Q4 2017 Earnings Call

Company Participants

- Calvin Darling, Senior Director of 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
- Lawrence Biegelsen, Analyst
- Robert Adam Hopkins, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Surgical Q4 2017 Earnings Release Conference Call. At this time, all participants are in listen-only mode. Later, we will conduct a question-and-answer session, and instructions will be given at that time. As a reminder, today's conference is being recorded.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon and welcome to Intuitive Surgical's fourth quarter earnings conference call. With me today, we have Gary Guthart, our President and CEO; and Marshall Mohr, our Chief Financial Officer. Note that Patrick Clingan, who has participated on these calls in the past, will not be joining us today. Patrick's scope of responsibilities in the company has grown over the past couple years, and going forward, he will be dedicating less time to Investor Relations.

Before we begin, I'd like to inform you that comments mentioned on today's call may be deemed to contain forward-looking statements. Actual results may differ materially from 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 6, 2017, and 10-

Q filed on October 20, 2017. These filings can be found through our website or at the SEC's EDGAR database. Prospective 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 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 fourth quarter results, as described in our press release announced earlier today, followed by a question-and-answer session. Gary will present the quarter's business and operational highlights. Marshall will provide a review of our fourth quarter financial results, then I will discuss procedures and clinical highlights and provide our 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. As you know, Intuitive is dedicated to the mission of expanding the availability of minimally invasive surgery, increasing its efficacy and decreasing its invasiveness. The fourth quarter concluded a solid year in pursuit of this mission.

During the year, we made progress in several areas, including accelerated use of our systems and the related growth in our installed base, along with the achievement of significant milestones and regional market access and product development. While we're pleased with our progress in the year, the opportunity for improvement in surgery is substantial, and much work remains to be done.

Global procedure growth was strong at approximately 17% in the fourth quarter and 16% for the full year. Growth patterns in procedures were largely consistent through the year, with increased use of da Vinci in general surgery in the United States, continued growth in urology in Europe and Japan, and multispecialty growth in Korea and China.

General surgery growth was led by hernia repair and colon resection, while mature procedures in the United States, particularly prostatectomy, outperformed our expectations, predominantly due to macro trends in the prostate cancer market. Procedure growth in several countries, including Germany, Korea and China, was healthy through the year, and adoption in Japan was solid for those procedures that have been reimbursed.

This month, the Ministry of Health in Japan listed for reimbursement 12 procedures in which da Vinci could be used in addition to prostatectomy and nephrectomy, which are already reimbursed. While this is clearly a positive step regarding interest in da Vinci procedures in Japan, the final level of reimbursement has not been communicated. Calvin

will review procedure trends and Marshall our progress in Japan in greater detail later in the call.

Turning to capital placements, we expanded our da Vinci System offering this year with the launch of our da Vinci X Surgical System, a response to customer need. da Vinci X delivers our fourth generation robotics, imaging and fully articulated instrumentation, an attractive – at an attractive entry price and procedure capability with logical upgrade pathways.

Reception to X has been positive, catalyzing interest in robotics programs in price-sensitive markets. Taken together, our generation 4 products, da Vinci X, da Vinci Xi and our future da Vinci SP, which is not yet cleared, represent a balanced and upgradable portfolio of choices for customers building or expanding their robotic surgery programs.

Overall, our capital placement performance in 2017 accelerated relative to 2016, with growth in total placements rising 27% from 537 in 2016 to 684 in 2017. Net of trade-ins and retirements, our da Vinci installed base grew 13% over 2016 from 3,919 to 4,409. U.S. capital placements stood out in the year and the fourth quarter, largely driven by growth in general surgery. European placement performance in the fourth quarter was strong. Placements in the fourth quarter in Japan were also healthy, perhaps a one-time uptick in anticipation of broader reimbursement. Capital placements overall had been lumpy, and we anticipate volatility in placements in 2018.

Operating performance in the fourth quarter and for the full year exceeded our expectations, with strong performance in manufacturing efficiency, product quality, and cost-reduction projects, and with the average selling prices as expected. Investments to deepen our regional capabilities and to develop new technologies and services were important in the past year. As our business strengthened, we increased some investments through 2017 to strengthen our corporate infrastructure and position us to benefit from increased scale.

Turning to highlights of our fourth quarter operating results, procedures grew approximately 17% over the fourth quarter of last year. We shipped 216 da Vinci Surgical Systems, up from 163 in the fourth quarter of 2016. Revenue for the quarter was $892 million, up 18%. Pro forma gross profit margin was 72.3% compared to 71.1% in the fourth quarter last year. Instrument and accessory revenue increased to $457 million, up 18%.

Total recurring revenue in the quarter was $618 million, representing 69% of total revenue. We generated a pro forma operating profit of $384 million in the quarter, up 20% from the fourth quarter of last year. Pro forma net income was $298 million, up 23%, and we concluded our accelerated share buyback program initiated in Q1 of 2017 at a weighted average price of $310 per share.

Highlights of the full year 2017 are as follows: procedures grew approximately 16% over 2016. We installed 684 Systems in 2017, up from 537 in 2016. Revenue for the year was $3.1 billion, up 16%. Pro forma gross margin was 71.9% for the full year, compared with 71.6% for 2016. Total recurring revenue for the year was $2.2 billion, representing 72% of total

revenue. Pro forma operating profit for the year was $1.3 billion, up 13% from 2016, and pro forma net income was $1 billion, up 19%. Marshall will take you through our finances in greater detail shortly.

