcomes associated with robotic-assisted inguinal hernia repair cases compared to more experienced open cases from the same surgeons. In the matched analysis of 444 subjects in each cohort, robotic-assisted inguinal hernia repair cases demonstrated statistically significant lower post-discharge complication rates through 30 days with no re-operations related to the inguinal repair.

A multivariate analysis showed the open repair approach as a risk factor for complications within 30 days of the inguinal repair procedure. This study confirm the robotic-assisted approach to inguinal hernia repair may provide patients with the benefits of minimally invasive surgery with the authors who had variable laparoscopic experience among them, concluding that the robotic-assisted repair approach is a promising and reproducible approach which may facilitate the adoption of MIS repairs of inguinal hernia. This study adds to the growing body of evidence demonstrating comparable or improved outcomes for subjects undergoing a robotic-assisted inguinal hernia repair independent of a surgeon's laparoscopic experience.

I will now turn to our financial outlook for 2018. Starting with procedures. On our last call, we forecast full-year 2018 procedure growth within a range of 11% to 15%. We are now refining the range and estimate full-year 2018 procedure growth of 12% to 15%. With respect to revenue, as we have mentioned previously, capital placements are ultimately driven by procedure growth, catalyzing hospitals to establish or expand robotic system capacity. Capital placements 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 and competitive factors.

We had strong first quarter capital placements, driven by customer capacity expansion and bolstered by a higher volume of capital upgrade transactions involving trade-ins of older da Vinci models than in recent quarters. In addition, as anticipated, a higher proportion of Q1 system placements were under operating lease terms, 23%. This proportion may fluctuate some in the near-term but may trend further upwards in the long-term.

Turning to gross profit. We continued to expect our pro forma gross profit margin to be within a range of between 70% and 71.5% of net revenue. This is modestly lower than our Q1 result of 71.6%, primarily reflecting higher costs associated with new products we

expect to introduce later in the year. Our actual gross profit margin will vary quarter-to-quarter depending largely on product and regional mix.

Turning to operating expenses, we continue to expect to grow pro forma 2018 operating expenses between 16% and 18% above 2017 levels, as we follow through on investments in several strategic areas intended to benefit the company over the long-term. We expect our non-cash stock compensation expense to range between $245 million and $255 million in 2018 compared to $225 million to $235 million forecast on our last call. We expect other income, which is comprised mostly of interest income, to total between $55 million and $60 million in 2018, up from $45 million to $55 million forecast on our last call.

With regard to income tax, on our last call, we forecast our 2018 pro forma income tax rate to be between 20% and 22% of pre-tax income. We are now refining our estimate to the lower half of the range between 20% and 21% of pre-tax income. Note that in the future as the IRS issues additional guidance and interpretation of the new tax law, our estimated rate may be impacted.

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

Q&A

Operator

Our first question will come from the line of David Lewis with Morgan Stanley. Please go ahead.

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

Good afternoon. Congrats on quite a good quarter. So, Gary, a couple strategic questions for you. The first is on leasing. So, there is more operating leases in the last two quarters than the prior four quarters, and it feels like the 23% number is frankly going higher. So, it's starting to feel this is much more company-driven than customer-driven. So, the question is really, to what extent does leases make a lot more sense as competitors are coming to market? Sort of, in what way can leasing be very powerful defense?

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

Yeah. So, I'd first thank you. I think to the extent that we can help customers access robotics for their programs and do it in a way that fit their needs, we're happy to do it with leasing. I don't think it's a massive strategic change one way or another vis-à-vis competition. From our point of view, we're confident in our products. We understand and are confident in the value they bring. If we can be flexible with customers and allow them to get access to the products they need when they need it, if we can make it a little easier for them to do it sooner or rather than later in terms of their finances that helps us, and we're willing.

I think over time, customers are going to evaluate competitive systems. They're going to go look at them. And if somebody brings out a product that meets their needs better, I

don't know that leasing one way or the other is going to make a difference. For us, it really is kind of a first principles thing. Do you believe in robotic surgery as a way to increase the availability and quality of minimally invasive surgery? If you do and you're committed to it, and we can find a way to help you get a system, then we're happy to do it.

