Q4 2016 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan, Director - Medical Devices
- Bob Hopkins, Managing Director
- Craig William Bijou, Analyst
- David Ryan Lewis, Analyst
- Lawrence Keusch, Analyst
- Margaret M. Kaczor, Analyst
- Rich S. Newitter, Analyst
- Tao L. Levy, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Intuitive Surgical Q4 2016 Earnings Release Call. At this time, all lines are in a listen-only mode. Later, we'll conduct a question-and-answer session. And as a reminder, today's conference is being recorded.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon, and welcome to Intuitive Surgical's 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 routinely participates on these calls, will not be on the call today to attend to personal matters. We look forward to his return next time.

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

from those expressed or implied as a result of certain risks and uncertainties. These risks and uncertainties are described in detail in the company's Securities and Exchange Commission filings, including our most recent Form 10-K filed on February 2, 2016, and 10-Q filed on October 19, 2016. 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 2017.

And finally, we'll host a question-and-answer session. With that, I'll turn it over to Gary.

Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Good afternoon, and thank you for joining us on the call today. Intuitive was founded on the mission to expand the availability of minimally invasive surgery, increase its efficacy, and decrease its invasiveness, and the fourth quarter capped a strong year in pursuit of this mission, led by continued growth in da Vinci procedures and expansion of our installed base.

Annualized global procedure growth was approximately 15% in the fourth quarter and 15% for the full year. Trends and procedures were consistent through the year with increased use of da Vinci in general surgery in the United States, continued growth in urology in Japan and Europe, and multi-specialty growth in Korea and China.

Mature procedures in the United States, including prostatectomy and hysterectomy, outperformed our initial expectations, largely due to macro trends in diagnosis of prostate cancer and treatment patterns for hysterectomy.

Procedure growth in Europe, Korea, and China were healthy through the year, procedure adoption in Japan was solid for those procedures that have been reimbursed. Calvin will review procedure trends in greater detail later in the call. Our capital placement performance in 2016 is strengthened over 2015, resulting in a growth of total placements from 492 in 2015 to 537 this year. Net of trade-ins and retirements our clinical installed base grew from 3,597 to 3,919 in the year.

Our range of capabilities and price points and our ability to be flexible with acquisition methods has allowed us to meet varying customer needs in a competitive capital

environment. Customers have chosen our most capable system, da Vinci Xi in roughly three quarters of new capital placements for the full year.

da Vinci Xi is well matched with procedure opportunities in thoracic and general surgical procedures such as colon and rectal surgeries. U.S. capital placements stood out in the year while capital placements in Asia were consistent with prior trends. As we've said in prior calls, system quotas in China and reimbursements in Japan temper placement growth and make it hard to predict.

Turning to Europe, while procedure growth was solid in 2016, system placements declined versus 2015 for reasons that vary by country. In our largest European markets, we believe the long-term procedure and system opportunity is significant, with further adoption benefiting from additional economic validation, and mature procedures like prostatectomy, and from country specific clinical and economic data for emerging procedures like colorectal surgery. Overall, despite the slowdown in capital in 2016, we're positive about our long-term prospects in Europe, and continue to develop our organization and invest in European clinical and economic data to support our customers.

Turning to highlights of our fourth quarter operating results, procedures grew approximately 15% over the fourth quarter of last year, we shipped 163 da Vinci Surgical Systems, up from 158 in the fourth quarter of 2015. Revenue for the quarter was $757 million, up 12% from prior year. Pro forma gross profit was 71.1%, compared to 69.6% in the fourth quarter of last year. Instrument and accessory revenue increased to $386 million, up 19%. Total recurring revenue in the quarter was $521 million, representing 69% of total revenue.

We generated a pro forma operating profit of $320 million in the quarter, up 9% from the fourth quarter of last year, and pro forma net income was $242 million, up 8% from Q4 of 2015. Highlights of the full year 2016 are as follows: procedures grew approximately 15% over full year 2015; we shipped 537 systems in 2016, up from 492 in the prior year; revenue for the year was $2.7 billion, up 13%; pro forma gross margin was 71.6% for the full year, compared to 68.2% in 2015.

Total recurring revenue for the year was $1.9 billion and represented 71% of total revenue. Pro forma operating profit for the year was $1.2 billion, up 22% from 2015, and pro forma net income was $879 million, up 20%.

As we mentioned in mid-December, our Board of Directors increased our stock buyback authorization to $3 billion, and we announced today an accelerated repurchase program in the amount of $2 billion. We retained the flexibility to act on the remaining $1 billion in authorization in parallel with the ASR. Overall, we're committed to the thoughtful return of excess capital to shareholders, and believe our buyback program will serve shareholders well.

Marshall will take you through our finances in greater detail shortly. As our businesses strengthened, we have increased our mid and long-term investments in creating our next generation of products and services. These investments are based on our belief that

substantial opportunity exists to enable more minimally invasive surgery, better outcomes, and to expand access to our technologies globally.

Our current da Vinci SP System met its development goals in the fourth quarter, and we initiated its first clinical feasibility study. As we've discussed on prior calls, we planned first markets to include head and neck surgery, urology, and colorectal surgery.

SP is a platform technology that allows high dexterity access with great 3D vision to confined surgical spaces. Early surgeon response to SP in the trials has been very positive. We anticipate initiating an SP IDE trial in the United States for TransOral Robotic Surgery, as well as submitting a 510(k) for urologic applications, both in the first half of 2017.

We're also making good progress on our flexible robotics platform, first targeted to address the acute need and diagnosis of lung cancer, one of the most commonly diagnosed forms of cancer in the world, and for which early detection is important.

