Q2 2017 Earnings Call

Company Participants

- Calvin Darling, Senior Director, 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
- Patrick Clingan, Vice President, Finance and Sales Operations

Other Participants

- Amit Hazan, Analyst
- Brandon Henry, Analyst
- David Ryan Lewis, Analyst
- Isaac Ro, Analyst
- Larry Biegelsen, Analyst
- Rich S. Newitter, Analyst
- Robert Hopkins, Analyst
- Tao L. Levy, Analyst
- Travis Steed, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Intuitive Surgical Second Quarter 2017 Earnings Release Call. At this time, all lines are in a listen-only mode. Later, there will be an opportunity for your questions and instructions will be given at that time. And as a reminder, this conference is being recorded.

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

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon, and welcome to Intuitive Surgical's second quarter earnings conference call. With me today, we have Gary Guthart, our President and CEO; Marshall Mohr, our Chief Financial Officer; and Patrick Clingan, Vice President of Finance and Sales Operations.

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 6, 2017 and 10-Q filed on April 19, 2017. These filings can be found through our website, or at the SEC's EDGAR database. Prospective investors are cautioned not to place undue reliance on such forward-looking statements.

Please note that this conference call will be available for audio replay on our website at intuitivesurgical.com on the Audio Archives section under our Investor Relations page. In addition, today's press release and supplementary financial data tables have been posted to our website.

Today's format will consist of providing you with highlights of our second 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 second quarter financial results, Patrick will discuss procedure and clinical highlights, then I will provide our updated financial outlook for 2017. And finally, we will host a question-and-answer session.

With that, I will 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. As you know, Intuitive is focused on significantly improving surgery and enabling access to our products and services in pursuit of this mission globally. The momentum built over the past several quarters continued into the second quarter of 2017, with solid performance in procedures and strong growth in system placements.

Growth in procedures for the quarter was 16% over the second quarter of 2016. Overall, trends in the first quarter remained stable into the second. Starting with United States, both the emerging category of general surgery and more mature categories in urology and gynecology performed well.

Hernia repair continues to stand out in the general surgery category, with additional contributions coming from colon procedures. As we mentioned last quarter, European performance in Q1 of 2017 benefited from calendar tailwinds that we expected to balance out in the second quarter.

Indeed, this occurred with core growth staying roughly steady through the first half of 2017 and European second quarter growth moderating. Procedure performance in Asia was solid, with growth in China being a highlight from a constrained installed base. Patrick will take you through these factors in more detail later in the call.

Our capital placement performance in Q2 of 2017 strengthened with the growth in total placements from 130 in Q2 of 2016 to 166 this quarter. As we mentioned on these calls, capital placements can be lumpy as evidenced by our performance in the first half of the year. In the United States, placements rebounded from a softer Q1 to a strong Q2, anchored in repeat purchases by existing customers and multi-system placements.

System placements in Europe grew moderately, aided in part by the launch of da Vinci X. In Asia, the placements grew slightly over the prior year period and over last quarter, constrained for the time being by the lack of a new system quota in China and limited reimbursements in Japan. Marshall and Patrick will take you through system placement dynamics in greater detail.

Turning to profitability for the quarter. Strong system placements led to gross margins that are lower than last quarter. These margins are at the top of our expected range because of the strength in procedures and improvements in our operating efficiencies.

Our fixed cost growth met our expectations with increases in R&D expenses, growth in staff in European and Asian markets, investments in clinical trials and growth in our corporate computational capabilities.

Our second quarter pro forma operating results were as follows; procedures grew approximately 16% over the second quarter of last year. We shipped 166 da Vinci Surgical Systems, up from 130 in the second quarter of 2016.

Revenue for the quarter was $756 million, up 13% from the prior year. Instrument and accessory revenue increased to $398 million, up 17%. Total recurring revenue in the quarter was $540 million, representing 71% of total revenue.

Pro forma gross profit margin was 71.3% compared to 71.9% in the second quarter last year. We generated a pro forma operating profit of $313 million in the quarter, up 5% from the second quarter of last year. And pro forma net income was $228 million, up 4% from Q2 of 2016. Marshall will take you through our finances in greater detail shortly.

Turning to our product pipeline. As you know, in the back half of 2016 and the first half of 2017, we increased our mid-term and long-term investments in creating our next generation of products and services. We anchored on our belief that substantial opportunity exists to enable more minimally invasive surgery, better outcomes and to expand access to our technologies globally.

Starting with our multi-port portfolio. We developed a system pathway that responds to our customers' desire for choice in clinical capability and choice in total economics. In the quarter, we received our CE Mark and 510(k) clearance for da Vinci X, a system that brings core Xi technology into a highly capable, lower entry price surgical system. We're pleased with the early reception of X by our customers and the choice it brings to those around the world who seek to build robot-assisted surgery programs with logical upgrade pathways and affordable access to our leading robot-assisted surgery ecosystem.

Our SP program continues to progress in its human clinical trial work and pilot production capability. We now have four clinical trial sites active, three in the United States and one in Asia. Cases in Asia have included transoral, urologic and colorectal surgery, while those in the U.S. are focused on transoral robotic-assisted surgery.

As we mentioned on our call last quarter, we anticipate filing our 510(k) for SP in urology in the back half of 2017. Surgeon feedback from our trial sites is very encouraging. Our teams continue to work on product validations and manufacturing capability to support submission and launch. Lastly, our flexible robotics program is meeting our expectations and making good progress in its product design phases and definition of regulatory pathways.