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

Okay. And then, Gary, just a question on the flexible catheter system as well. So, based on your timeline I'm kind of assuming you're nine months behind a recent competitive launch. So, I just wonder how concerned are you about this window? And you talked a lot about the ecosystem, both at SAGES and again in this call. In what ways can sort of the multi-system ecosystem approach be sort of a barrier to entry for new robotic entrants in this segment?

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

Yeah. I think in terms of any of the systems that we're going to place or somebody else places, I think the robot itself or the product itself is just the first step. You have to provide the robot, but you also need the instruments and accessories. You need to be able to help do product training. You need to build proctoring networks. You want to be able to help your customer do benchmarking and analytic analysis of usage patterns relative to what the rest of the world is doing.

And so, I think they expect support beyond the dropping off of the system at the back door. And we have built that over years. We've come to understand it deeply, and I think it is valuable to our customer. And I think that helps us. I think other companies have various degrees of enablement in that space.

With regard to flex catheter in particular, we have been investing in it, as you know, for years and years. This has been a long-term investment. We have built technologies and made decisions about our architectures based on first principles, not by looking over our shoulder at what other people are doing, but by really engaging customers deeply and understanding their clinical needs. That has driven us, continues to drive us.

We have connections into the customer base, because of those first principle investigations, and those folks visit us, they look at our technologies, they visit others and look at technologies on the market or soon to be on the market, and they make decisions. We're going to make decisions based on clinical value and demonstrable outcomes. You've seen the early parts of that with regard to the publications at CHEST.

I think there are advantages for people who are first movers, but I think they're short-lived. I think that, in this space, because there are a lot of alternatives in the marketplace and because it's going to be a market that's driven by clinical data over time, the best solutions are going to win. And I'm confident in our technology and even more confident in our team.

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

Okay. Thanks, Gary. Great quarter.

Operator

Our next question comes from the line of Bob Hopkins with Bank of America. Please go ahead.

Q - Robert Hopkins {BIO 2150525 <GO>}

Oh, great. Thanks for taking the question, and good afternoon. So, as I looked at your print, obviously there's lots of big impressive numbers in this first quarter report, but one that really caught my eye was the system sales number. And I know historically that's primarily driven by procedure volumes, and procedure volumes have been very strong. But I was wondering given this is really the best growth I think you've seen in system placements since 2010, was there anything in particular that that drove the strength this quarter? Just wondering if we can sort of tease out a little bit more what happened in systems placements this quarter. Thank you.

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

So, Bob, you're absolutely right. Systems placements are driven primarily by a procedure growth. And you have to look at it over a period of time because systems can be lumpy in any particular quarter. So, if you look at 2017, the installed base grew 13% and procedures grew 16%. So, it's procedures that were really driving that installed base growth. This quarter, we had a little bit higher proportion of trade-outs that reflects, I think, as I said in my script, customers wanting to avail themselves to fourth generation capabilities. And we also saw high sales of Xi validating that that system has features that really are driving adoption.

So, I think it's lumpy. I think it's hard to make conclusions based on one quarter of increased trade-in volume. And I just would be cautious there, and we expect to see some volatility. But overall, over a longer period of time, systems will follow procedure growth.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. Thank you for that. And then, I wanted to follow-up also one more question on flex catheter. Just curious what's left to do before you file with the FDA? And just maybe thinking a little bit longer term, but when do you think we might start to hear a little bit more about other potential indications for flex catheter beyond lung?

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

Sure. For now, as we said in earlier in the script, the teams are really doing the product validations, they're doing testing that supports our submissions. And we're stabilizing the supply chain and that's important when we launch we want to feel good about our ability to make the products and our sub-suppliers ability to make their parts. We're progressing. I think the team is doing a very good job. So, we're progressing against our plan.

For starters, as I've said, I think in the past, I'm excited about the flex catheter technology, because I think it's a platform and we'll have other opportunities outside of the lung. Where we are today is highly focused on bringing this first product to market and satisfying the needs of the interventional pulmonologists and thoracic surgeons. I think

that is a major opportunity. I think perfecting the clinical pathways, the use of the product and data generation is important for us to focus on. And so, our organization is tightly focused on that mission now.