The technology underpinning the system is based on computer-controlled catheters, advanced image processing, and sophisticated sensing. As we mentioned previously, this system is in its early stages of our human clinical experience.

This experience has been compelling, and our design and operations teams are working hard to incorporate feedback and complete its production design and supply chain optimization. Given the long-term opportunity for this system in lung cancer detection and other potential applications, we've been growing our team in this space. We do not anticipate revenue from this product in 2017.

Imaging and intelligent algorithms offer significant opportunities to enhance surgeon capabilities. Our investments include hardware and image processing updates to our Xi platform to enhance imaging performance and reduce costs.

We're also investing in contrast agents for specific anatomical structures, recently announcing our plan to commence Phase 1 trials of a ureter imaging agent, compatible with our Firefly Imaging hardware and software.

Imaging and intelligent algorithms work also includes processing and presentation of preoperative imaging and other offline data for use during surgery, sometimes called augmented reality or mixed reality technology. We've been working on these technologies for several years, and more recently with our partner, InTouch Health.

Our next step in mixed reality technology is working in prototype form in laboratory settings today, and we'll move towards first human use in 2018. Bringing new platforms to the market represents a significant investment, and we expect to invest up to $80 million more in 2017 than our typical operating expense run rate growth. These investments are focused on clinical and economic data, particularly in Europe and Asia, expansion of our operations capability to include da Vinci SP, investments in our diagnostics platform, and continued investments in imaging.

Calvin will take you through the spending implications later in the call. In closing, entering 2017, we are focused on the following: 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 diagnostic platform progress; and finally, support for additional clinical and economic validation by global region.

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

Marshall L. Mohr {BIO 5782298 <GO>}

Thank you, Gary. I'll describe our results on a non-GAAP or pro forma basis, which excludes specified legal settlements and claim accruals, stock based compensation, and amortization of purchased IP. We provide pro forma information because we believe that business trends and operating results are easier to understand on a pro forma basis. I will also summarize our GAAP results later in my script. We have posted reconciliations of our pro forma results to our GAAP results in our website so that there is no confusion.

Consistent with our preliminary press release on January 11, fourth quarter 2016 revenue was $757 million, an increase of 12%, compared with $677 million for the fourth quarter of 2015, and an increase of 11% compared with the third quarter revenue of $683 million.

Fourth quarter 2016 procedures increased 15% compared with fourth quarter of 2015, and increased 9% compared with last quarter. Procedure growth relative to last year and the third quarter has been driven by general surgery in the U.S. and urology worldwide. The increase relative to the prior quarter also reflects procedure seasonality.

Revenue highlights are as follows: instrument and accessory revenue of $386 million increased 19% compared with last year, and increased 11% compared with the third quarter of 2016. Instrument and accessory revenue realized per procedure, including initial stocking orders, was approximately $1,900 per procedure, compared with $1,840 last year and $1,870 last quarter. The increase relative to the fourth quarter of 2015 primarily reflects increased sales of our stapling and vessel sealing products. The increase compared with the third quarter of 2016 primarily reflects the impact of customer buying patterns.

System revenue of $236 million increased 2% compared with the fourth quarter of 2015, and increased 15% compared with last quarter. The year-over-year increase reflects higher system placements and higher revenue associated with lease buyouts and operating leases, partially offset by lower average selling prices. The quarter-over-quarter increase reflects higher system placements, partially offset by lower lease buyout revenue and lower average selling prices.

163 systems were placed in the fourth quarter of 2016, compared with 158 systems in the fourth quarter of 2015 and 134 systems last quarter. 13 systems were placed under operating lease transactions in the quarter, including our first two into Germany,

compared with 16 in the fourth quarter of 2015 and 15 last quarter. As a reminder, revenue on operating lease transactions is recognized ratably over the life of the lease.

As of the end of the fourth quarter, there were 79 systems out in the field under operating leases. We generated approximately $5 million of revenue associated with operating leases in the quarter, compared with $3 million in the fourth quarter of 2015 and approximately $4 million last quarter.

We generated approximately $7 million of revenue during the quarter from lease buyouts, compared with $3 million in the fourth quarter of 2015 and $13 million last quarter. We exclude the impact of operating leases and lease buyouts from our system ASP calculations.

Globally, our ASP was $1.48 million, compared with $1.55 million last year and $1.53 million last quarter. We sold a higher proportion of Xi refurbished systems in India and Europe in the quarter, as we seized cost sensitivities in certain segments of these markets.

Service revenue of $135 million increased 12% year-over-year and increased approximately 4% compared with the third quarter of 2016. The year-over-year and quarter-over-quarter increases reflect growth in our installed base of da Vinci systems.

Outside of the U.S., results were as follows; fourth quarter revenue outside of the U.S. of $212 million decreased 4%, compared with $219 million for the fourth quarter of 2015, and increased 12% compared with $189 million for the third quarter. Recurring revenue increased 24% compared with the previous year and 10% compared with the third quarter, reflecting procedure growth and distributor buying patterns. Systems revenue decreased 27% compared with the fourth quarter of 2015, and increased 14% compared with the previous quarter.

Outside of the U.S., we placed 63 systems in the fourth quarter, compared with 75 systems in the fourth quarter of 2015, and 49 systems last quarter. The increase in system placements relative to the prior quarter reflects seasonality. The decrease in system placements relative to the prior year reflected 10 fewer systems into China, where we await a new quota and 4 fewer systems into Brazil, where we are in the early stages of market adoption.