While Intuitive completed its 22nd year in 2017, I firmly believe that computer-assisted medical interventions are in their infancy. A careful read of the clinical literature makes clear the need for more effective, less invasive, and lower total cost to treat solutions to many disease states. The rise of robotic technology, powerful computing, improved sensing, micro fabrication and molecular imaging enable new approaches to old problems.

We have been investing in improvements, both incremental and revolutionary, towards the same and anticipate continuing this investment trajectory in 2018. The opportunity to improve surgery using advanced technologies is now recognized broadly, and we anticipate the entry of additional competitive systems into some regions of the world over the next several quarters.

Customers appreciate choice, and it is possible that sales cycles lengthen in some countries as customers evaluate more options. Our company has anticipated increased competition, and we are focused on understanding the market's needs and excelling in delivering products and services today and in the future that meet them.

Turning to our da Vinci SP System, we submitted our 510(k) for urology last month. Recall SP is a platform technology that allows high dexterity access with great 3D vision to confined surgical spaces. As we've discussed on prior calls, we plan first markets to include urologic surgery, head and neck surgery, and colorectal surgery. In 2017, SP was used in human trials in the United States and Hong Kong, completing cases spanning initial target procedures. We anticipate a phased launch of SP in 2018 pending clearance.

We are also making good progress on our flexible robotics platform, first targeted to address the acute need in diagnosis of lung cancer, one of the most commonly diagnosed forms of cancer in the world and for which early detection is important. Our program hit its milestones in 2017, completing its first clinical experience in Australia. Preliminary results were reported at the CHEST conference in Q4 of 2017. Feedback from physicians evaluating our technology relative to existing and emerging alternatives has been strongly supportive of our efforts.

Our design and operations teams are working hard to incorporate feedback, complete its production design and supply chain optimization, and complete validations for regulatory submissions. We do not expect revenue from our flexible robotics program in 2018.

Our fourth generation product platform has enabled greater access to our latest advanced instruments. Use and satisfaction with our stapling and energy products has been rising, as gen 4 products have increased in the installed base. Both stapling and energy instruments are important to surgeons, and we've been investing in broadening our product line and incorporating customer feedback in both areas. In the fourth quarter

of 2017, we submitted our 510(k) application for our 60-millimeter stapler for da Vinci X and Xi.

Lastly, our imaging teams continue to explore new ways to identify tissue, including good progress in our molecular imaging program, as well as improvements to our endoscopes and image processing algorithms. We've been introducing improvements in our imaging hardware routinely and expect to continue to do so in 2018. Molecular imaging agents are long-term investments. We expect our lead agent to enter Phase 2 trials in 2018.

In closing, as we start 2018, our focus remains in completing the task we've 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 diagnostic platform; and finally, support for additional clinical and economic validation by global region.

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

Marshall L. Mohr {BIO 5782298 <GO>}

Good afternoon. Overall, our fourth quarter financial performance was strong. I will start by describing highlights of this performance on a GAAP and non-GAAP or pro forma basis. I will also take you through our analysis of the impact of the U.S. 2017 Tax Cuts and Jobs Act on our financial results. As a reminder, our results are also posted on our website.

Consistent with our preliminary press release on January 10, fourth quarter 2017 revenue was $892 million, an increase of 18% compared with $757 million for the fourth quarter of 2016, an increase of 11% compared with the third quarter revenue of $806 million.

In the fourth quarter, we completed the da Vinci X trade-out program offered to certain first quarter customers. The impact of this program was to increase fourth quarter revenue by approximately $2 million, and third quarter revenue by approximately $21 million. As mentioned earlier in the call, fourth quarter 2017 procedures increased approximately 17%, compared with the fourth quarter of 2016, and increased 12% compared with last quarter. Procedure growth continues to be driven by general surgery in the U.S. and urology worldwide. Calvin will review details of procedure growth later in this call.

Instrument and accessory revenue of $457 million increased 18% compared with last year, which is slightly higher than procedure growth. Instrument and accessory revenue realized per procedure was approximately $1,910, which is relatively unchanged compared to last year, reflecting increased advanced instrument usage, mostly offset by customer buying patterns.

Systems revenue of $283 million increased 20% compared with the fourth quarter of 2016, primarily reflecting higher System placements. We placed 216 Systems in the fourth quarter of 2017, compared with 163 Systems in the fourth quarter of 2016, and 169 Systems last quarter. 40 Systems were placed under operating lease transactions in the current

quarter, compared with 13 Systems in the fourth quarter of 2016. Systems placed under operating leases represented 19% of System placements compared with 8% last year. Our installed base of da Vinci Systems ended the year at 4,409 Systems, up 13% year-over-year. Consistent with recent trends, average system utilization continues to grow in the mid-single-digit range.

Globally, our average selling price, which excludes the impact of operating leases and lease buyouts and revenue deferrals, was approximately $1.47 million, which is similar to the fourth quarter of 2016 and the same as last quarter. 51, or 24% of Systems placed in the quarter were da Vinci X Systems, compared with 16 or 9% of Systems last quarter.

We are seeing demand for da Vinci X from cost-sensitive customers as well as customers wishing to upgrade to, or standardize on, our fourth generation technology. We believe that flexible financing programs like operating leases have allowed us to be more agile in meeting customer needs for Systems. While the number of leases is difficult to predict in the short term, we expect the proportion of these types of arrangements will increase over time.