Q - Robert Hopkins {BIO 2150525 <GO>}

Perfect. And then, Gary, any update on China at all or...?

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

Marshall, you might speak to kind of where – I think you're implying the quota, but why don't you speak to that?

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

Yeah, we really don't have much of an update on the quota. We still sit here awaiting the finalization of that quota. Again, just to give you the background, the quota really applies to the years, 2016 through 2020. It's part of the five-year planning budgeting process that Chinese government goes through. Central government has finalized its budget, but it has not yet completed its negotiations with provinces and hospitals about who will get how many systems. And so, we wait.

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

I think, in general, what's going on there doesn't appear to be intuitive specific. I think it's more rolling through the centralized government processes. We think that the core interest by Chinese customers in our products in the company and robotic surgery more broadly is strong. And we feel slight forward progress in terms of the way the process has been moving. We just can't call what the timelines are. And so, we're at the limits of our ability to influence that outcome.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. Thanks for taking the questions.

Operator

Next question will come from the line of Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. It looks like you guys had a 99% or almost 100% increase in the international system revenue, but about a 30% increase in the year-over-year systems shipped. Marshall, what drove the difference in those growth rates?

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

Sure. So, a couple of things that I pointed out. One was that in 2017 we had six leases, in 2018 we had one. Obviously when you have an operating – and these are operating

leases. Operating leases you don't have revenue, so some of that is attributable to it. Also have a foreign exchange or currency exchange that was a wind at our back here as the U.S. dollar has weakened over the year.

And we also had a favorable mix of product. As I said in my script, we had a high mix of Xi around the world that also included OUS and we also had a favorable geographic mix. If you noticed, there was substantive sales into Europe. And again, these are lumpy so you can't take one geography and extrapolate that forward. But in Europe, we did well. We did a little bit lower sales relative to the prior year in some of our distribution markets where we sell at a lower price. So, you just put all those factors together and it adds up to increasing revenue to the extent that it did.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks. And then for my follow up, we've been increasingly hearing that India could present itself as a large opportunity, potentially even becoming the number one international market. Could you talk a little bit about how you see that market developing this year and over the next few years? Thanks for taking the questions.

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

Yeah. We're optimistic that India will represent a good market long-term, but I think in the short-term to think that it's just going to snap to our second-largest market or our first-largest market is not going to happen. We have a distributor there that we've been working with for years. I think we have around 40, 50 systems installed in India. But the total number of procedures that they generate is maybe 1% of our total procedures. So, it's not consequential yet. We are making investments in it. We do it's, again, long-term that it's a viable market and a good one for us, but we're at the very, very, very early stages.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, we're actually at 68 systems in India currently.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for taking the questions, guys.

Operator

Our next question comes from the line of Tycho Peterson with JPMorgan. Please go ahead.

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

Thanks. I'll add my congrats on the quarter. Maybe first question on emerging procedures. Bariatric got a little bit more attention at SAGES this year, and I know, Calvin, you called that out in your comments. I know you're in the process of getting back to the FDA with the questions on the stapler, but, Gary, can you maybe just talk a little bit about

how you think about this market evolving and how much market development you guys need to put behind it once you get the stapler out?

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

It's going to be an interesting one to see evolve. I think it's early for us to put much commentary on it. We see interest by surgeons. Having said that, it's a highly penetrated procedure with laparoscopy. And there are a lot of highly skilled laparoscopists in that market. In that sense , it stands in contrast to prostatectomy or hysterectomy for malignant conditions, which were predominantly open procedures. So, we see some core demand and interest. Certainly, we want to complete the product offering in the stapler. I think the real question there of where could it go over time, I'd like to answer in future calls as we get a few quarters underneath our belt.

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

Okay. And then speaking a little bit about Japan with reimbursement coming out at parity to lap, does that change your view on the adoption curve at all? And are there steps you can take to try to increase these codes over time, presumably that won't require additional studies?