Current quarter system sales included 26 into Europe, 3 into China, 15 into Japan, and 19 in the rest of world markets. System placements outside of the U.S. will continue to be lumpy as some of the O-U.S. markets are in early stages of adoption, some markets are highly seasonal, reflecting budget cycles or vacation patterns, and sales into some markets are constrained by government regulations.

Moving on to the remainder of the P&L, total pro forma gross margin for the fourth quarter was 71.1%, compared with 69.6% for the fourth quarter of 2015, and 73.1% for the third quarter of 2016. The pro forma gross margin for the third quarter of 2016 included $7.1 million of medical device tax refunds, which benefited the third quarter gross margin by approximately 100 basis points.

Excluding this impact, the decrease in gross margin relative to the third quarter reflects a higher mix of systems revenue and higher scope repair costs. Compared with the fourth quarter of 2015, the higher gross margin reflects reduced product costs and manufacturing efficiencies.

Future margins will fluctuate based on the mix of our newer products, the mix of systems and instrument and accessory revenue, costs associated with our scope exchange program, our ability to further reduce product costs and improve manufacturing efficiency, and in the long term, the potential reinstatement of the medical device tax.

Pro forma operating expenses increased 23%, compared with the fourth quarter of 2015, and increased 14% compared with last quarter. The increases primarily reflect increased head count, increased product development activities, and investments in our O-U.S. commercial organization. We accelerated some operating expenses into the fourth quarter in anticipation of spending growth in 2017.

Our pro forma effective tax rate for the fourth quarter was 26.9%, compared with an effective tax rate of 24.9% for the fourth quarter of 2015 and 22.7% last quarter. The pro forma third quarter 2016 tax rate reflected $16 million of tax benefits or $0.40 per share realized as a result of the statute of limitation expirations in various jurisdictions.

The fourth quarter of 2015 tax rate reflected a full year benefit associated with the reinstatement of the R&D tax credit, whereas the R&D credit has been recognized ratably during 2016. Our tax rate will fluctuate with changes in the mix of U.S. and O-U.S. income and with the impact of one-time items.

Our fourth quarter 2016 pro forma net income was $242 million or $6.09 per share, compared with $224 million or $5.89 per share for the fourth quarter of 2015, and $246 million or $6.19 per share for the third quarter of 2016. Excluding the one-time income tax and medical device tax benefits, pro forma net income for the third quarter of 2016 would have been $225 million or $5.65 per share. As I indicated earlier, pro forma income provides an easier comparison of our financial results and business trends.

I will now summarize our GAAP results. GAAP net income was $204 million or $5.13 per share for the fourth quarter of 2016, compared with $190 million or $4.99 per share for the fourth quarter of 2015, and $211 million or $5.31 per share for the third quarter of 2016.

We ended the quarter with cash and investments of $4.8 billion, up from $4.6 billion as of September 30, 2016. The increase was primarily driven by cash generated from operations and proceeds from stock option exercises.

During the quarter, we repurchased 55,000 shares for $34 million. In mid-December, the board of directors increased the amount authorized for stock buybacks to $3 billion. Today, we entered into a $2 billion accelerated stock buyback program with Goldman Sachs. The total number of shares repurchased will be based on a negotiated discount to the volume weighted average price of the stock over the contract period, which is expected to end in the fourth quarter, unless terminated earlier by Goldman Sachs.

Goldman is expected to deliver approximately 2.4 million shares, representing the initial delivery within the next week. We will retire these shares as soon as practical thereafter. A final delivery of shares under the program, if any, will be delivered at the end of the contract period. Under our agreement with Goldman Sachs, we reserve the ability to repurchase additional shares in the open market up to the Board's authorization during the accelerated stock buyback period.

And with that, I'd like to turn it over to Calvin, who will go over our procedure and clinical highlights.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall fourth quarter procedure growth was approximately 15%, as U.S. procedures grew approximately 13%, and outside the U.S. procedures grew approximately 23%. For the full year 2016, global procedure growth was also 15% overall, 13% U.S. and 24% OUS.

In the United States, fourth quarter procedure trends were similar to the third quarter, characterized by strong general surgery growth, continued relative strength in gynecology, and modest dVP growth. Full year 2016 U.S. procedures totaled approximately 563,000, growing approximately 13%, compared to 11% in 2015.

Fourth quarter U.S. general surgery procedure adoption remained strong, led by solid growth in hernia repair and continued adoption of colorectal procedures. Hernia repair continues to contribute the largest volume of new procedures in general surgery, as surgeon retention and expansion remains encouraging. Full year 2016 U.S. general surgery procedures totaled approximately 186,000, reflecting growth of approximately 33%, compared to 31% in 2015.

In U.S. gynecology, fourth quarter procedures again grew modestly year-over-year, with growth led by malignant and complex-benign hysterectomy. Procedures for other benign gynecologic conditions also grew modestly. Full year 2016 U.S. gynecology procedures totaled about 246,000, up approximately 3%, compared to growth of approximately 1% in 2015.

In U.S. urology, fourth quarter da Vinci prostatectomy procedures grew at low single-digit rate, consistent with the third quarter. We believe that our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market. Approximately 70,000 dVPs were performed in the U.S. in 2016, up approximately 5%, compared to 11% growth in 2015.

Full year 2016 U.S. urology procedure volume of approximately 109,000 grew approximately 7%, compared to approximately 12% in 2015. In other U.S. procedures, early stage adoption of lobectomies and other thoracic procedures was strong during the quarter and year. These set of procedures are particularly well served by our da Vinci Xi product and 30-millimeter Stapler products.

Turning abroad, procedure growth outside of the United States was approximately 23% in the fourth quarter, and approximately 24% for the full year 2016. Growth was driven by the continued adoption of da Vinci Prostatectomy with solid contributions from kidney procedures.

