Sloomberg Transcript

Q1 2017 Earnings Call

Company Participants

- Calvin Darling, Senior Director, Finance and 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
- Bob Hopkins, Analyst
- Brandon Henry, Analyst
- David Ryan Lewis, Analyst
- Larry Biegelsen, Analyst
- Rich S. Newitter, Analyst
- Rick Wise, 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 Q1 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 of Finance and Investor Relations, Calvin Darling. Please go ahead, sir.

Calvin Darling (BIO 17664656 <GO>)

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

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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. 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 intuitive surgical.com on the Audio Archives section under our Investor Relations page. In addition, today's press release and supplementary financial data tables have been posted to our website.

Today's format will consist of providing you with highlights of our first quarter results as described in our press release announced earlier today, followed by a question-and-answer session. Gary will present the quarter's business and operational highlights, Marshall will provide a review of first quarter financial results, Patrick is rejoining us to discuss procedures 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'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. This first quarter of 2017 was a dynamic one for Intuitive with strong performance in procedures and solid growth in system placements. We are making good progress in developing deeper connections to our customers worldwide in advancing technologies and offerings that fundamentally improve surgery. Procedure growth accelerated in the quarter, rounding up to 18% over the first quarter of 2016.

The growth was broad based by procedure category as well as global region. Starting with the United States, procedure growth in both the emerging category of general surgery and more mature categories in urology and gynecology exceeded our expectations.

General surgery growth continues to be encouraging with supportive early clinical reports, surgeon interest and utilization. Procedure growth in Europe, Korea and China were strong in the quarter while reasons for quarter-to-quarter fluctuations can be hard to assess, we estimate that Q1 benefited from some tailwinds that will balance out through the remainder of the year. Patrick will take you through these factors in more detail later in the call.

Our capital placement performance in Q1 2017 strengthened over Q1 of 2016, resulting in a growth in total placements from 110 to 133 this quarter. As we mentioned on these calls, capital placements can be lumpy and after a strong 2016, U.S. capital placements settled into moderate growth relative to Q1 of last year.

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Outside the U.S. placement growth in the quarter was a highlight with 56 systems sold in the quarter versus 36 in Q1 of 2016.

The lack of a new system quota in China and limited reimbursements in Japan constrained placement growth in these regions. Marshall will take you through system placement dynamics in greater detail.

Turning to profitability for the quarter, strong procedure growth in solid system placements combined with favorable product mix and improvements in product cost, to lead to gross margins at the top of our expected range and solid operating margin performance.

Our fixed cost growth was as expected with significant increases in R&D spending that reflect investments and bringing new products through clinical trials on the path to market.

A summary of our first quarter pro forma operating results is as follows; procedures grew approximately 18% over the first quarter of last year. We shipped 133 da Vinci Surgical Systems, up from 110 in the first quarter of 2016.

Revenue for the quarter was \$674 million, up 13% from the prior year, instrument and accessory revenue increased to \$381 million, up 18%. Total recurring revenue in the quarter was \$521 million, representing 77% of total revenue. Gross profit margin was 72% compared to 70% in the first quarter of last year. We generated a pro forma operating profit of \$264 million in the quarter, up 15% from the first quarter of last year and pro forma net income was \$196 million, up 15% from Q1 of 2016. In the quarter, we also entered into a stock repurchase agreement in the amount of \$2 billion. Marshall will take you through our finances in greater detail shortly.

Turning to our product pipeline, as you know, we've increased our mid and long-term investments in creating our next generation products and services. Based on our belief that substantial opportunity exists to enable more minimally invasive surgery, better outcomes and to expand access to our technologies globally.

To bring these investments to market, we have developed our product pathway that responds to our customers' desire for choice in clinical capability and choice in total economics. Over the next several quarters, we plan to launch a new technology upgrade to Si, named da Vinci X, that enables a compelling entry point to our advanced technologies. da Vinci Xi will remain our flagship, and we will provide customers with logical upgrade paths for more affordable entry-level systems like Si and X to Si and SP.

We have submitted our documents for CE Mark review for X and anticipate it will be available in Europe in the second quarter, with clearances in other regions following over time. We'll provide you with additional information on X as it launches. The upcoming availability of da Vinci X has some accounting implications, which Marshall will describe in greater detail later in the call.

Our SP program continues to progress in its clinical trial work and new site initiation. Cases at our active trial site in Asia have included transoral, urologic and colorectal surgery. We are also on track in initiating our U.S. IDE sites to gather clinical data in transoral surgery.

In reviewing feedback from surgeons in Asia and the latest standards for human factors validations, we have elected to pull forward a software release for SP ahead of our urology 510(k). This will push back our urology 510(k) submission into the back half of 2017 and is likely to delay the launch of SP in the U.S. by one or two quarters. While I'm disappointed by the delay, we believe it simplifies our submission and our ultimate path to market.

In our flexible robotics program, we completed our first clinical experience in Australia in the quarter. Surgeon commentary on its performance has been enthusiastic. They are finishing patient follow-up and preparing their manuscript for publication. The overall program is in now its design for pilot production phase.

In closing, the first quarter of 2017 has been a busy one for Intuitive. 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 platform, 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'll 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, excess tax benefits related to employee stock awards 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'll 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.

First quarter 2017 revenue was \$674 million, an increase of 13% compared with \$595 million for the first quarter of 2016, and a decrease of 11% compared with fourth quarter revenue of \$757 million.