In closing, the second quarter of 2017 has carried forward momentum built in prior quarters and we remain focused on the following for the balance of the year. 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 flexible robotics progress, and finally, support for additional clinical and economic validation by 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 will describe our results on a non-GAAP or pro forma basis, which excludes specified legal settlements and claim accruals, excess tax benefits associated with employee stock awards and charges associated with stock-based compensation in 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've posted reconciliations of our pro forma results to our GAAP results on our website so that there is no confusion. Second quarter 2017 revenue was $756 million, an increase of 13% compared with $670 million for the second quarter of 2016, and an increase of 12% compared with the first quarter revenue of $674 million.

We launched the da Vinci X system during the second quarter in the U.S. and European countries covered by CE Mark. In conjunction with the launch, we offered certain customers who purchased systems in the first quarter, the opportunity to upgrade or trade-out their systems for the X system.

As a result, we deferred $23 million of first quarter revenue, which we recognize when customers either trade-out their systems or when the offers expire, whichever comes first. None of the deferred revenue was recognized in the second quarter. We expect substantially all of the deferred revenue to be recognized by year-end.

Second quarter 2017 procedures increased approximately 16% compared with the second quarter of 2016. It increased 5% compared with last quarter. Procedure growth relative to last year and the first quarter has been driven by general surgery in the U.S. and urology worldwide. Patrick will provide more detail concerning procedure adoptions.

Revenue highlights are as follows. Instrument and accessory revenue of $398 million, increased 17% compared with last year and increased 4% compared with the first quarter of 2017, which closely reflects procedure growth. Instrument and accessory revenue realized per procedure was approximately $1,830 per procedure compared with $1,810 last year and $1,840 last quarter.

The increase relative to the second quarter of 2016 primarily reflects increased sales of our stapling and vessel sealing products, partially offset by customer buying patterns. The decrease compared with the previous quarter primarily reflects customer buying patterns.

System revenue of $216 million increased 7% compared with the second quarter of 2016 and increased 41% compared with last quarter. The year-over-year increase reflects higher system placements and operating lease revenue, partially offset by lower average selling prices and lower lease buyout revenue.

System revenue for the first quarter of 2017 excluded the $23 million of deferred revenue. Had the first quarter included that revenue, quarter-over-quarter increase would have been 23%, reflecting a higher number of system placements, partially offset by lower lease buyout revenue.

166 systems were placed in the second quarter of 2017 compared with 130 systems in the second quarter of 2016 and 133 systems last quarter. 27 systems were placed under operating lease transactions in the current quarter compared with 15 systems in the second quarter of 2016 and 21 last quarter.

As a reminder, revenue on operating lease transactions is recognized ratably over the life of the lease. Of the 166 second quarter systems, 11 were X systems. As of the end of the second quarter of 2017, there were 120 systems out in the field under operating leases. We generated approximately $6 million of revenue associated with operating leases in the quarter compared with $4 million in the second quarter of 2016 and approximately $5 million last quarter. We generated approximately $5 million of revenue during the quarter from lease buyouts compared with $13 million in the second quarter of 2016 and $10 million last quarter.

Globally, our average selling price, which excludes the impact of operating leases and lease buyouts and revenue deferrals, was $1.46 million compared with $1.56 million last year and $1.46 million last quarter. The decrease in ASP compared to the second quarter of 2016, primarily reflects lower priced systems sold to cost-sensitive market segments and lower pricing offered to customers purchasing multiple systems.

We believe the flexible financing programs, like operating leases, have positively impacted our ability to grow our installed base. We expect the proportion of these types

of arrangements will increase over time. Service revenue of $142 million increased 11% year-over-year and increased approximately 1% compared with the first quarter of 2017. The year-over-year and quarter-over-quarter increases reflect growth in our installed base with da Vinci systems.

Outside of the U.S., results were as follows. Second quarter revenue outside of the U.S. of $205 million increased 11% compared with $185 million for the second quarter of 2016 and increased 12% compared with $183 million for the first quarter. The increase relative to the prior year primarily reflects increased system placements net of leases and increased instruments and accessories, reflecting procedure growth, partially offset by lower system ASPs.

Patrick will provide procedure growth information. The year-over-year decline in system ASPs reflects increased sales of lower-cost systems to cost-sensitive markets. The increase in revenue relative to the last quarter reflects increased system placements and increased instrument and accessory growth.

Outside of the U.S., we placed 63 systems in the second quarter compared with 51 in the second quarter of 2016 and 56 last quarter; 5 of the system placements in the current quarter were operating leases compared with 2 last year and 6 last quarter.

Current quarter system placements, including 29 into Europe, 14 into Japan, 5 in India, 5 into Australia, and 3 into China. System 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.

Moving on to the remainder of the P&L. The pro forma gross margin for the second quarter of 2017 was 71% compared with 72% for the second quarter of 2016 and 72% for the first quarter of 2017. The decrease compared with the second quarter of 2016, primarily reflects decreased service margin associated with higher scope repair costs. The decrease compared with the first quarter reflects a higher proportion of system revenue relative to total revenue.

Since we deferred cost associated with the $23 million revenue deferral, the trade-out program had little impact on our margins. Future margins will fluctuate based on the mix of our newer products, the mix of systems and instrument and accessory revenue, 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 second quarter of 2016 and increased 2% compared with last quarter. The increases are consistent with our planned investments in product development, specifically da Vinci Sp, flexible robotics, imaging and advanced instrumentation and the expansion of our OUS markets. The year-over-year growth rates will subside over the remainder of the year with total year growth still expected to be around 18%.