Total procedure growth in Asia overall was strong, notably so in key strategic markets of China, Japan, and Korea. In Europe, procedure performance varied by country, approximately 190,000 procedures were performed outside of the U.S. in 2016.

As Marshall mentioned earlier, our average instrument and accessory revenue realized per procedure increased on a year-over-year basis, largely attributable to the adoption of our stapling and vessel sealing technologies.

During the fourth quarter, one of the first studies on our EndoWrist Stapler was published in the Journal of Laparoendoscopic & Advanced Surgical Techniques by Dr. Holzmacher and colleagues from the George Washington University School of Medicine.

In their small case series, comparing an EndoWrist to a laparoscopic 45-millimeter Stapler for colorectal procedures, the authors found that the EndoWrist Stapler was safe and effective, while using fewer stapler fires, reducing the cost per procedure by approximately $150. The authors stated, advantages of the robotic stapler include large range of motion and 90-degree articulation. The robotic stapler has a comparable level of safety as a 45-millimeter laparoscopic stapler, and is more cost effective.

Beyond the Stapler study, Q4 was another quarter with a large number of clinical publications evaluating da Vinci Surgery. Dr. Cigdem Benlice and colleagues from the Cleveland Clinic of Colorectal Surgery, Digestive Disease Institute recently published a study titled: Robotic, Laparoscopic, and Open Colectomy: A Case-Matched Comparison from the ACS-NSQIP.

The study aimed to compare perioperative outcomes of patients undergoing robotic, laparoscopic, and open colectomy, using the procedure targeted database of the American College of Surgeons National Surgical Quality Improvement Program, ACS NSQIP.

Robotic, laparoscopic, and open groups were matched 1 to 1 to 1 based on age, gender, body mass index, surgical procedure, diagnosis, and ASA classification. Out of the 12,790 patients, 387 fulfilled criteria per group after matching.

Univariate comparisons showed operating time was longer and hospital stay was shorter in the robotic group. Important complication rates, including morbidity, superficial SSI, bleeding requiring transfusion, ventilator dependency, and ileus rates were demonstrably lower in the robotic group. The authors concluded that the ACS NSQIP data demonstrated several short-term advantages of robotic surgery, compared with laparoscopic and open surgery.

I will now be providing you with our financial outlook for 2017. Starting with procedures, as described in our announcement last week, 2016 total da Vinci procedures grew approximately 15% to roughly 753,000 procedures performed worldwide.

During 2017, we anticipate full-year procedure growth within a range of 9% to 12%. We expect 2017 procedure growth to continue to be driven by U.S. general surgery and procedures outside the United States, while we are still in early stages of adoption.

Our 2017 procedure growth expectations are directionally lower than the 2016 results, based upon the following assumptions for 2017: moderating growth in our mature U.S. dVP and gynecology procedures that benefited from favorable macro trends in 2016; moderating international procedure growth as we await additional da Vinci procedure reimbursement in Japan and additional systems sales quota in China; and lower percentage growth in U.S. general surgery off a larger base of procedures. We expect similar seasonal timing of procedures in 2016, as we have experienced in previous years, with Q1 being the seasonally weakest quarter as patient deductibles are reset.

With respect to revenue, as we have mentioned previously, capital sales by their nature can vary from period to period based upon many factors, including hospital response to the evolving healthcare environment under the new U.S. administration, hospital capital spending cycles, reimbursement and government quotas, and competitive factors. Within this construct, we'd expect 2017 capital sales to follow historical seasonal patterns.

Turning to gross profits, as Marshall described, our full year 2016 pro forma gross profit margin was 71.6%, as we ended the year at 71.1% in Q4. In 2017, we expect our pro forma gross profit margin to be within a range of between 69% and 71% of net revenue.

We are projecting a modestly lower gross profit margin in 2017, reflecting the unfavorable impact of the stronger U.S. dollar on OUS revenue and margin, non-recurrence of the medical device tax refund recognized in 2016, higher costs associated with new products, and directionally lower system ASPs, as we see incremental market interest in our lower priced offerings in certain geographic markets. Our actual gross profit margin will vary quarter to quarter, depending largely upon product and regional mix.

Turning to operating expenses, as Gary and Marshall described, we are accelerating up to $80 million in investment in several strategic areas that will benefit the company over the long term. Consistent with that direction, we expect to grow pro forma 2017 operating expenses between 15% and 18% above 2016 levels.

We expect our non-cash stock compensation expense to range between $190 million and $200 million in 2017, compared to $178 million in 2016. We expect other income, which is comprised mostly of interest income, to total between $25 million and $30 million in 2017. With regard to income tax, consistent with our 2016 guidance, we expect our 2017 pro forma income tax rate to be between 26.5% and 28.5% of pre-tax income, depending primarily on the mix of U.S. and international profits.

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

Q&A

Operator

Our first question will come from the line of Margaret Kaczor with William Blair. Please go ahead.

Q - Margaret M. Kaczor {BIO 18099474 <GO>}

Hi. Good afternoon, everyone. The first question for me is you guys have been pretty busy announcing, obviously, the R&D spend, you've got the ASR, so clearly, you guys are seeing a ton of opportunity.

And so, to that end, how should we think about the composition of the business three years from now, five years from now? Whether it's based on disease state or sales channels, ASCs versus hospitals, or even product categories, so diagnostic surgery or even post-op.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

This is Gary. I think in the next few years, I would expect the business categories to be more or less as we describe them now. I think over time, as SP comes into the market, it will feel like a surgical device in the kind of settings that you're used to. We do see increasing use of our products in ASCs, it's not a dominant part of the business at this time. I do think it will grow over time.