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

Yeah. I think that in general, I think the reimbursement decision is a positive for us. It's not an unalloyed positive. I think that it will concentrate adoption into the bigger centers. That's okay. I think we're in a position to support that and we will do so. We will make investments for data collection in Japan, and the use of that data collection will be certainly something we can share with surgical societies and with the government as time goes on. And to the extent that we show additional value, I think it's something that the government will consider for future reimbursements.

I wouldn't ink anything on your calendars yet as to changes in reimbursement from this base level. I think that there's some water to go under the bridge here. Having just been in Japan, I think the interest is high. I think the surgical society is seeing it as a positive step and an endorsement by the government. I think that the economics in the right centers will work well for them. And it's an exciting time for us and our team in Japan and I'm looking forward to seeing them have a chance to broaden their base of business and get to know more customers.

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

Okay. And then lastly on Sp, are you willing to comment? Were there any surprises in the FDA questions from your perspective? And then, as we think about the rollout, obviously, you've talked about the three initial application areas. It seems like there's already some interest in other use cases. So, I'm just curious about how much pent-up demand you think there is out there today.

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

In terms of the nature of the questions that came back, I think it's within the kinds of conversations we've had with FDA over the years. And so, I think our teams are working on it. I don't see commentary that I would signal to you one way or another either particularly small questions or particularly big ones. I think it's right down the middle.

With regard to potential applications over time, I think general interest in Sp is high. What's exciting to me and I think one of the things that made us excited to investing in the first place is that it allows an approach to entry into the body that's a little more flexible than multi-port approaches. And I think that will open some opportunities in the future for surgeons who are looking for alternatives.

Of course, that takes time. We'll have to do protocol development and data collection to get additional clearances as needed, but that was not unanticipated. That was part of what we had thought in terms of investing in the platform. This year will be a limited launch as we build volume and as we start to do things like enabling the proctor network and pursuing the sequential indications that we've talked about. So far so good. I think the team is on plan. I think the clinical response we've been getting from surgeons who are evaluating the data and looking at the basic architecture looks really good.

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

Okay. Thank you very much.

Operator

Our next question comes from the line of Amit Hazan with Citi. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Hey. Good afternoon, guys. Just want to ask couple guidance questions and then one other for Gary. First on the procedure guidance, just trying to understand the changes that you move the numbers modestly but not too much that this was the toughest comp you had all year. You put up a nice 15% right at the top of your prior guide. Your installed base growth is still at 13% here, holding really nicely. Just trying to understand what you're thinking about at the midpoint and low end of that guidance now. Is it OUS returning to 20% type growth or what else should we be thinking about towards the low-to-mid end of procedure guidance?

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

Yeah. The elimination of the low end of the range reflects our Q1 performance, including the continued growth in general surgery, colorectal, U.S. kind of on pace with trends we saw in 2017. We also benefited from growth in, again, mature gynecology, urology procedures. Our current guidance assumptions at the low end on the U.S. side probably in gynecology shifting over to a low-single-digit decline, which we think is aligned with the overall benign hysterectomy market, moving to low-single digit in urology growth and then some moderation within general surgery, mostly reflecting a lot of big numbers with some modest contributions in thoracic, bariatrics and other earlier-stage procedures.

OUS, no system quota in China to the extent that's going to add capacity and kind of a slower ramp in Japan with the new procedure set. On the high end, still maintaining the trends in gynecology with low-single-digit growth. Urology maybe just minor moderation there to mid-single-digit growth, and very select moderation in U.S. general surgery, and continued nice trends in bariatrics and the emerging procedures. We do expect some moderation in China, but probably less so at the high end of the range.

Q - Amit Hazan {BIO 6327168 <GO>}

Good color. And then kind of burning question here that we haven't asked in a while for Gary. I just want to ask, so given the success you've been experiencing, what's the biggest risk you see for the Intuitive story today?

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

I guess, I'd start with I think the opportunity for the use of advanced technologies to help surgery is really substantial. And there are both a lot of interesting scientific advances in the space we're in and there's a lot of need. I think, as always, there's kind of two or three risks that an organization like ours, I think, has to manage.