Our pro forma effective tax rate for the second quarter was 29.2% compared with an effective tax rate of 27.8% for the second quarter of 2016 and 28.1% last quarter. The increase in our tax rate reflects an increased proportion of U.S. income relative to total income. Our tax rate will fluctuate with changes in the mix of U.S. and OUS income and with the impact of one-time item.

Our second quarter 2017 pro forma net income was $228 million or $5.95 per share, compared with $220 million or $5.62 per share for the second quarter of 2016 and $196 million or $5.09 per share for the first quarter of 2017. The $23 million revenue deferral, including the associated deferral of cost of sales and the income tax effects, reduced GAAP and pro forma net income per share in the first quarter of 2017 by approximately $0.28 per share.

Earnings per share benefited from the full impact of our $2 billion stock buyback as we retired approximately 2.4 million shares on January 27, 2017. At this point, given the increase in the share price since the start of the ASR, the ultimate number of shares delivered under the ASR may not change materially from the initial delivery.

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 $222 million or $5.77 per share for the second quarter of 2017 compared with $185 million or $4.71 per share for the second quarter of 2016, and $180 million or $4.67 per share for the first quarter of 2017.

GAAP net income for the second quarter included a net benefit of $5 million associated with litigation settlements, net of charges, compared with $4 million of charges in the second quarter of 2016, and $21 million of charges last quarter. GAAP net income for the second quarter of 2017 also included a charge of approximately $6 million associated with purchased IP.

Beginning in 2017, we are required under GAAP to report the excess tax benefits or deficiencies associated with employee stock awards in our tax provision, rather than as an adjustment to paid-in capital as in prior periods. The excess tax benefit included in our GAAP results for the second quarter was $31 million, contributing $0.80 per share compared with $33 million, contributing $0.85 per share in the first quarter of 2017. We have excluded these benefits from our pro forma results. This amount will fluctuate quarter-to-quarter based on the volume of employee stock option exercises and the number of RSUs vesting and the value of our stock.

We ended the quarter with cash and investments of $3.4 billion, up from $3.1 billion as of March 31, 2017. The increase reflects cash generated from operations and proceeds from stock option exercises.

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

Patrick Clingan {BIO 16639980 <GO>}

Thanks, Marshall. Of our second quarter procedure growth of 16%, U.S. procedures grew approximately 14%, and outside of the United States procedures grew approximately 22%. Procedure trends were consistent with the first quarter, with growth led by U.S. general surgery and global urology. In the United States, both mature and growth procedures, such as general and thoracic surgery, outperformed our plan. Majority of the outperformance was driven by continued growth in our mature procedures.

In U.S. urology, the second quarter growth rate for da Vinci Prostatectomy was modestly higher than the first quarter. We believe that our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market.

In U.S. gynecology, second quarter procedure growth sustained trends observed during the first quarter. Procedure growth in U.S. GYN appears to be driven by consolidation of surgeries towards physicians that specialize in complex and cancer surgery who tend to be users of the da Vinci system.

First quarter U.S. general and thoracic 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 the United States, and existing surgeon retention and utilization remained sound.

Growth trends in lobectomies and other thoracic procedures continue to show strength off of a small base. Second quarter was another quarter with a large number of clinical publications evaluating da Vinci Surgery. One that we'd like to highlight is from Dr. Rashidi (21:10) from the University of Texas and colleagues from Providence Health & Services, who published a study of more than 3,500 colorectal patients treated by 58 high-volume surgeons within the Providence Health & Services network in the American Journal of Surgery.

The authors found that in exchange for a longer operating time, patients treated on the da Vinci system experienced a threefold reduction in conversion rate and nearly a day shorter length of hospital stay compared to laparoscopy. In addition, the authors found that there was no difference in total direct cost between the two cohorts.

Turning abroad, procedure growth outside of the United States was approximately 22% in the second quarter, led by the global adoption of da Vinci Prostatectomy, with solid contributions from kidney procedures, general surgery and gynecology.

As we discussed last quarter, the timing of the Easter holidays from Q1 into Q2, which provided a tailwind to our first quarter results, served as a headwind in the quarter, likely reducing our outside of the United States procedure growth by an estimated 3%. Taken together, first half procedure growth of 25% provides a better representation of procedure performance outside of the United States and either quarters result.

Procedure growth was led by China, Germany and Japan. Procedure growth in China was driven by a strong expansion in system utilization, as system placements remain constrained pending the issuance of a new quota for civilian hospitals. Procedure growth in China is broad-based with a number of specialties contributing to the strong performance.

In Germany, procedure growth is supported by installed base expansion that is driving strong adoption in urology with contributions from general surgery. In Japan, dVP and dVPN continued to grow, though year-to-year comparisons have begun to slow as dVP adoption has crossed 80%.

During the quarter, the first clinical experience on da Vinci X occurred in Germany. Initial procedures included urology and gynecology with strong early utilization. Commenting on the experience, Dr. Vitt (23:14), from San Antonio's Hospital (23:14) stated, da Vinci X is, quote, ideal add-on to our existing da Vinci Xi's same feeling on the console, close quote.

Globally, evidence continues to build in support of the clinical and economic validation of da Vinci Surgery. During the quarter, an economic analysis studying the impact of da Vinci Partial Nephrectomy in England was published in European Urology.