And then on the diagnostic segment, too early to tell what those segments will break out into. I think it's a platform. I think over time, it will broaden. In the early stages, we'll be talking to you about a lung cancer diagnosis as it comes out.

Q - Margaret M. Kaczor {BIO 18099474 <GO>}

Great. And then on the imaging side, there's a few angles to come at it, and so, I think, Gary, you've talked about delivering therapy through energy potentially. So I guess, what would that mean to you?

And then has anything changed on your view of your willingness to bring in-house either radio or chemiluminescent agents or do you prefer partnerships? And that would include the ureter agent that you talked about earlier.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah, so there were kind of two different concepts in the question, so I'll just tease them apart a little bit. On the imaging side of showing surgeons more of what's going on during surgery, we really view that in kind of three different buckets.

There's better hardware, better imaging sensors and endoscopes. We've been working on that diligently and releasing updates to that product line on a pretty regular cadence.

There's analytics and image processing that is more software based. We've also been working hard on that and have been increasing our investments.

And then last one are kind of better sensors, better contrast agents like the ureter agent. In some of them, we do the primary part of the design in-house. In other places, for example in agents, we have an active licensing and co-development effort going on. So we really partner that activity with others, and a little bit of everything in between.

So that was the imaging side. On the therapeutic side, pretty early to tell. I do think the flexible robotics platform, the computer-controlled catheters have the ability to ultimately deliver therapy. What exactly that looks like will be disease state dependent and is likely to involve different kinds of technology over time. Too early for us yet to call where that ends up.

Q - Margaret M. Kaczor {BIO 18099474 <GO>}

Great. And then one more maybe for Marshall. How should we think about the cadence of the $80 million in spending? And why shouldn't we continue to expect it to go up in 2018 and beyond, given the opportunities and kind of this long-term horizon that we've been talking about? Thank you.

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

Yeah, so to be clear, what we said was we would accelerate spending of $80 million. We would expect to more normalize our margins in future years. As far as the cadence within the year, spending, particularly as it relates to engineering and prototypes and so forth, can be pretty lumpy, so we haven't given you specific guidance, but I think you should expect it will go up as we go through the year.

Q - Margaret M. Kaczor {BIO 18099474 <GO>}

Thank you.

Operator

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

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

Okay, thanks. A question on expectations around Xi for the year. For starters, you mentioned historical seasonal patterns, it sounds like you're not factoring any ACA associated slowdown in the first half of the year. And then in the back half of the year, how should we think about maybe incremental placements ahead of the SP rollout?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

For starters, first, the question on ACA. Our sense here is that utilization probably won't change very much. We don't have a crystal ball, but so far, the early indications are that will be stable. On the capital placement side, highly uncertain for us. We don't know. Early

indications are that it's pretty stable, but depending on how policy ultimately is implemented, that uncertainty may roll through some capital planning processes for some of our customers. I wouldn't call it out yet, not clear that that's happening, but it's a potential.

With regard to kind of timing in the year and SP, I'll let Marshall answer that question.

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

From an SP perspective, what we've been communicating is consistent with what I'll say now, which is that SP will contribute very little in terms of revenue in 2017, and will be more of a factor in 2018.

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

But in terms of driving incremental upgrades to Xi ahead of the rollout, should we think about any dynamic there?

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

Not really, no.

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

And will we get SP data at SAGES? When can we start to think about some early user feedback?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

We should have the opportunity to close this clinical feasibility trial and then initiate the IDE head and neck trial in the first half of the year, and as the one closes and the other opens, we'll be in a better position to share with you that feedback.

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

Okay. And then last one on hernia, can you just give us an update of where we are from a penetration standpoint, in terms of both inguinal and ventral and how you think about the relative growth rates this year?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, generally speaking, we think we're still in fairly early stages on both the ventral and the inguinal opportunity. You saw we talked about the results in general surgery, again, up over 30% this year. Obviously, we had a lot of new procedures, and we gained confidence as the year went on, I think, regarding our opportunity on the inguinal side with demonstrated stickiness on surgeons and growth in that category.

But it's still difficult for us to assess how many of, let's call it, the close to 300,000 ventral hernias and 700,000 inguinals will ultimately be robotic candidates, but we feel pretty confident that it's going to be driving growth for us into 2017 and beyond.

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

Operator

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

Q - Bob Hopkins {BIO 6184955 <GO>}
Great, thanks. Can you hear me okay?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}
Hi, Bob. Yes.

Q - Bob Hopkins {BIO 6184955 <GO>}
Great. So, Gary, I have a question for you. From a signaling perspective, this quarter is very interesting because you're accelerating $80 million expend, and you're announcing a $2 billion ASR.

So those are two very kind of positive signaling events, in my view, so I was just wondering, can you just help us understand why now is the time to be doing these things? What are the things you're seeing that give you confidence in the business? Or am I not phrasing it correctly that the $2 billion ASR is really just to offset the spending?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}
I think our process to get to both of these, I'll just describe how did we get to accelerating investment and how did we get to the ASR. With regard to accelerated investment, I think we are feeling good and increasing confidence in the use of our products in general surgery. I think that while we're still in early innings, I think the early results have been really strong, so that has been positive for us.

As we look at where we sit on kind of the competitive landscape with regard to technologies and opportunities, both here at home and abroad, we also are feeling confident that we have a very good technology pipeline, and our positioning is quite good. And so, as we look at then the opportunity to invest, our first priority is to fund the existing business.