One of them is, I think, the day-to-day operations that are required to supply your customers can keep you from making the long-term investments you need to keep advancing the yard. And so, we manage that firmly, but I think that you need to do both. And I think that we'll have missed a serious opportunity if the systems that are in the world a decade from now look like today. So, I think that there's real opportunity for advancement. So that's one.

I think the second thing that's just vital is that these things are complex technologies. They absolutely require outstanding human beings and human capital. And they need to be brought into a company that has a culture of satisfying the customer and of performance. And so, I think washing out culture with growth can be something that is a problem, and we need to attend to it.

And I think the last thing is that healthcare is local. I think that when we want to make progress outside the United States, it takes a deep understanding of the countries that we're working in and real skill and capability there. The metal may look the same, but the healthcare system and the way it values products differs. And I think that being too shallow in those assessments can lead to risk and underperformance. And if we underperform, then others will satisfy the need. So, those are kind of the big three for me.

Q - Amit Hazan {BIO 6327168 <GO>}

Very good. Thank you.

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

Thanks, Amit.

Operator

Our next question comes from the line of Richard Newitter with Leerink Partners. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thanks for taking the questions, and congrats on the quarter. I just wanted to clarify on the comments with respect to guidance and how China fits in. I think, Calvin, you said China utilization or growth slowed in 1Q, as you had called out previously. If the current level of China growth were to hold and persist for the rest of the year, is there still a way for you to get to the upper end of your guidance, assuming no quota? In other words, how dependent on China with where your run rate is now with your latest data point to hit the upper end of your guidance?

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

No, I think it'd be possible. Again, I think again we are calling for some moderation in China and just order of magnitude, right? The U.S. business general surgery is our largest category in the U.S. Gynecology is a large set of procedures in that mature category, as is urology. So I think those just have larger basis of business that kind of – things impacting them are going to have a bigger impact at least on this year in terms of the growth rates and guidance.

Q - Richard Newitter {BIO 16908179 <GO>}

Okay. Thanks. And maybe just one follow-up an earlier question on bariatric. One of the things that we continue to see in this market is the adoption of sleeve gastrectomy at the expense of gastric bypass. And I was just wondering, are you guys feeling like the application of the robot has a bigger appeal or bigger unmet need in either one of those two? And can you succeed if the world goes the way of sleeve gastrectomy? Thank you.

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

I understand the question right that the difference in suturing is a lot in terms of the amount of suturing between those two. I think it's too soon to tell right now what kind of the value statements are going to be in bariatric surgery over time. Like I said, I think there's some core interest here. The procedures are taxing on surgeons. They're a demanding procedure. And there are differences between those two techniques. I think, stay tuned is really the short answer here. We'll let it play out over the next few quarters and report back.

Q - Richard Newitter {BIO 16908179 <GO>}

Thank you.

Operator

Our next question comes from the line of Rick Wise with Stifel. Please go ahead.

Q - Rick Wise {BIO 1490589 <GO>}

Good afternoon, Gary, and thanks for the awesome quarter. Just two questions from me. Maybe just a little more color on hernia adoption, hernia outlook obviously it continues to go great. Just curious from your perspective, what inning do you think we're in, in terms of robotic adoption? How sustainable is this kind of growth you're seeing over the next few years? And maybe a little color on, is this, I assume, largely driven by incisional at this point. Or is the inguinal catching up? Can you just help us reflect on the drivers as you look out over the next few years?

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

Sure. This is Gary. I think we're still in the early part of the game. I don't know exactly what inning and whether there'll be extra innings or not, but we're not in the first inning. It's now becoming evaluated fairly broadly.

Inguinal has been the primary driver in the hernia space to-date. We think incisional hernias are also an opportunity, and that may rise in the future relative to inguinal. So, you know, so far so good. We look at, of course, clinical publications and presentations and value statements as reported by clinicians, we also look at reorder patterns and use. Are they trialing, are they sticking with it? And so far, the performance in terms of ongoing use and stickiness, sticking with the procedure once they've tried it is quite good in inguinal hernia repair, and that's a good sign for us. So, we think we bring real value here, and our customers seem to report back as much. We look forward to the next several quarters.