The work was completed by HCD Economics, an affiliate of the University of Chester. Comparing more than 4,200 partial nephrectomy patients between open and da Vinci Surgery, the authors found that da Vinci Surgery lowered the total cost to treat during the first year after the procedure by an average of £900, primarily by reducing postoperative in-patient utilization from length of stay, cancer and other readmissions and 90-day complications.

This concludes my remarks. I'll now turn the call over to Calvin.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Patrick. I will be providing you with our updated financial outlook for 2017. Starting with procedures; on our last call, we estimated full year 2017 procedure growth of 12% to 14% above the approximately 752,000 procedures performed in 2016. Now, based largely upon continued strong results in U.S. growth and mature procedure categories and China, we are increasing our estimate for 2017. We now anticipate full year 2017 procedure growth within a range of 14% to 15%.

During the second half of the year, we expect our procedure growth rate to moderate, in part, due to one fewer operating day during the third quarter. As we move into the second half of the year, we also expect contributions from China and Japan to temper until we obtain a new quota and place additional systems in China and obtain additional procedural reimbursements in Japan.

With regards to system placements, a record high of 27 of the 166 second quarter system placements were structured as operating leases. In the second half of 2017, we expect the proportion of systems placed under operating leases will continue to increase. The

average selling price per system sold outright will vary quarter-to-quarter based upon factors, including product, regional and trade-in mix.

With increasing placements into cost-sensitive markets, we expect that our average system selling price will continue to trend gradually lower in the back half of 2017. As Marshall mentioned, no amounts were either deferred or released in Q2 related to our da Vinci X trade-in program. Going forward, we expect to defer no further revenue related to this program and expect to release and recognize substantially all of the $23 million accrued during the first quarter by the end of this year.

Turning to gross profit. On our last call, we forecast 2017 pro forma gross profit margin to be within a range of between 70% and 71% of net revenue. We are now modestly raising the top end of the range and expect pro forma gross profit margin to be between 70% and 71.5% of net revenue.

Turning to operating expenses. As we have described previously, we've accelerated our investments in several strategic areas that will benefit the company over the long term. Accordingly, we have ramped our operating expenses as we focus on execution. On our last call, we forecast pro forma 2017 operating expenses to grow at the higher end of a range between 15% and 18% above 2016 levels. We continue to expect results at the high end of the range between 17% and 18% for the year.

On our last call, we forecast our non-cash stock compensation expense to range between $190 million and $200 million in 2017. Now based upon updated Black-Scholes evaluation estimates, we expect our non-cash stock compensation expense to range between $200 million and $210 million. We expect 2017 other income to be between $35 million and $40 million compared to the $30 million to $35 million range forecast on our last call.

With regard to income tax, we now expect our 2017 pro forma income tax rate to be between 28% and 29.5% of pre-tax income, higher than our previous guidance of 26.5% to 28.5% based upon a higher anticipated mix of U.S. pre-tax profits.

During Q2, we had 38.4 million diluted shares outstanding for EPS calculations, roughly equal to the first quarter as the share reduction related to the full quarter impact of the Q1 accelerated share buyback was mostly offset by the dilutive effects of our higher stock price. As a result of our higher stock price, we don't expect the ultimate number of shares received and retired when the ASR closes later this year to vary significantly versus the 2.4 million shares already retired in January.

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

Q&A

Operator

Thank you. And our first question will come from Tycho Peterson with JPMorgan. Go ahead please.

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

Hey thanks. First, on X, I know its early days, obviously, but any color you can provide on the funnel in terms of new versus existing customers, and maybe the types of customers that are emerging?

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

Hi, Tycho. I don't think we'd call out anything surprising here. We had indicated to you in prior quarters that we think cost-sensitive customers, particularly in Europe, are going to be interested, and that remains so. It may have broader remit than that over time.

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

Okay. And then urology continues to do well here. That hasn't reverted to lower growth rates, I think you had previously expected, you talked about that sequential pickup? Can you maybe just talk to the sustainability of those trends in the U.S. urology dVP market?

A - Patrick Clingan {BIO 16639980 <GO>}

Hey, Tycho, I think we continue to believe that our prostatectomy volumes are following broader prostate surgery trends. As you know, prostate surgery really only represents about a third of all men diagnosed in the U.S. with prostate cancer. So, time to time, you'll see movements between (29:59) radiation and surgery. We think – mostly, you've seen the procedures recover from the prior USPSTF decision in 2012, where we worked through patients who had the disease progressed. We think at this stage you're just seeing general small movements between populations period-to-period.

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

Okay. I will leave it at that. Thanks.

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

Thanks, Tycho.

Operator

Thank you. Our next question is from Bob Hopkins with Bank of America. Go ahead please.

Q - Robert Hopkins {BIO 2150525 <GO>}

Hi, thanks, good afternoon. Can you hear me okay?

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

Hi, Bob. Yes.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. Good afternoon. So, the first thing I wanted to touch on, just kind of looking through the results, which were obviously strong pretty much across the board, but the U.S. capital number really stuck out as a strong number. And you mentioned more kind of multisystem sales and repeat customers. Is this really a function of the increase in procedure volume growth and higher utilization, or was there something else going on this quarter?