The second priority is look for organic growth opportunities that can drive profitable growth in the future. That's where that $80 million is going, and we evaluate platforms, and we look at total available market for those platforms, estimate what the profitability might be, and stack rank them, and then invest.

We look for acquisitions as the third priority or things that can add to our company, and if we have excess capital, then opportunities to return it to shareholders. And so we walk

through that process this year carefully and robustly, and that led to both the pull forward of investment because we think there's opportunity and momentum, and the opportunity to return some cash through the buybacks, and so, those time together more by process than by some algorithm.

Q - Bob Hopkins {BIO 6184955 <GO>}

Great, that's very helpful. And then just the one thing I wanted to follow up on is not asking you to commit here, but at least is there the potential for 2018 to be a year where you have three new product platforms? SP, potentially biopsy, and then on the new imaging agent side? Is that potential at least exist?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

I think SP is the furthest along of the new platforms, and I think that SP in 2018 has the opportunity to do some interesting things, should we execute well on our regulatory pathway.

Molecules, or the molecules side of imaging, is further out than 2018. There are some interesting things in imaging that are in 2018. They're more software and hardware related, as opposed to molecular component.

On the diagnostic platform, we're not yet ready yet to kind of anchor revenue expectations. I would not expect much in the 2018 timeframe, although, I think we're going to make great progress on the technology and the learning on it.

Q - Bob Hopkins {BIO 6184955 <GO>}

Wonderful. Thanks very much.

Operator

Our next question comes from the line of David Lewis with Morgan Stanley. Please go ahead.

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

Good afternoon. Gary, I'm just trying to put the spending into perspective here. It seems hard to us that on individual trials, you could pull forward the magnitude of spending you're pulling forward. So, is it safe to assume that at least some significant component of this pull forward does relate to a new platform that you're working on? That's sort of number one.

And then not just the R&D spending, Gary, the other piece was there is commercial spending. Can you sort of help us understand the areas that you're spending on commercially that are different than the two R&D investment?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah. Yeah, fair questions. On the first one, absolutely, the incremental spend relates to building out second platforms. SP has a lot of shared components with Xi, but not entirely shared components, and so bringing that out has a new supply chain, a new set of testing, and manufacturing resources that have to get invested in.

Then in addition to some of the trial work, so that's a platform. The diagnostics side, we're really excited about, and we think there's great opportunity at home and abroad. And so, we're earlier in that platform, but we're doing what amounts to the design and early trial investments there.

And then there are clinical and economic data investments on our existing platforms, particularly in Europe and in Asia, where we think reimbursement or access, other kinds of access, payer access are important, and that's been data that we're happy to go invest and collect.

So, it really is a mix of those elements, as you called out in the question. Moving on to your second piece, remind me the second half of your question.

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

Just commercial and the non-developmental piece and commercial development. (42:57)

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah, yeah, commercial investments. Good example of that is we think there's real opportunity for us in the major markets in Europe if we can increase our total business footprint. It's not just commercialized and sales folks, but some of it is sales staff. We have added a seasoned executive in Germany as a German General Manager. We're adding some clinical resources into Germany as well to kind of round out the team there.

I think it makes a lot of sense, early returns on that are strong in terms of just their ability to get things done. And so, those kinds of investments have been going on. Likewise, in places like Japan, where we're – have been investing in reimbursements, anticipating additional reimbursement in 2018, there's some prep work to get done in terms of both the customer base and commercial, as well as the government side.

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

And Gary, just a quick second question on SP just to be clear. There are three approvals you talked about in this call, head and neck, urological, as well as TORS. Is it safe to assume those are the three clinical opportunities here near term? I'm trying to get at ease, can you not launch SP in more of a full commercial way until you have one of those three approvals? Or that's not necessarily true?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

So, those are the first ideas. Which one comes first will depend on how regulatory bodies view it. I suspect urology will actually be earlier than the other ones, just based on existing data and past history.

We think that those are good opportunities for the platform. They are not the only opportunities for the platform. So, we are pursuing those – the workup to those in parallel because we think it gives our customers the best financial flexibility to take advantage of the capital investment they'd make in the platform. Does that make sense?

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

Makes perfect sense. Thank you so much.

Operator

And our next question will come from the line of Amit Hazan with Citi. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Hey, good afternoon. I want to just come back to the R&D spend, the increased investment spend for one second, just to clarify 2018, in particular. And this kind of goes off, Gary, what I think you talked about earlier this month at the investor conference and that kind of tailing off in 2018.

And I think about that as I think about SP, maybe that launch coming out so you get some savings there, but diagnostics, certainly imaging, seems like new and ongoing spend, and so I wanted to maybe try to get you to clarify why that increased spending is just one year and not more than that. And so in terms of just the R&D as a percent of sales, why wouldn't that just continue into next year? It seems like a lot of your spending is actually going to be ongoing.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah, so what we're describing is that we're growing R&D spend, and it's really operations, not just R&D, so operating expense is unusually in 2017 as a run rate, and we think it will return to more normal growth rates in 2018.

There's a couple of reasons that we think that's so. One of them is the biggest spend on a platform launch is actually the year before launch. That's where both you're building a lot of product, you're doing a lot of validations, you're getting ready, you're doing a lot of the staging, so that bolus will go through.

We have been investing sequentially over time a fair amount more in imaging. So, imaging in 2017 isn't a huge bolus. It's kind of a ratable growth. And you're right, we expect revenue growth 2017 to 2018, so we expect growth in total OpEx expense in 2018, it's just that the growth rate will modulate relative to 2017.