Outside of the U.S., results were as follows. Fourth quarter revenue outside of the U.S. of $248 million increased 17% compared with both the fourth quarter of 2016 and the third quarter of 2017. OUS procedures grew approximately 21% compared with the fourth quarter of 2016. Outside the U.S., we placed 86 Systems in the fourth quarter, compared with 63 in the fourth quarter of 2016, and 62 systems last quarter. Current quarter system placements included 47 into Europe and 22 into Japan. 25 of the 47 Systems placed into Europe were X Systems. Placements outside of the U.S. will continue to be lumpy as some of the OUS markets are in early stages of adoption, some markets are highly seasonal reflecting budget cycles or vacation patterns, and sales into some markets are constrained by government regulations.

As Gary indicated, a committee of the MHLW in Japan has recommended 12 procedures for reimbursement. It is anticipated that by the end of this quarter, MHLW will determine the reimbursement levels for each procedure. The applicable opportunity for da Vinci surgery within this set of procedures is difficult to estimate at this time due to the uncertainty in reimbursement levels, as well as the perceived value of da Vinci relative to alternative surgical approaches. With nearly 300 systems installed in Japan, the level of system expansion over the next year or so is difficult to predict. We expect system expansion in Japan to be modest in 2018.

Moving on to the remainder of the P&L. The pro forma gross margin for the fourth quarter of 2017 was 72.3%, compared with 71.1% for the fourth quarter of 2016, and 71.8% for the third quarter of 2017. The increase compared with the third quarter primarily reflects lower manufacturing costs, partially offset by seasonally higher proportion of Systems revenue. Future margins will also fluctuate based on the mix of our newer products, the mix of Systems and instrument and accessory revenue, System ASPs, and our ability to further reduce product costs and improve manufacturing efficiency.

Pro forma operating expenses increased 19% compared with the fourth quarter 2016, and increased 13% compared with last quarter. The increase compared with the third quarter reflects increased variable compensation. Our spending was consistent with our plan, reflecting investments in da Vinci SP, catheter-based robotics, imaging and advanced instrumentation, and expansion of our OUS markets. These investments involve multiyear commitments.

Our pro forma effective tax rate for the fourth quarter was 24.9%, compared with our expectations of 26.5% to 28.5%. I will take you through the items included in our GAAP tax rate, including the impacts of the U.S. Tax Act in a minute. Our tax rates will fluctuate with changes in the mix of U.S. and OUS income, changes in tax rates made by local authorities, and with the impact of one-time items.

Our fourth quarter 2017 pro forma net income was $298 million, or $2.57 per share, compared with $242 million, or $2.03 per share, for the fourth quarter of 2016, and $324 million, or $2.77 per share, for the third quarter of 2017. All per share amounts reflect the 3-for-1 stock split effected in October.

Third quarter 2017 GAAP and pro forma net income per diluted share benefited by $0.09 per share from the recognition of $21 million of deferred revenue, net of costs and income tax, and by $0.59 per share related to the tax reserve reversal of $68 million.

I will now summarize our GAAP results. Inclusive of the impacts of the U.S. Tax Act, we incurred a GAAP net loss of $39 million, or $0.35 per share, for the fourth quarter of 2017, compared with GAAP net income of $204 million, or $1.71 per share, in the fourth quarter 2016, and GAAP net income of $298 million, or $2.55 per share, for the third quarter of 2017.

The following items are excluded from our fourth quarter pro forma net income but included in our GAAP net loss: $270 million, or $2.41 per share, reflecting a 14% one-time tax for historical OUS earnings and profits under the U.S. Tax Act; $48 million, or $0.42 per share, for the write-down of net deferred assets to reflect the reduction in corporate tax rates under the U.S. Tax Act; $20 million, or $0.18 per share, of excess tax benefits associated with employee stock awards; and $57 million of net charges, or $0.51 per share, associated with employee equity charges, IP charges, and legal settlements.

Note that the IRS has not issued final tax rate regulation associated with the recent U.S. tax legislation. Therefore, impacts of the U.S. Tax Act reflected in our fourth quarter results and our projection of future tax rates represent our best estimates of the impact of the U.S. Tax Act and could change as tax regulations are finalized and interpreted. We ended the quarter with cash and investments of $3.8 billion, approximately the same as at September 30, 2017.

During the quarter, cash generated from operations were mostly offset by a final payment of $274 million associated with the accelerated share repurchase agreement we entered in the first quarter. Under the agreement, we purchased 7.3 million shares at approximately

$310 per share. We have approximately $718 million remaining under the Board buyback authorization.

As a result of the 2017 Tax Act, we have the option to repatriate OUS cash with minimal tax impact. We have significant opportunity for growth outside of the U. S. We will evaluate the need to repatriate cash relative to our business and overall environment over time.

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 fourth quarter procedure growth was 17% compared to 15% during the fourth quarter of 2016 and 15% last quarter. Our Q4 procedure growth was driven by strong results globally and 16% growth in U.S. procedures, reflecting broad-based strength across our procedure categories. Q4 likely benefited modestly from cases deferred out of Q3 due to hurricanes.