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

I think it's the former. I – we're seeing – first of all, I think the consolidation of U.S. customers into IDNs means that the negotiations are often happening one layer up. And I think they're looking across their portfolio of MIS opportunities and making decisions in broader settings. I think it's a continuation of a trend we've been seeing for the past several quarters.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. And the other thing I just want to follow up is a couple of quick checks on the pipeline timelines. You mentioned China and Japan as constraining you in the back half. Is there any update at all on the China quota from a timing perspective, or even your sense as to whether or not it could happen this year? And also wanted to just get a quick update on the timelines for SP beyond urology and the filings we could expect, either later this year or into 2018? Thank you.

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

Sure. Marshall, I'll let you take the China quota, and I'll take the SP.

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

Okay. China quota, there is no new news here. It is as we've stated before, the quota system involves, first, the government – is tied up in the overall government – the government's overall planning process. They did approve their budget in December. We – after that it then rolls through a series of decisions about province spending, as well as hospital spending. And then eventually, we'll hear something about a quota. We don't know when that will be.

And what we would caution is that you put anything in the models for this year, frankly, because last time, when the quota was approved, it took some time before the tender offers that the hospitals have to go through to get them done.

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

On the SP regulatory question, we are targeting 510(k) for urology in the back half of the year. There's a data collection going on at the IDE sites for transoral robotic surgery and some lab-based clinical development for other procedures, as well as the trial site in Asia. We haven't yet publicly projected our timelines for submissions after the urology 510(k).

There will be a set that come. It will be months, not years after the 510(k) submission. What that looks like will depend on the speed of closure of the clinical trial data and some of the conversations with FDA about what kind of submissions they'd like. And we're not ready yet to anchor down those dates.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. That's helpful. Thank you.

Operator

Thank you. We'll go next to David Lewis with Morgan Stanley. Go ahead, please.

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

Good afternoon. Just maybe a few quick questions here. Gary, just for you. Just SP timing, I know it came up in the pipeline, but on FC and I know it's pretty early. Can you give us any sense of the major markets, U.S., China, Europe, which one? Our sense is U.S. and China are kind of ahead of Europe, but that's not based on a whole bunch. Which region you think proceeds the other? And is 2019 a reasonable estimate for a launch in some geographic locale?

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

So, first to the question of which regions matter. We think it will have a global appeal, but I think you're right that United States and China, and then Europe will be interesting. In terms of timing, a lot of it will be predicated on regulatory pathways and what kind of data requirements there are.

We think there are real opportunities in China. We're going to make sure that we do that right with our joint venture partner. We likewise think there is in the U.S., I'm not ready yet to call when the launch dates are for both sets because of negotiations with clinical trial results.

Europe, likewise, I think there's a little bit of uncertainty right now as to what kind of submission package will be required, and that's one of the things we're in the midst of working out both internally, and we have conversations with regulatory authorities over time.

We will do a controlled launch when we're ready. So we've told you don't model any revenue in say 2018. We have not yet published and are not ready to publish when the final launch will be. We'll let you know as we get closer to some of the certainty on regulatory timelines.

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

Okay, very helpful. And Marshall, just two quick kind of margin related questions for you. The first is, on gross margin. Given the greater systems mix, I guess I was surprised to see gross margins as strong as they were. And I wonder, who would've thought that X, which

wasn't very material in the quarter would have also pressured margins. So what's driving the margin strength? And as it relates to X, is that just because a lot of the components of X frankly are ready at scale in other places of the business?

And the second question related is, you're looking at hiring, we typically don't ask about hiring, but I think your hiring level this quarter is 25% above the next highest level. That's pretty remarkable. I wonder if you would just share with us where you're hiring and where those people are being deployed. Thank you.

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

Sure. On the X margins – X margins, we had communicated before, typically when we introduce a new product you see a little bit of a decrease in the margin and then we work to improve it over time. You should – we did not expect as much of a decrease in margins due to X. X, as we said really is a result of putting together parts that are already manufactured for other systems, and so we have worked out most of the cost effectiveness of that.

As far as total margins, yeah, the total margin came down a little bit due to the mix of systems. I think it exceeded our expectations just because of the overall strength of procedures and the drive of – and driving instrument and accessory revenue above our original expectations.

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

As far as head count goes, David, we ended the quarter with 4,108 employees. That was up a little over 100 from the last quarter-end, and it was 19% year-over-year. And it really does vary up with the strategic investments that we're making in the business on that side. The majority of the investments were in our product operations group in the quarter.

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

Thank you very much.

Operator

Thank you. Our next question comes from Tao Levy with Wedbush. Go ahead please.

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

Great. Thanks. Good afternoon. May I could, I wanted to ask on the SP platform. So the pathway for the filing later on, towards the end of this year, and then assuming approval sometime next year, how is the launch going to proceed? Is this a – well – is an experienced da Vinci surgeon going to be able to sit in front of the SP – in front of the console and use the SP right off the bat, or are they going to have to go through proctoring of different types of cases? Just any color there would be great.

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

Yeah. Just in broad brushes, it's a family member in the da Vinci family and a lot of – we believe a lot of the learning and skills will be portable from one of the family members to the other. They're not identical. So, there'll be some learning that goes through that transition. We think experienced da Vinci surgeons will find that transition to be pretty manageable. What that looks like and how it's finally framed will evolve as we finish our clinical trials and our validations.

But I'd expect a lot of that to be portable. I think, in terms of rollout, we'll be at a controlled rollout when we come out. And part of that controlled rollout will be for data generation at the first sites. And also, we'll have some constraints due to what our labeling will be at the first launch given the regulatory sequence and pathway.

