Company Name: Intuitive Surgical
Company Ticker: ISRG US
Date: 2018-01-25
Event Description: Q4 2017 Earnings Call

Market Cap: 50,400.24
Current PX: 449.81
YTD Change($): +84.87
YTD Change(%): +23.256

Bloomberg Estimates - EPS
Current Quarter: 2.069
Current Year: 9.704
Bloomberg Estimates - Sales
Current Quarter: 777.750
Current Year: 3489.941

Q4 2017 Earnings Call

Company Participants

- Gary S. Guthart
- Marshall L. Mohr
- Calvin Darling

Other Participants

- Robert Adam Hopkins
- David Ryan Lewis
- Tycho W. Peterson
- Lawrence Biegelsen
- Amit Hazan
- Isaac Ro

MANAGEMENT DISCUSSION SECTION

Gary S. Guthart

Business Highlights

Opening Remarks

- As you know, Intuitive is dedicated to the mission of expanding the availability of minimally invasive surgery, increasing its efficacy and decreasing its invasiveness
- Q4 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

- Global procedure growth was strong at approximately 17% in Q4 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

- 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

Capital Placements

- 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

Capital Placement Performance

- 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 Q4, largely driven by growth in general surgery
    - European placement performance in Q4 was strong
- Placements in Q4 in Japan were also healthy, perhaps a one-time uptick in anticipation of broader reimbursement

Operating Performance

- Capital placements overall had been lumpy, and we anticipate volatility in placements in 2018
- Operating performance in Q4 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

Operating Results

Revenue and Pro Forma Gross Profit Margin

- Turning to highlights of our fourth quarter operating results, procedures grew approximately 17% over Q4 last year
- We shipped 216 da Vinci Surgical Systems, up from 163 in Q4 2016
- Revenue for the quarter was $892mm, up 18%
- Pro forma gross profit margin was 72.3% compared to 71.1% in Q4 last year
- Instrument and accessory revenue increased to $457mm, up 18%

Recurring Revenue and Pro Forma Net Income

- Total recurring revenue in the quarter was $618mm, representing 69% of total revenue
- We generated a pro forma operating profit of $384mm in the quarter, up 20% from Q4 last year
- Pro forma net income was $298mm, up 23%, and we concluded our accelerated share buyback program initiated in Q1 of 2017 at a weighted average price of $310 per share

FY Highlights

Revenue and Pro Forma Gross Margin

- 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 $3.1B, 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 $2.2B, representing 72% of total revenue
- Pro forma operating profit for the year was $1.3B, up 13% from 2016, and pro forma net income was $1B, 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

Investments

- 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

da Vinci SP System

- 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

SP

- 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

Design and Operations Team

- 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 Q4 2017, we submitted our 510(k) application for our 60-millimeter stapler for da Vinci X and Xi

Imaging Program

- 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

Closing Remarks

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

Marshall L. Mohr

Financial Highlights

Opening Remarks

- 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 $892mm, an increase of 18% compared with $757mm for Q4 2016, an increase of 11% compared with Q3 revenue of $806mm

da Vinci X Trade-Out Program

- In Q4, 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 $2mm, and third quarter revenue by approximately $21mm
- As mentioned earlier in the call, fourth quarter 2017 procedures increased approximately 17%, compared with Q4 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

- Instrument and accessory revenue of $457mm 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

- Systems revenue of $283mm increased 20% compared with Q4 2016, primarily reflecting higher System placements
- We placed 216 Systems in Q4 2017, compared with 163 Systems in Q4 2016, and 169 Systems last quarter. 40 Systems were placed under operating lease transactions in the current quarter, compared with 13 Systems in Q4 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% y-over-y
- Consistent with recent trends, average system utilization continues to grow in the mid-single-digit range

Operating Leases

- Globally, our average selling price, which excludes the impact of operating leases and lease buyouts and revenue deferrals, was approximately $1.47mm, which is similar to Q4 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

U.S

- Outside of the U.S., results were as follows
- Fourth quarter revenue outside of the U.S. of $248mm increased 17% compared with both Q4 2016 and Q3 2017
- OUS procedures grew approximately 21% compared with Q4 2016
- Outside the U.S., we placed 86 Systems in Q4, compared with 63 in Q4 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