In total, approximately 877,000 da Vinci procedures were performed in 2017, up about 16% for the year. In the U.S., general surgery, on a run rate basis, has surpassed gynecology as our largest specialty. Approximately 246,000 U.S. general surgery procedures were performed in 2017, up 32% compared to 2016. 2017 growth was again driven by hernia repair, ventral and inguinal combined, which continued to drive the most incremental cases and continued da Vinci adoption in colorectal procedures.

Early-stage adoption in bariatric procedures and growth across the general surgery category also contributed to growth. In U.S. gynecology, fourth quarter and full year 2017 procedures grew modestly year-over-year, with growth led by hysterectomy. We continue to see an increasing proportion of U.S. gynecology procedures being performed by physicians that specialize in complex benign and cancer surgery, who tend to be users of da Vinci Systems. U.S. urology procedures exceeded our expectations for the fourth quarter and the year, 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 strong during the fourth quarter and full year. This set of procedures is particularly well served by our da Vinci Xi System and surgical staplers.

Outside of the United States, approximately 233,000 procedures were performed in 2017, up approximately 21% in the fourth quarter and approximately 23% for the full year. Growth was driven by the continued adoption of da Vinci prostatectomy, with solid contributions from kidney procedures and earlier stage growth in general surgery and gynecology.

Fourth quarter OUS procedure growth was slightly lower, largely reflecting leveling system utilization and moderating growth in China, as we anticipate future system sales

quota. The value proposition regarding any da Vinci procedure is based upon the differentiated clinical value that can be offered to patients compared to other treatment alternatives, including economic factors. Since the introduction of the da Vinci System, over 15,000 clinical papers have been published involving da Vinci surgery, including approximately 2,300 in 2017 alone.

As I mentioned in my procedure discussion, long procedures in the U.S. have contributed to recent procedure growth. In November 2017, a team of investigators from the University of Southern California, the University of Michigan-Ann Arbor, Penn State Health, and Intuitive published a large-scale study titled Robotic-Assisted, Video-Assisted Thoracoscopic and Open Lobectomy: Propensity-Matched Analysis of Recent Premier Data in The Annals of Thoracic Surgery.

In this study, the Premier Healthcare Database was analyzed for open, video-assisted thoracoscopic, or VATS, and robotic-assisted lobectomies performed between January 1, 2011 and September 30, 2015. The results from this study show a continual increase in the number of robotic-assisted lobectomies during the study period. The combined total of robotic-assisted and VATS approaches accounted for more than half of the lobectomies in the U.S. database, indicating a strong trend towards adoption of minimally invasive approaches. While a proportion of VATS remained virtually unchanged during the study period, the robotic rate grew as open declined.

After propensity score matching, which controls for heterogeneity of patients in hospitals, the robotic-assisted cases were compared to VATS procedures in a sample size of 2,775 in each group, and robotic-assisted cases were compared to open with 2,951 patients in each group. Compared to open surgery, robotic-assisted lobectomy demonstrated statistically significant lower postoperative complication rate, shorter hospital stay, higher percentage of patients discharged to home, and lower hospital mortality rate. Compared to VATS, robotic-assisted surgery demonstrated statistically significant lower rate of conversion to thoracotomy, lower postoperative complication rate, shorter hospital stay, and a higher percentage of patients discharged to home.

As we've said in the past, we continue to invest in clinical research in our key geographic markets to assess da Vinci surgery outcomes and help educate the market. We support large-scale data registries, including those managed by the American Hernia Society Quality Collaborative and The Society of Gynecological Oncology Clinical Outcomes Registry. As large da Vinci datasets accumulate in these registries and are compared to baseline results, the value of da Vinci surgery can be evaluated. We also support clinical research grants at SAGES, ASCRS, and the European Coloproctology Society, as well as da Vinci Fellowship Programs with several surgical societies, which often yield clinical studies.

I will now turn to our financial outlook for 2018. Starting with procedures, as described in our announcement earlier this month, 2017 total da Vinci procedures grew approximately 16% to roughly 877,000 procedures performed worldwide. During 2018, we anticipate full-year procedure growth within a range of 11% to 15%.

We expect 2018 procedure growth to continue to be driven by U.S. general surgery and procedures outside of the United States, where we are still in earlier stages of adoption. We expect similar seasonal timing of procedures in 2018, as we've experienced in previous years, with Q1 being the seasonally weakest quarter, as patient deductibles are reset. In Q1, we expect a modest procedure headwind compared to Q1 2017 as a result of our estimates of working days, mostly due to the timing of the Good Friday holiday.

With respect to revenue, as we've mentioned previously, capital sales are ultimately driven by procedure growth, catalyzing hospitals to establish or expand robotic system capacity. Capital sales can vary substantially from period-to-period based upon many factors, including U.S. healthcare policy, hospital capital spending cycles, reimbursement in government quotas, product cycles, and competitive factors. Within this framework, we'd expect 2018 capital placement seasonality to generally follow historical patterns by quarter. During the fourth quarter of 2017, 40 of the 216 systems shipped, or 19%, were under operating leases. In 2018, we'd expect the proportion of systems placed under operating leases to trend modestly up from there, with variation by quarter.

Turning to gross profit. Our full year 2017 pro forma gross profit margin was 71.9%. In 2018, we expect our pro forma gross profit margin to be within a range of between 70% and 71.5% net revenue. We're projecting a modestly lower gross profit margin in 2018, reflecting higher costs associated with new products. Our actual gross profit margin will vary quarter-to-quarter, depending largely on product and regional mix.