Feedback from the clinical trial sites has been really good about usability of the system and meeting the expectations they had for what they believe they could do with it clinically; so, so far, so good there. And we also get pretty good insight into the characteristics of the system vis-à -vis what they're used to on Si and Xi and kind of the response to your initial question.

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

Got you. Perfect. And then just lastly what's – anything special going on in Japan? They've got way more systems than they need at this point, and they keep on buying more. I don't know if there's – is there a government incentive or any credit there that they're using? Thanks.

A - Patrick Clingan {BIO 16639980 <GO>}

Hey, Tycho – sorry, Tao.

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

That's close, don't worry.

A - Patrick Clingan {BIO 16639980 <GO>}

Japan has a very diffuse healthcare system and hospital network system, so they're not very concentrated in terms of where the patients are. So while we are at a high level of penetration in dVP, you still have a lot of pockets of patients who are treated in fairly remote areas in local hospitals, so they continue to buy systems, even we'd be able to access some of the remaining urology patients that are out there.

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

We've also been in Japan for some number of years here, and I think there's a little bit of building capacity in hopes of broader reimbursements over time.

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

Perfect. Thanks guys.

Operator

Thank you. And we'll go next to Amit Hazan with Citi. Go ahead, please.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks, hey. Good afternoon, guys. Just one on the quarter and then a couple longer-term ones. So on the quarter, obviously, going – just going back to the U.S. system number, a really strong number. I wanted to ask about trade-ins though. They were weak again in the U.S., it's a second quarter in a row. I'm trying to kind of better understand why, on one hand you've got this obvious growing pool of systems that need to be replaced that you shouldn't (41:02) and you're replacing more systems every year.

On the other hand, there seems to be a relationship between quarters where you had a really strong de novo units like this, this year so far, both quarters. And then trade-ins, kind of, tend to be inversely weaker in those quarters. What's kind of the correct way to be thinking about modeling trade-ins in the U.S.?

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

Let me speak to our intent a little bit, and I'll ask Calvin to jump in on the modeling side. For us, our thought process really has been to enable accounts with technologies and support that help them get to their clinical goals and in support of their MIS and – MIS program goals.

And if they can do that effectively with an Si, we're happy to support them in that regard. If they want to add capacity or grow their system capability in some way that is benefited by our advanced technologies that helps us and drives a new system placement or new system sales.

So our incentives aren't strongly built on trade-outs. Much more interested in aligning with how they want to build their programs and giving them access to technologies that make a difference in their procedures. That leaves the lumpiness in trade-outs. And that's okay with us. Calvin, to the modeling, I just gave you a little time to think about it. Go ahead.

A - Calvin Darling {BIO 17664656 <GO>}

What I say, I mean, is that you have such strong procedure growth and such demand for access to systems among the surgeon population that in a lot of cases when hospitals are seeking to acquire new systems, they look at the procedures and the surgeons that they want to be able to do within their robotics program. And Si can still serve a broad range of patients and can help them facilitate, that's why they tend to be buying more incremental systems than trading in.

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

As X matures in the market, X may be an opportunity for some folks who are happy with their capacity, but want to upgrade up to additional capabilities, and that may provide an

opportunity for us in future quarters.

A - Patrick Clingan {BIO 16639980 <GO>}

And just quickly from the modeling perspective that you asked. Beware of using our past experience with our Xi and previous system launches as the model for what's going to happen now, because it's a different world where you have, again, consolidated hospital networks that can align certain procedure characteristics with sets of procedures with a lot more ability to do so now than in the past. So, it could very well follow a different pattern this go around, than it has in the past.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. So that maybe possibly leads me into the next question, which is on reimbursement. It looks like prostate is getting a new Medicare outpatient reimbursement quote for the first time, I believe. And I realize most of the dVP procedures can't really be done in one day just yet. But it just got me thinking about the question of what the trigger might be for hospitals to start equipping their outpatient settings with da Vinci?

I have to imagine that between hysterectomies moving that way and things like hernia now. There's already enough volume to justify it nowadays. So is something like prostate reimbursement, any kind of an anchor that can maybe drive boxes into outpatient setting? And if not, then what could be the trigger to do that?

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

Two important thoughts here, Amit. One is, in order to be able to do a surgery like a dVP in an outpatient setting, first off, it has to be done in a minimally invasive fashion, so that you can have the patient be able to recover quick enough to get out of that setting.

The second thing is, outpatient is really a billing setting, not necessarily a site of care differentiator. What we see over time is that as programs mature in the robotics capacity, and they have a array of systems that can both serve really complex inpatient surgeries, like thoracic or colorectal. And they have a sufficient volume of outpatient procedures like the ones you mentioned in hernia, in benign gynecology and you could potentially dVP where you have a technique and a surgeon capable of getting a result that can get the patient out the same day.

You'll see them actually put systems into multiple different types of settings. Typically, still under the hospitals umbrella because they're the ones who have the capability of treating the range of patients who come in with different complexities that might be either inpatient or outpatient, but it's usually a byproduct of the maturity of the program as opposed to a specific reimbursable event.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. Thanks very much guys.

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

Thanks, Amit.

Operator

Thank you. Our next question comes from Isaac Ro with Goldman Sachs. Please go ahead.