Q - Rick Wise {BIO 1490589 <GO>}

Yeah. And just last for me, Gary. You've been kind enough in the past to be, I think, very frank and direct about the competition, looming competition. And just I'd be curious to hear your latest thoughts. The two larger companies since we last spoke in this kind of context, one of the competitors seems to be delayed. You now have a smaller competitor approved in U.S. and Europe. Just curious how all this is changing or affecting the market or selling discussions. Is it slowing down or is it a positive? Is there a slowdown? Again, any updated perspective would be very welcome, and thanks again.

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

As we said before, I think that the need is clear and I think that the opportunity afforded by the kind of the core technologies that are available are also clear now, have become clear. I think customers are always interested in choice. We can provide them choice within our ecosystem, but they'll look for choice outside that ecosystem also, and I anticipate it. And my response to customers when they ask is, they should evaluate the alternatives. I guess what I would say is, the hardest thing to compete with is the power points that don't yet exist in a product. There're concepts that can't really be evaluated. I think in general, the existence of competition validates the space. I think that it signals to surgical societies the broader acceptance of the concept itself. I think that's generally positive.

I think these organizations out there that are large and small are staffed by capable people. And I think that they're going to work hard and look at alternatives. And to the

extent that they come up with some really strong ones, I think that'll change what's happening at our customer base, but so far so good.

I haven't seen product concepts so far that Intuitive hasn't either considered and built or considered and consciously passed on. It doesn't mean that we're not wrong. We could be, but I feel like we have a good team. I think our team thinks about these problems holistically and from the customers' perspective. And if we continue to do that, I think we'll be well-positioned vis-à-vis competition.

Q - Rick Wise {BIO 1490589 <GO>}

Appreciate that. Thank you.

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

Thanks, Rick. One last questioner, please.

Operator

And that question will come from the line of Isaac Ro with Goldman Sachs. Please go ahead.

Q - Isaac Ro {BIO 15121543 <GO>}

Thanks, and good afternoon. Appreciate that. So, a quick follow up on the outlook in Asia, specifically Japan and China. So, in Japan, wondering if you're expecting any meaningful uptick in system placements with the new reimbursement in place. And, the reason for asking is, it seems like you had a fair amount of what I would call idle capacity for existing placements prior to the updated reimbursement. So, I'm wondering if you'd help us nab back what the new reimbursement means for incremental system demand.

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

Yeah, I mean, we mentioned in our comments, Isaac, we're expecting it'll probably be modest. We've got nearly 300 systems in Japan currently. And so, I think, there's a lot of capacity that can be applied to this new set of procedures. These set of procedures is going to involve a process here of bringing up the teams and going through training and gradually building as we gain experience and confidence. So, I don't think there's going to be a tremendous need to expand capacity here in the early days. It is true that some of these new procedures in the general surgery and thoracic categories can definitely benefit from our fourth-generation technology, Xi technology. There'll be some interest on the part of some folks to upgrade to the newer models. But for us right now, I think it's really about building the foundation clinically in the market. And like we always say, eventually the capital will follow but we're not predicting anything too dramatic this year.

Q - Isaac Ro {BIO 15121543 <GO>}

Okay. Thank you. And then on China, just a follow up there. It sounds to us like there will be a hopefully some kind of update at the federal, national level with essentially a number, if you will, for the new quota. But can you help us think through your

understanding of how that number will then disseminate to the provincial level and eventually convert to orders and revenue, whether it be the order of process, how it varies, timeline, anything to help us understand the translation of the quota to actual action?

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

It's a negotiation that occurs between the central government and the provinces. So, we're not privy to that negotiation and I don't really understand or know what the timetable is. I can tell you that last time a quota was approved that it took several quarters for it to translate into any kind of sale to us. So, if you recall, the last quota we got was around 2013 and yet we sold most of the systems at the end of 2015. So, you go through that negotiation between central government and the provinces and then you also then have a tender process with each hospital at the end of it and that takes time.

Q - Isaac Ro {BIO 15121543 <GO>}

Understood. Thank you.

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

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

This concludes today's call. I 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

And ladies and gentlemen, that does conclude today's conference. Thank you for your participation. You may now disconnect.