Turning to operating expenses. As Gary and Marshall described, in 2018, we will continue to make substantive investments in several strategic areas that are poised to benefit the company over the long run. As a result, we expect to grow 2018 pro forma operating expenses between 16% and 18% above 2017 levels. We expect our non-cash stock compensation expense to range between $225 million and $235 million in 2018, compared to $209 million in 2017. We expect other income, which is comprised mostly of interest income, to total between $45 million and $55 million in 2018.

With regard to income tax, incorporating projected impacts of the new U.S. tax law, we expect our 2018 pro forma income tax rate to be between 20% and 22% 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.

Our share count for calculated diluted EPS pro forma EPS in Q4 was 117.4 million shares. In Q1, we expect our diluted share count to range between 117.6 million and 118.4 million shares. The actual diluted share count will depend on several factors, including the share price.

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

Q&A

Operator

And our first question today comes from the line of Bob Hopkins with Bank of America. Please go ahead.

Q - Robert Adam Hopkins {BIO 2150525 <GO>}

Thanks very much. Appreciate the opportunity to ask a few questions here. So maybe just to start out on the product side. Just want to make sure I have a good sense for what you're saying. So, Gary, I guess on the flexible endoscope platform, I realize you said no revenues in 2018. But is there a scenario where you have any regulatory approvals for flexible endoscope in any major country maybe towards the end of 2018?

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

We're not – hi, Bob. We're not calling the clearance date yet of the flex platform. I'm pleased with where we are. We're working the plan. Our tradition with you has been to let you know when we do a submission, and that gives us a little bit better estimate of timelines, and I'd rather not guess in this setting. So, we're feeling good about it, but I don't have a date for you yet.

Q - Robert Adam Hopkins {BIO 2150525 <GO>}

Okay. Feeling good about it, does that mean the potential for submissions in 2018?

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

No, I'm feeling good about the progress of the team and their ability to deliver on what we think this is capable of doing.

Q - Robert Adam Hopkins {BIO 2150525 <GO>}

Okay. And then on your comments on Japan, I'm just curious, what do you assume for Japan in the current 11% to 15%? And maybe said another way, if reimbursement comes in the way you would hope, does that suggest the potential for the higher end of that 11% to 15%?

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

We haven't baked a lot of growth in there. Again, we don't really know at this point what the reimbursement levels are going to be. And therefore, that could vastly impact the number of the procedure adoption curve. So, there's not a lot in there, but even then, the magnitude of Japan relative to the total world is not substantial. And the highest growth drivers for us for next year really are general surgery procedures in the U.S. and urologic procedures outside of the U.S.

A - Calvin Darling {BIO 17664656 <GO>}

And with these clearances, Bob, or reimbursements, I should say, it's really – it's going to be building a foundation time for us. There's going to be large investments made, or we have been baking, and we're going to follow through on the things like training surgeons and building the teams up to speed. So it's really more about building a foundation here for the future in 2018 than a substantive contribution to the growth.

Q - Robert Adam Hopkins {BIO 2150525 <GO>}

And then Gary, just real quickly, given the success you've had as a company in 2017 on the procedure side, I want to ask one quick question on how you view the market opportunity, because in 2016 to 2017, your slide decks talked about 4 million accessible procedures worldwide for approved technologies. And I'm just curious if you could update us on your latest thoughts on kind of the addressable procedures, where you stand today relative to that 4 million, given that you've got SP coming, along with obviously other technologies.

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

Yeah. Yeah, fair question. As you described, I think the – for current products in the market and current countries in which we operate, I think our estimates are that we're under – we're not yet a quarter penetrated. So even with what our commercial teams have to do, we have plenty of upside.

I think as you move – whenever you talk about total available market, I'll tell you how we think about it. We look out and start with where do we see differentiated clinical value by procedure, given what we can bring and try to get an estimate of what segment or population of our customer base that can make a positive impact. And we, you know us, start conservatively. And what tends to happen over time as we get into those, history has been that as we get clinical data and our customers use our products, we get a better, clearer view of TAM. Often, the TAM has increased, not always. Some TAMs have decreased, but mostly they've increased. And so that's how we look at it.

SP is clearly an opportunity for us to explore some procedures in patient populations that we have not done a lot in, and that, I think, is why we're excited about it. And flex, I think, opens a new set of opportunities for us. That's why we have done the investments. I think flexible technologies we are pursuing in the pulmonology space and the thoracic cavity, and we'll be focused on that for the next few years. But as you know, we're really excited about platform ideas, things that have generic capability that can be broadened over time. And we think flex robotics, diagnostics, and other interventions can do that as well.

We don't have a crystal ball as to those TAMs, and we're not ready yet to describe how big we think they can be in part because our estimates are large ranges, could be quite a lot of variability. But we invest in them because we think they bring the real opportunities for outcome improvements in the hands of our customers, decreases in variability across the customer base, and as a result, an opportunity to grow the footprint of Intuitive going forward.

Q - Robert Adam Hopkins {BIO 2150525 <GO>}

Fair enough. Thank you very much.

Operator

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

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

Good afternoon. Few quick questions for me. First, Gary, just coming back to the pipeline, just on SP, is there a chance we get additional label approvals or submissions for head, neck and colorectal this year on SP? And is second half of the year a decent time for him to think about the 40-millimeter stapler approval?