Q - Isaac Ro {BIO 15121543 <GO>}

Thanks very much. Good afternoon. Question for you on the X. Just trying to think through the gross margin implications of that product cycle as it plays out. I realize it's a little early, but just trying to think through some of the comments you made earlier around how purchasing is evolving for hospitals and so forth. As that product cycle plays out, if could you give us some sense of what it means for your gross margin profile based on what you know now, that would be helpful?

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

Initially, the gross margin profile is not substantially different than our other products. So it kind of fits in nicely. I think what you're asking is, over time, could we see that there's pressure on the ultimate price that we charge for an X? I think we'll see. We don't know. It's only been out in the market for a quarter, but what we've said in the past is that we're about -market expansion. And if there's the opportunity to expand the market at the expense of a little bit of price, we'd do that.

Q - Isaac Ro {BIO 15121543 <GO>}

That's helpful. And then just as a follow-up on the expense side. As you move towards expanding the market, interested in sort of allocation of resources and the sales force, can you talk a little bit about just qualitatively, how you're moving some of your top performers to help drive X conversion, and then at the same time maybe thinking about adding new heads, just interested in the interplay on investment in sales force? Thank you.

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

Yeah. How we think about sales force investments really varies by region and maturity of the market. So how we're building the sales team in Germany, for example, will look kind of qualitatively different than what's happening in the United States.

In general, the United States, we've had a stable structure growth in our key accounts teams. No surprise. And a little bit better stratification of levels in the force itself that gives us the opportunity to provoke and engage high-level sales people at the same time bring in people who can support high-volume accounts that are premature. So the U.S. is a well-stratified sales force. And Germany, in places like Japan, we're really at the basic building stages. And so the investments there are a little more filling empty slots and making sure the territory coverage is right.

Q - Isaac Ro {BIO 15121543 <GO>}

Thank you.

Operator

Thank you. We now have a question from Richard Newitter with Leerink Partners. Please go ahead.

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

Hi. Thanks for taking the questions. It seems like for the third quarter in a row, China, on the procedure growth side, is exceeding your expectations. And seemingly, you're at capacity or you thought you were at capacity in the fourth quarter, and yet this is still kind of – your capacity utilization seems to be creeping higher. Anything to explain that? Are there certain types of procedures that are maybe just quicker? And that as a percentage of the mix in China is different than the U.S.? Or can you explain what might be driving this?

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

I think, at the top line, what's going on here is, high belief in value of the procedures and the technology and a willingness to expand the number of hours that people are able to get procedure. So I think the biggest effect is that, which is a willingness to work on weekends, and for them to expand the after-hours use of the devices. That will dwarf the underlying, which procedures in the mix. But Marshall, you can clean up that answer, if you like.

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

It's absolutely right. I mean, this is all about – it's a theoretical capacity that you're quoting. And that theoretical capacity is based on just averages that we see around the world. Be careful of averages. And in China, they are operating on Saturdays, Sundays and late at night in order to get things done. So I think Gary's answer is right.

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

I think there's also an opportunity for us to learn from their experiences, which is under capital constraint, what kinds of barriers can they remove to get both good outcomes and high volumes. And I think that's exciting for us. And we have an open mind toward how they're approaching it.

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

Great. And then maybe just one follow-up on Japan. That's the other area where you're kind of seeing capacity constraint. And so you get additional – on the procedure side, at least, until you get additional approvals. Can you maybe just remind us the key procedures that you're hoping are up for consideration next year? And maybe – which ones represent the biggest market opportunities? And do you feel there's any that might be further along with the approval agencies over there?

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

In terms of maturity, there are some that have been going through clinical trials and have a lot of data behind them and others that are using kind of existing data sources. So, the one that has the most structured data so far is gastrectomy. And that is going to be exciting for us over time. It's a real market in Japan. The prevalence is quite high, and so we have good hopes and optimism that that will go through the process. Other categories are things like GYN oncology that is of interest, salpingectomy, Calvin, there are some others that...

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. Lobectomy procedures and some of the lower colon LAR procedures are potential.

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

Yeah. So I think the interest in broad use of da Vinci in Japan is very high. We do not have assurance of that MHLW will accept it in the next insurance cycle. Although, so far, so good. And we don't have assurance that the reimbursement levels will be any particular level. And again, so far the indicators are pretty good for us, but that's still a work in process from the government's evaluation point of view. And we stand by to support the surgical societies and answer questions for them as they need it.

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

Thank you.

Operator

Thank you. Our next question is from Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Hey, guys, thanks for taking the question. Let me just start with hernia. You received recently a specific inguinal hernia indication, which includes positive data in the label. Could you talk about the implications of that label and data? And are you pursuing other specific indications for other procedures? And I had one follow-up.

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

Sure. On the first one, this really is something around what gives us a little bit freedom of – a little more freedom about what we can claim in our materials. And so it allows us to be a little bit more specific versus the general. And so for us, we think that, that just clarifies what our teams can speak about. And so we think it's an incremental positive – it's a small positive, I think the data underlying it is supportive, and the interactions with FDA, I think are ultimately helpful for the whole process.

This is one of a set of specific indications that we have pursued over the last couple of years. And we do have a pipeline of the next set of things we want to do and aligned. And we have not publicly disclosed what those are and what the order is, but I'd guess what I'd tell you is I'd expect more to come. And again, I think it's a healthy process between us

and the agency to supply data as we get it and that allows us a little more specific capability in terms of what we talk about.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks. And then I think on the – you're planning to filing launch of 45-millimeter stapler, which should help with bariatric procedures. Is there any update on the timing there? Thanks for taking the questions.