MHLW

- 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

P&L

Pro Forma Gross Margin

- Moving on to the remainder of the P&L
- The pro forma gross margin for Q4 2017 was 72.3%, compared with 71.1% for Q4 2016, and 71.8% for Q3 2017
- The increase compared with Q3 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

- Pro forma operating expenses increased 19% compared with Q4 2016, and increased 13% compared with last quarter
- The increase compared with Q3 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

Pro Forma Effective Tax Rate

- Our pro forma effective tax rate for Q4 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

Pro Forma Net Income

- Our fourth quarter 2017 pro forma net income was $298mm, or $2.57 per share, compared with $242mm, or $2.03 per share, for Q4 2016, and $324mm, or $2.77 per share, for Q3 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 $21mm of deferred revenue, net of costs and income tax, and by $0.59 per share related to the tax reserve reversal of $68mm

U.S. Tax Act

- I will now summarize our GAAP results
- Inclusive of the impacts of the U.S. Tax Act, we incurred a GAAP net loss of $39mm, or $0.35 per share, for Q4 2017, compared with GAAP net income of $204mm, or $1.71 per share, in Q4 2016, and GAAP net income of $298mm, or $2.55 per share, for Q3 2017

GAAP Net Loss

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

Tax Rate Regulation

- 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 $3.8B, approximately the same as at September 30, 2017

Share Repurchasing

- During the quarter, cash generated from operations were mostly offset by a final payment of $274mm associated with the accelerated share repurchase agreement we entered in Q1
- Under the agreement, we purchased 7.3mm shares at approximately $310 per share
  - We have approximately $718mm remaining under the Board buyback authorization

Tax Act

- 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

Calvin Darling

Q4 Highlights

Procedure Growth

- Our overall fourth quarter procedure growth was 17% compared to 15% during Q4 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

U.S. General Surgery

- 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

U.S. Gynecology

- 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 y-over-y, 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 Q4 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

da Vinci Xi System and Surgical staplers

- In other U.S. procedures, adoption of lobectomies and other thoracic procedures was again strong during Q4 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 Q4 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

OUS Procedure Growth

- 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

U.S

- 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

Premier Healthcare Database

- 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

VATS Procedure

- 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

Clinical Research

- 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

Outlook

Procedure Growth

- 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

Revenue

- 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 Q4 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

Gross Profit

- 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

Operating Expenses

- 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 $225mm and $235mm in 2018, compared to $209mm in 2017
- We expect other income, which is comprised mostly of interest income, to total between $45mm and $55mm in 2018

Income Tax

- 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

Share Count

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

QUESTION AND ANSWER SECTION

<Q - Robert Adam Hopkins>: 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>: 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>: Okay. Feeling good about it, does that mean the potential for submissions in 2018?

<A - Gary S. Guthart>: 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>: 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>: 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>: 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>: 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 4mm 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 4mm, given that you've got SP coming, along with obviously other technologies.

<A - Gary S. Guthart>: 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 - David Ryan Lewis>: 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 H2 the year a decent time for him to think about the 40-millimeter stapler approval?

<A - Gary S. Guthart>: 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>: 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 $150mm of incremental OpEx and probably $50mm 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>: Great.

<Q - David Ryan Lewis>: Thanks so much.

<A - Gary S. Guthart>: 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>: 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>: 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 - Tycho W. Peterson>: 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 vs. lap across the 12 that have been approved?

<A - Marshall L. Mohr>: 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>: 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 vs. 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>: 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 vs. the X?

<A - Gary S. Guthart>: 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>: 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>: Okay.

<A - Gary S. Guthart>: And I think you were also asking about Europe and the trade-ins in Europe, is that correct?

<Q - Tycho W. Peterson>: Yeah.

<A - Gary S. Guthart>: 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>: 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>: 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 - Lawrence Biegelsen>: 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>: Thanks, Larry. Why don't you take that first one, Marshall?

<A - Marshall L. Mohr>: 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>: 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>: 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>: 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>: 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 - Amit Hazan>: 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>: 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>: 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 y-over-y, 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>: 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>: 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>: 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>: 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 - Isaac Ro>: 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>: 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>: 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.

Calvin Darling

Closing Remarks

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.