So what we're trying to communicate to everybody here is that the growth rate in 2017 is unusual. We'd expect revenue growth in 2018, we'd expect op expense growth rate in 2018 as well, but more aligned with historical norms. In other words, the growth rate in 2017 is not the new normal.

Q - Amit Hazan {BIO 6327168 <GO>}

That's helpful. And then gynecology would be my second question. The 3.5% growth for the year, that's better than we expected, too. I think that's another year of improving growth for your second year in a row.

And you kind of seem to be cautioning a little bit that some of this is not sustainable, that it's something like migration of procedures to GYN oncologists might run its course. (47:31) And it strikes me just a little bit too earlier, little bit early to be concerned about that trend, and so it kind of seems like a newer trend to me. I'm just kind of wanting to get you a little bit to comment on whether that's a real concern for 2017, or whether you're just kind of putting out potential risk factors for the year.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

The gynecology is one of those mature procedure categories in the United States. If you look at benign hysterectomy, the largest procedure in the category, over 80% of those procedures are performed in some minimally invasive fashion, whether it be with laparoscopy, vaginal techniques or robotic, and it's kind of been that way the last two or three years.

So in that sense, we would expect – our starting thought will be we're likely to move with the market in that scenario. So if you look back a couple years ago, at 2014, that's what happened. We declined low single-digits. We think the total number of benign hysterectomies being performed is probably gradually declining in response to payer pushbacks on that procedure encouraging other treatment modalities.

So, 2015, that kind of moved to the other side as 1% growth like I said in the comments. This year, it ramped up to about 3% growth. And you're right, I think it's largely reflecting a trend towards a higher proportion of the cases being performed by the gynecologic oncologists, a set of surgeons that are more aligned with robotics.

So that's been a benefit. So our guidance would suggest we'd expect this to moderate a little bit in 2017. We don't have a perfect crystal ball in this area, but at some point, we think the more complex cases are the ones being referred, and you hit a certain level where – that you're getting very adequate clinical outcomes with the other minimally invasive approaches. So, you know, we'll see how it plays out.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks, guys.

Operator

And our next question will come from the line of Tao Levy with Wedbush. Please go ahead.

Q - Tao L. Levy {BIO 6307976 <GO>}

Great, thanks. Good afternoon. Just maybe you could update on the status of China and the quota sort of next steps there, as well as what's needed to get the Xi approved in China.

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

Yeah, so, two parts to the question. On the quota side, the quota is dependent upon the approval of their budget and the Chinese government budget, and then allocations are then done down through MOH and then to the hospitals and so on and so forth, until they get to which hospitals can buy specifically da Vinci product.

They've taken the first step. They have approved – they did approve the budget at the end of 2016, or so in December. However, they did not take it further to the allocations to specifics as to who gets to buy a da Vinci or how many will be bought. That process is still in motion. It's not something we can control, and frankly, we don't have great visibility as to what's going on behind the curtains to get there.

And so, at this point, we'll sit and wait for the next quota to be approved. I think what we've also told people is if you look at the last time quota was approved, it still takes some time for the hospitals to actually complete the tender process and buy product, so if you're putting together a model, looking at the last time quota was approved in 2013, most of the systems were bought near the end of 2015. So, the likelihood that there's going to be a lot of revenue coming out of a quota in 2017 is not very high.

Q - Tao L. Levy {BIO 6307976 <GO>}

And on the Xi?

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

Xi is in process. It is a long approval process. We'll tell you when we get it, which is our typical pattern of disclosure. We don't know where it is in the process.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah. We're encouraged. I don't see a major impediment to Xi clearance in China. And in general, we're encouraged by the response of the market to robotics surgery and to Intuitive in China. So, I think, in general, with the caveat that Marshall has outlined, as a whole, we look positively on the opportunity there.

Q - Tao L. Levy {BIO 6307976 <GO>}

Great. Thanks.

Operator

Our next question comes from the line of Larry Keusch with Raymond James. Please go ahead.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Sorry and thanks, good afternoon. Marshall, excuse me, Gary, in your prepared comments, I think I've heard this correctly, but you were referencing sort of long-term investments and you were talking about investments for products and services. And I just want to make sure I've heard that correctly, and if that is correct, what were you sort of thinking about when you're talking about services?

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah, we provide a series of things now to the customer that are kind of an ecosystem around the product itself. So, the simple things you think about are things like maintenance services.

But we increasingly have access to interesting data on the use of devices, our devices, benchmarking that are international, and things like efficiency metrics for the use of robotics systems in the last couple of years, we have partnered with hospitals to provide that set of data to them and to help them improve their systems, and that's been a real positive for them and for us. And so that's what I meant when I said services. I think those data opportunities and benchmarking opportunities increase in the future.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay, great. And then I just want to pick up on some comments that you made earlier in the month, and specifically get your thoughts on as you talk about, again, some of this imaging technology and the ability to perhaps be involved in pre-procedure planning, is that – is the way to think about that, that that would really be done with the surgeon interfacing with the imaging capabilities and the machine itself? Or is there an element there where Intuitive can insert itself more from a service perspective in perhaps procedure planning?

And then the other question around that was just getting your thoughts on where you think the machine learning goes, as it relates to robotic surgery.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Sure. I think, to the first question of what does it change or where we interact at the hospital, I think in the near term, the answer is yes, but only a little bit. I think that there's an opportunity to look at things like preoperative images that patients are required to do as part of their diagnostic workup, and to be able to use and do some post processing and machine learning on those preoperative images to improve surgeons' navigation or other capabilities during the case. That looks pretty interesting. That's some of the technology I showed you a few weeks ago at JPMorgan.