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

Sure. Yeah, we are working on additional staplers besides the ones that are in the market, we have a 30-millimeter and a 45-millimeter. Remember, staplers are characterized by not only their length, but also the length of the staples that go into jaw. There are a set of things that we're working on beyond that.

We do think that there are opportunities to build staplers that can have broader use in general surgery. We have not yet predicted or publicly disclosed what the expected time lines are. We do have technology in development. When those things approach maturity, we'll share with you where we are.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for taking the questions.

Operator

Thank you. We'll go next to Brandon Henry with RBC Capital Markets. Please go ahead.

Q - Brandon Henry {BIO 18858621 <GO>}

Yeah, thanks for taking my question. Can you provide an update on the Australian clinical trial for the flexible catheter platform? And any lessons that you've learned from that trial? And then when and where do you think we can see the data from the trial being published or presented? And a couple of follow-ups.

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

Yes. Thanks, Brandon. I think the short answer is no. I can't provide an update. The data is being analyzed. The clinical teams that are there are preparing their abstracts, and they'll decide in which meeting they want to show it. And once they've made that decision then we're happy to share it with you.

As we said last time, the results were very positive for us. We were really happy with what we saw. I think the scientific principal investigators need the chance to write their manuscripts and analyze the data and present it in a way that makes sense to them. So we will wait for that. And as we get clarity there, we're sure to share it with you.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. And then – just more broadly, can you help me understand some of the differences or the benefits for Intuitive's flexible catheter platform relative to some of the other platforms in the market, like Medtronic with its superDimension platform?

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

Sure. I think what we can bring in our concept and our technology here is a couple of things. One is we have novel sensing technologies that allow us to sense all the way along the catheter length with a high degree of certainty. That helps us in terms of understanding and navigating tortuous pathways, that's one.

The second thing is the use of robotic assistance gives you stability and navigation capabilities that are very hard to do manually. And so those are technical benefits. What could they result in, in terms of clinical benefits? The hope there is that you can get to more distal locations that are otherwise hard to get to in tortuous pathways and that you're more accurate in terms of tissue sampling because you have high degree of stability and better imaging and targeting now.

Those plans have to be backed up, and so that's the hypothesis. And that's the set of trials and data and analysis that we're going after. And I think people are excited about flexible technologies in general by some of the technologies that our competitors and other med companies have put out there. I think the excitement is there. And the question is, can you go a little further and get a little more predictability. And we think we have technologies and capabilities that can do that.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. Thank you.

Operator

Thank you. Our next question is from Travis Steed with Cantor Fitzgerald. Please go ahead.

Q - Travis Steed {BIO 18228465 <GO>}

Thanks for taking the questions.

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

Travis, you'll be the last questioner, so make it a good one.

Q - Travis Steed {BIO 18228465 <GO>}

Okay. So you placed a decent amount of Si systems in the quarter. Did those customers have an option to purchase X? And just any color on how customers are deciding between the two systems, recognizing we're still very early on?

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

So I think the question was, there's a fair number of Si's in the system in the quarter despite the availability of X.

Q - Travis Steed {BIO 18228465 <GO>}

Yes.

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

Right? I think, first, while we were pleased with the approval timelines of X in the U.S. and Europe, there are still many markets that X is not yet approved in, so some of the Si's are just purchases by folks whose choices were Si or Xi. And in case of China, their choice is Si right now, not Xi. So, some of it is just that. In other cases, some of the negotiations are multi-quarter negotiations and are right at the endpoint.

And so they will finish the transaction based on where they started. Those are opportunities for us to go back to those customers over time. That's one of the reasons that we had the revenue deferral and the offers for people to evaluate whether they wanted to make a change. So that's mostly what the dynamics are.

A - Patrick Clingan {BIO 16639980 <GO>}

And then, Travis, the other part to think about is just – the accruals came mid-quarter, so I think Europe was in the beginning of April and the U.S. was in the beginning of May. So you didn't really have a full quarter to get out with the team and communicate to all your customers what X is, relative to other products that may have already been in a long sales cycle.

Q - Travis Steed {BIO 18228465 <GO>}

Okay.

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

Just a little color commentary on X. I think the customer base and our field understood well what X is, what its benefits are. I think the logic of X is well understood and where it fits in the line is well understood. And we're pleased with that.

Q - Travis Steed {BIO 18228465 <GO>}

Okay. And just one quick follow-up, I think I know the answer to this, but is it still your view we should be modeling in 2018 expense growth below your revenue growth?

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

Actually, what we've said is that expense growth – operating expense growth will grow 18% for the year.

Q - Travis Steed {BIO 18228465 <GO>}

I'm sorry, in 2018, kind of, longer-term.

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

Sorry. And, in 2018, what we've said is, we expect to dial it back so that we are adding leverage.

Q - Travis Steed {BIO 18228465 <GO>}

Okay. All right. Thanks for taking the questions.

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

Thanks, Travis. Well, that was our last question. As we've said previously, while we focus on financial metrics such as revenues, profits and cash flow during these conference calls, our organization's focus remains on increasing value by enabling surgeons to improve surgical outcomes and reduce surgical trauma.

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

This concludes today's call. We thank you for your participation and support on this extraordinary journey to improve the surgery, and we look forward to talking with you again in three months.

Operator

Thank you. And ladies and gentlemen, that does conclude our conference for today. Thank you for your participation, and for using AT&T Executive Teleconference. You may now disconnect.