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

Yeah, so let's go to the – I think you meant 60-millimeter stapler. On the SP front, not ready to call timing on labeling – additional indications. We'll pursue them with FDA over time, and depends a lot on what kind of data requirements we have and how that conversation goes. We're focused right now on the first one. And in terms of clinical capability and customer feedback, we're feeling quite positive. And so I think the conversation with FDA should be pretty direct and grounded. Predicting the timeline, we're not ready to do yet at this time.

On the 60-millimeter stapler, that's a set of products that we have gone back and forth over the years with approvals. I don't think it's wildly different in terms of what we can expect, and I think historical timelines for approvals for us are probably good predictors of what happens on the 60-millimeter stapler. So, I'm hopeful that we'll see it this year.

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

Okay. And just a couple more for me, Gary, just one on spending. I think that you're wisely investing away some of the tax benefit, but year-on-year, it's probably $150 million of incremental OpEx and probably $50 million more than we expected for 2018. If you could just sort of give us a sense of where some of the key investment dollars are going here in 2018?

And then you mentioned this last quarter, but not this quarter, in terms of hiring the management team for the China JV, where are you on CEO, CFO? And what are their near-term priorities?

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

Great.

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

Thanks so much.

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

Yeah. Fair question. On the investment side, as the businesses strengthened over the last couple of years, we've increased our investments, I think, rationally. They have been focused on a couple of things. One has been building depth in OUS markets, our market presence and penetration in places like Japan and China and Germany, France, U.K. and so on are less than they are in the U.S. We think there is real opportunity for value creation

in those markets. We want to make sure that we're not underinvesting there relative to the opportunity. So that's one segment.

The next segment is, I really believe, computer-assisted surgery, I think, has moved from an interesting part of minimally invasive surgery department to a kind of an essential part of the portfolio. And as that happens, I think more and more opportunities, competitors, and interest is being generated, and we want to make sure that Intuitive is investing for the long term. And I think you all will hold us to the quality of those investments. Mostly, the challenge here has not been identifying opportunity. It's been making sure that if we invest in something, that we have the skill and capabilities to deliver it with excellence. And so we've been investing behind things that we think are good opportunities, and I think over time, the wisdom of those decisions will play out. So that's kind of mark two.

I think the last thing for us has been, as the business has accelerated, we see opportunities for taking advantage of scale and efficiency, and we think that will serve the company well and our customer base well in the future. So as volumes go up, we can convert some capital investments into operating efficiency. You've seen us doing that, and I think that that allows us to share with the customer some of those efficiencies that drives better quality performance in our products. We think that's important as well. And so we've – as we've seen strengthening, we've loosened some of those dollars, and I have to thank our operations team who've done a beautiful job investing them wisely.

Marshall, why don't you take the JV and China question, and I'll fill in behind.

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

Sure. In China, we have hired a CEO. We actually have also hired a CFO and a few other key members of the management team. Right now, they are focused on building out that management team and getting prepared for eventual launch of the business itself. Of course, the gating factor there is we're still working on the development of the catheter-based product here in the United States. And as that's completed, then elements of it in the business will start to be handed over to the JV.

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

The early performance of that team as they've entered our organization is encouraging. The human capital that they bring to the board looks pretty strong. So that has been a positive step for us in 2017.

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

Thanks so much.

Operator

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

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

Hey, thanks. I guess, first question on Japan. I know you don't want to comment on reimbursement levels at this point. It's a bit of a waiting game here. But if we think about the 12 procedures that you got approval for, are there ones you want to call out that may be more exciting than others? And maybe could you talk about what percentage of those are done open versus lap across the 12 that have been approved?

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

Well, it's hard to characterize which ones you're most excited about when you don't know what reimbursements are going to be. So I – you've seen the list, and I think you can size yourself what you think the market opportunity might be. But again, to caution you that until reimbursements are announced, we're really not going to know. And as Calvin said, there's also an element of adoption in terms of – that will take place in terms of building out the sales force, building training capabilities and so forth.

There's also the – as I said in my script, there's the alternate surgical approaches that may be used, that you also have to deal with in adoption. So I think, once we understand reimbursement and we start to dig into it a little bit more after April 1 is when we'll know that, maybe we can start to talk a little bit more about the specific procedures.

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

For me, just looking at the clinical side, I think there are a few things that are pretty exciting in the underlying dynamic in conversations that surgical societies have been having. First, Marshall had mentioned that laparoscopy is fairly penetrated in some of the markets in Japan. Laparoscopic surgeons are quite capable and skilled in that market. And yet we continue to have quite strong interest in the use of our technologies there.

And I think that's a positive development for us. It indicates that they are looking for clinical improvements and tool improvements over time. And so things like hysterectomy, I think, are interesting for us. Hard for us to predict exactly what will happen. It's a highly penetrated laparoscopic procedure with various skilled surgeons in Japan. And yet the interest is quite high, and that was one of the things that was studied pretty deeply. And so I personally am excited to see how that unfolds over time.

It will change, as to Bob Hopkins' earlier question, how do you think about TAM? Japan is a great example of thinking through how do you do these TAM calculations, because we'll see what the mix is with regard to laparoscopy versus robotics. But I'm excited to see how that unfolds. There are thoracic opportunities in the reimbursement as well and other things in geo-oncology. So I think there are several things in there that, in the mid to long term, I think will be really exciting for us in Japan. I think the Japanese surgical societies and Japanese surgeons are thoughtful and deep, and that will be a great market to serve.