I think, in the near term, that's how I think about it. In the long term, I do think that there are interesting opportunities for analytics, as it relates to the workings of a robotic surgery program or a minimally invasive surgery program that are a little bit outside of what's happening in a single case, and that may change and provide an opportunity for Intuitive to engage conversations with the hospital in a little more broad manner, but I think we're at early days of those conversations.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay, great. And last quick one, just – Calvin, I know you made a mention on lobectomy, but again, any color that you could provide as to sort of the uptake, and perhaps the opportunity around that?

A - Calvin Darling {BIO 17664656 <GO>}

No, again, like I said, I think Q4 and really throughout the year in 2016, was a positive period of time for us. It's still fairly early in that category. We're focused, the field team more on the general surgery opportunity, but there's increasing sets of people engaging, some of the key thoracic surgeons getting some of the newer technology.

I mentioned the Xi system and 30-millimeter Staplers in those hands, and gaining that experience and building volumes from there is something we're focused on, but I think the value is high in that procedure, and the opportunity is significant in the U.S., but when you look outside the U.S. to Europe and particularly Asia with higher lung cancer rates, it's pretty interesting.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Great. Thank you.

Operator

Our next question comes from the line of Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Craig William Bijou {BIO 18909856 <GO>}

Hi, guys. It's actually Craig Bijou on for Larry. Thanks for taking the questions. I wanted to start, Calvin, with your comments on, as part of your procedure guidance, the moderating international growth, and I want to ask what's the risk to procedure growth given some of the slowdown in European system sales, and kind of balancing that with the strong procedure growth that you guys have said that you're seeing in Asia?

So, I guess, in the case where your European procedure does – or system sales don't pick up again, and maybe the China tender or the China quota doesn't come on board as quickly as you expect, what's the risk to that international procedure growth of 20%-plus?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. I mentioned it as one of the bullet points in there for the outlook for – a moderating outlook on overall procedure growth. Internationally, I think the year, as I pointed out, specifically, were for China. Marshall talked a little bit about the quota there. The fact is, that the systems we do have in China are some of the most productive systems we have, and our ability to continue to grow procedures now, somewhat paced by our ability to get more capacity in the field. So that can be a factor in 2017.

And then in Japan, we very successfully ramped up the procedures where we have reimbursement, the prostatectomy procedure, and earlier stage of a smaller category in the partial nephrectomy, so I think as those procedures have ramped, you've got less room and we're awaiting additional procedures in 2018, which will be required to sustain growth. Both those markets, I'd say, we've got very positive long-term views on, but some specific factors impacting 2017.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Operator, we have time for one last question.

Operator

Okay and that comes from the line of Richard Newitter with Leerink Partners. Please go ahead.

Q - Rich S. Newitter {BIO 16908179 <GO>}

Hi, thanks for squeezing me in. I had two, just – Marshall, just on the gross margin factors in the guidance for 2017. I heard FX, I heard the med-tech tax refund benefit not repeating. Could you just elaborate on the last two? And then I have one follow-up on thoracic.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

I don't think we have a follow-up, so Marshall, take that one and we'll go from there.

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

Yeah, I think the things that can affect the gross margin are – we, like we said, we had some experience in the quarter with selling the lower cost systems in cost sensitive markets, where we saw some success, so we'll see if that continues (59:07) but we'll see what happens.

Certainly, new product introductions and new products have lower margins than our older products, and so, that also has an impact as we increase the sales of vessel sealing and stapling, and even though we've cost reduced them somewhat, they're still lower margin than our historical products.

And so as we increase the sale of newer products, that will have a negative impact. Then the other item that we mentioned was repair costs associated with scopes, and we continue to work, as Gary said, iterate the imaging capability and the hardware. And as we do, we'll reduce the cost as well as improve the repairability, but that's a little ways off and so we're – it will happen incrementally over time.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

All right, Richard, Calvin says take your follow-up.

Q - Rich S. Newitter {BIO 16908179 <GO>}

I appreciate that. Thank you. Just on thoracic, is there any – can you just maybe talk about the type of surgeon that you need to target to kind of – and the phasing of it? Because I know there's some general surgeons that perform the procedures, and then you obviously have cardiothoracic surgeons and specialists.

Can you just describe kind of who you're targeting and when? And can that potentially give us a sense as to when we might begin to see more of an inflection point in the thoracic lobectomy segment? Thanks.

A - Gary S. Guthart, Ph.D. {BIO 1469479 <GO>}

Yeah, I'll answer that one. I think we're still in pretty early part of the market option for thoracic surgery. In general, it's been engaging thought leaders in thoracic surgery, some of whom are minimally invasive surgeons today, and some of whom are predominantly open surgeons. There's a mix. It tends less to be the generalist here and more to be the thought leadership in thoracic as a whole.

Part of, I think, what's been pacing growth here is just completing the product set for efficiency and speed of case. I think we're very close now to having complete product sets, things like 30-millimeter Staplers, and so on, and that's helped. So, I think as that product set completes, as we proliferate Xis in the world, that has made adoption more likely and easier.

I'll turn to our close. That was our last question. As we've said previously, while we focus on financial metrics such as revenues, profits, and cash flow during these conference calls, our organizational focus remains on increasing value by enabling surgeons to improve surgical outcomes and reduce surgical trauma.

We've built our company to take surgery beyond the limits of the human hand, and I assure you, we remain committed to driving the vital few things that truly make a difference.

This concludes today's call. We thank you for your participation and support on this extraordinary journey to improve surgery, and I look forward to speaking with you again on the next call.

Operator

Ladies and gentlemen, as you just heard, today's conference has concluded. Thank you for your participation. You may now disconnect.