The one caution you've heard us say several times is that it's more than reimbursement. We have to have the technology training pathways and resources in place. The proctoring networks will be built over time. Our sales team has to get deep with our customer. And

so the near term, there is some hard work and sleeve rolling to go do. That would not diminish my enthusiasm for the long term.

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

Okay, that's helpful. And then a question on older systems, kind of two parts here. One, you had a big o-U.S. trade-in number. Was that just a function of the end of the X trade-in program? And then you're still selling a number of Si Systems. I think it was 20 this quarter. Why are customers opting for that versus the X?

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

Yes. I'll answer the last one first. And for Si product, there are countries where we do not yet have regulatory approval for X, and therefore, we're still selling Sis. There's also some customers have Sis already, and they don't want yet to move away from – or move into a world where they have two sets of inventory and two sets of training protocol and so forth. And so they would rather step into an Si. And then there are some countries where reimbursements are not so high, and they're looking for the cheapest product they can get, and an Si refurb fits that bill. But you probably will see the number of Sis we sell decline over time going forward as we get regulatory approvals, and we're able to move Xs.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, on the system retirement side, I think there were 21 total, 18 retired in the field plus three that were lease returns. It's been higher than we've been running, but it's really an expected part of our business cycle. And as you know, when a customer elects to stop using a particular system, they're usually going to trade it in, purchase a new system or just retire it out there in the field, and most of them end up being traded in, but some will end up being retired in the field, and we saw that. In Q4, we're able to confirm that there were 18 of these over 4,400 systems in the field, mostly older models, who are no longer being used, so we just removed them from our installed base count.

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

Okay.

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

And I think you were also asking about Europe and the trade-ins in Europe, is that correct?

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

Yeah.

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

Yeah. Trade-ins in Europe, even despite what I said about some customers want – don't want to enter into a world where they have two sets of inventory, there are those customers that want to standardize in the fourth generation products, and there's also a

larger installed base of Ss and Sis in Europe in terms of mix relative to, let's say, the United States, and so we did see a number of customers in Europe trade out their Sis for X product, so to get into the fourth generation product and have access then to the latest instrumentation.

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

Okay. And then last one, thinking about the mature procedures, in particular dVP in the U.S., anything in 2018 that would change the trajectory relative to what you saw on 2017? I think you've kind of mentioned you're back to kind of the market growth rate there, but just curious, I mean, I think there's been this expectation that it would decelerate a little bit for a while. Curious as to your thoughts.

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

Yeah, I mean, the results in 2017 exceeded our expectation. Urology was up 8% for the year, and dVP is a big piece of that. So, as kind of the standard for the surgical treatment of prostate cancer, we think that we'd be moving with the overall incidence rate, which is more or like low-single digits. So our expectation within our guidance range at the low end of the high end is some moderation in the U.S. on prostatectomies in 2018.

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

Okay. Thank you.

Operator

And we do have a question from the line of Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the questions, guys. One on China, one in the flex catheter, and just on the tax rate as well. So on the Chinese quota, where are you guys in the process there? Do you have any visibility, and is it still – is it too late at this point to impact 2018? On the flex catheter, Gary, on the last call, you sounded maybe optimistic that the CHEST data would be enough for FDA clearance in the U.S. Do you have confirmation of that at this point or any clarification? And just lastly, Marshall, on the tax rate, I thought it would be a little bit lower than 20% to 22%. Is there some conservatism there given the uncertainty? Or is there something else that we maybe didn't factor into some of the estimates we had? Thanks for taking the questions, guys.

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

Thanks, Larry. Why don't you take that first one, Marshall?

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

Quota? There's no new news on the quota. I mean, we sit here waiting, as do you, for news as to what the quota will be.

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

On China, we don't have any indication that is either, A, Intuitive specific or something that we should be foundationally worried about, so we're not looking at it and thinking something's wrong here or there's an Intuitive specific indication. Nothing works like that. If – you asked the question, is it too late to impact 2018, I don't think so yet. Marshall, looking at you, I don't know how you feel about it.

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

Yeah, it's hard to know how long the tender process will take at the hospitals. Last time we got a quota approved, quota was approved in 2013, and we didn't see many of the systems sold until the end of 2015. I don't know whether that same timeline will apply here.

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

Moving to the flex question. No change in my opinion about data requirements, either way, I wouldn't read anything in my comments last time or this time that would indicate a change. And go to tax...

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

Tax – the tax rate, the rates that Calvin gave is our best estimate. You said that you thought it would have been lower. Clearly, a greater portion of our revenue is still generated in the United States, so more at the higher end. There are – there's the rate itself, the 21%, but then there are other elements of the Tax Act that add additional taxation on top of that. And so we've given you the range that we think will – is the best estimate of what it is. I don't – I wouldn't call it conservative.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Thanks for taking the questions, guys.

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

Thanks, Larry.

Operator

And we do have a question from the line of Amit Hazan with Citi. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Hey, good afternoon. Let me start with gross margin guidance. I think the last two years, you've kind of been nearing that 72% range. FX is now kind of in your favor. You had pretty big capital year last year, that's lower margin. You're kind of implying that might not repeat again in 2018, which is understandable. Seems like very little revenues from new products, like the SP, this year as you're talking about how we should think about the ramp. So, why shouldn't that gross margin number, at the very least, stay consistent with 2017, if not go up a bit?

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

Yeah. I think like we said in the prepared comments, Amit, the primary driver there is going to be impact of new products. And yeah, we are going to do a phased launch of SPs assuming we get clearance there in 60-millimeter stapler like we talked about. And you have the direct margin on the products, but there's investments we make in the lines and the teams and the kind of the structure to make these things that kind of run through on the cost line. It's – a lot of that runs ahead of the higher revenue amounts.

Q - Amit Hazan {BIO 6327168 <GO>}

Yeah. And then just a follow-up on the U.S. trade-in, I'm kind of looking at the year. Maybe a little bit surprised how – I think trade-ins ended the year in the U.S. market actually down 50 units year-over-year, below even 2016 levels. And I realize that's actually a positive for the installed base and for procedures. In terms of just thinking about the replacement opportunity, given an aging installed base in the U.S., how do we best think about the next couple years for trade-in?

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

Yeah. It's hard to estimate when the customers will get to where they want to either standardize on fourth generation product or avail themselves to latest generation. I mean, the Si drives a substantial amount of our procedures. It's a very capable system. And in fact, even in situations where customers have suggested that they want to do a trade-in, at the end of the day, they're keeping the Si for either an outpatient care meaning a point other than the surgery center or they decide that they've just got volumes such that they want to keep it. So, I don't know how to predict what the trade-in cycle would do over the next couple of years.

A - Calvin Darling {BIO 17664656 <GO>}

Directionally, in terms of our intent, we think gen 4 is quite strong. We think X is a good product, and we think we can deliver X to the installed base in attractive economic packages. And so that's an opportunity for us. It's just really a question – I think directionally, we know where it's headed. I think the question is just how long it takes. And we want to support our customers in their needs, but I think we have a good offer for them.

Q - Amit Hazan {BIO 6327168 <GO>}

And just last one. Maybe I heard you wrong on imaging hardware for this year. Just how much more you can tell us on what to expect in terms of timing of new products, if it's possible that they'd be introduced in 2018 like augmented reality, et cetera, and what we might expect there in terms of potentiality?

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

Yeah, fair question. So, you know what, when we think about imaging, there's three buckets that we think about in investments we make. There's the hardware endoscope side, the sensors, the chips, the optics, the package. And we have been investing in that and routinely improving those things, sometimes in big steps, sometimes in small steps.

Just as you would imagine, at each release of a cell phone has better camera systems, we follow a similar idea. And that's been powerful; those compound effects of improvements are pretty impressive.

Second thing is image processing software, the algorithms themselves to shape the image have also been improving over time, and also we can release in patches and updates. And then there's the contrast agents and molecules. And we work all of them. And we often talk about molecules, they're kind of the big thing to see. They are long-term investments. And I was reminding everybody here, there are other things going on, too, that the hardware and the underlying software is good.

Augmented reality and/or mixed reality, the idea that you can take preoperative images, manage them and get them in, we are making nice progress there. I don't expect material revenue in the year, but I do think that we'll start getting increased customer feedback over the year. And as we get close to the customer, we'll inform you more of where we are.

Q - Amit Hazan {BIO 6327168 <GO>}

Appreciate it. Thank you.

Operator

And we do have a question from the line of Isaac Ro with Goldman Sachs. Please go ahead.

Q - Isaac Ro {BIO 15121543 <GO>}

Good afternoon, guys. Thanks. Two questions on Asia, one on China. Just curious what you guys are doing to try and drive penetration while we wait for the quota. Are you better off waiting for the government to give official order? Are there other avenues that you're pursuing to try and drive access?

And then secondly on Japan, just appreciate all the comments you made earlier, but I'm wondering how we should think about market development in that region as you get new applications. Are there a couple obvious ways in which position, training and so forth need to be different, and how we should think about your process there? Thank you.

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

So for China, we have a number of systems, 38 systems, I think, it is installed at the public hospitals that were subject to the quota. But our distributor is driving clinical adoption there, training surgeons, and moving it up. That's why you see – why you've heard us talk about increased utilization of those systems and increased number of procedures. The systems that are not subject to the quota really are those in military hospitals in Hong Kong. We actually sold three systems this quarter. That's not merely the market, the public hospitals, but nonetheless, we are making progress in those markets and continue to try to drive expansion.

A - Calvin Darling {BIO 17664656 <GO>}

And we think demand from Chinese surgeons and Chinese hospitals is very high. And so education and engagement is something that we can continue to do. I'll answer the Japan question, and operator, this will be our last question after that answer.

With regard to Japan, I'd like to quote, history doesn't repeat, but it does rhyme. I think about what we need to do in Japan in terms of market development. Our team in Japan is quite capable. They are engaged deeply with – in communication with surgical societies around what training pathways look like, what educational and course work ought to look like, and things like Fellowship Programs and so on. And so I don't think the work is a mystery.

But it does take time in education, education of our own team and education of the market. I think we have a senior leader in our General Manager in Japan. I think this is a team that's capable. So, we will give them time to make progress here. But I think they have a playbook they can work down. And while it's not identical to the playbook that we used in the U.S. or the ones that we use in Germany, the main elements of engagement are present.

As we conclude this call, that was our last question. As we've said previously, while we focus on financial metrics such as revenues and 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 have 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 your conference for today. Thank you for your participation and for using the AT&T Executive TeleConference Service. You may now disconnect.