As Gary outlined, we'll be launching the da Vinci X system in certain markets pending appropriate regulatory clearances. In conjunction with the launch, we will offer 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 and consistent with prior deferrals, this revenue will be recognized when customers either trade out their systems

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or when the offers expire, whichever comes first.

First quarter 2017 procedures increased nearly 18% compared with the first quarter of 2016 and increased 2% compared with last quarter. Procedure growth relative to last year and the fourth quarter has been driven by general surgery in the U.S., in urology worldwide and reflects the benefit of Easter holiday being in the second quarter of 2017, rather than the first quarter of 2016. Patrick will provide more detail concerning procedure adoption.

Revenue highlights are as follows; instrument and accessory revenue of \$381 million increased 18% compared with last year and decreased 1% compared with the fourth quarter of 2016, which closely reflects procedure growth.

Instrument and accessory revenue realized per procedure including initial stocking orders was approximately \$1,840 per procedure compared with \$1,830 last year and \$1,900 last quarter. The increase relative to the first quarter of 2016 primarily reflects increased sales of our stapling and vessel sealing products, mostly offset by customer buying patterns.

The decrease compared with the fourth quarter of 2016 primarily reflects the impact of customer buying patterns. System revenue of \$153 million, which excludes the revenue deferred in conjunction with the customer trade-out program, increased 4% compared with the first quarter of 2016 and decreased 35% compared with last quarter.

The year-over-year increase reflects higher system placements and higher lease buyout and operating lease revenue, partially offset by the revenue deferral and lower average selling prices. The quarter-over-quarter decrease reflects seasonally lower number of systems, the revenue deferral, and lower average selling prices partially offset by higher lease related revenue.

133 systems replaced in the first quarter of 2017 compared with 110 systems in the first quarter of 2016 and 163 systems last quarter. 21 systems replaced under operating lease transactions in the current quarter compared with 19 systems in the first quarter of 2016 and 13 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 first quarter, there were 95 systems out in the field under operating leases. We generated approximately \$5 million of revenue associated with operating leases in the quarter compared with \$4 million in the first quarter of 2016 and approximately \$5 million last quarter. We generated approximately \$10 million of revenue during the quarter from lease buyouts compared with \$6 million in the first quarter of 2016 and \$7 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 \$1.5 million last year and \$1.48 million last quarter. The decrease in ASP compared to the fourth quarter primarily reflects geographic mix. The decrease compared to last year primarily reflects a higher proportion of Si refurbished systems sold to cost-sensitive market segments. We

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expect lower priced systems to be - to cost-sensitive market segments to represent an increasing proportion of our sales in the future.

Service revenue of \$140 million increased 13% year-over-year and increased approximately 4% compared with the fourth 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. First quarter revenue outside of the U.S. of \$183 million increased 12% compared with \$164 million for the first quarter of 2016, and decreased 14% compared with \$212 million for the fourth quarter. Recurring revenue increased 23% compared with the previous year and 5% compared with the fourth quarter, reflecting procedure growth partially offset by customer buying patterns.

Systems revenue decreased 9% compared with the first quarter of 2016 and decreased 39% compared with the previous quarter. The decrease in O-U.S. systems revenue relative to both the prior year and the prior quarter, reflect lower system ASPs reflecting sales of Si refurbished product to cost sensitive market segments, revenue deferrals, operating leases, six in the current quarter versus none in the prior year, and two in the prior quarter, geographic mix, and changes in the number of systems placed.

Outside the U.S. we placed 56 systems in the quarter, compared with 36 in the first quarter of 2016, and 63 systems last quarter. The decrease in system placements relative to the prior quarter primarily reflects seasonality. The increase in system placement relative to the prior year reflects higher sales into Europe, Korea, and India.

Current quarter system placements included 21 into Europe, seven into Korea, six into India, six into Japan and two into China. System placements outside of the U.S. will continue to be lumpy, as some of the O-U.S. markets are in the 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 first quarter of 2017 was 72%, compared with 70% for the first quarter of 2016, and 71% for the fourth quarter of 2016. The increase compared to the prior year reflects reduced product costs and manufacturing efficiencies. Compared with the fourth quarter of 2016, the higher gross margin reflects a higher mix of instrument and accessory revenue relative to systems revenue.

Since we defer costs 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 19% compared with the first quarter of 2016 and increased 1% 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 O-U.S. markets.

Our pro forma effective tax rate for the first quarter was 28.1%, compared with an effective tax rate of 27.4% for the first quarter of 2016, and 26.9% last quarter. 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 first quarter 2017 pro forma net income, which excludes income associated with the revenue deferral, was \$196 million or \$5.09 per share, compared with \$170 million or \$4.42 per share for the first quarter of 2016 and \$242 million or \$6.09 per share for the fourth quarter of 2016.

The \$23 million revenue deferral including the associated deferral of cost of sales and income tax effect, reduced GAAP and pro forma net income per diluted share by approximately \$0.28 per share. Earnings per share benefited from our \$2 billion stock buyback as our average shares outstanding were reduced by 1.7 million shares as we retired 2.4 million shares on January 27, 2017. A final delivery of shares under the ASR, if any, will be delivered at the end of the contract period.

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 \$180 million or \$4.67 per share for the first quarter of 2017 compared with \$136 million or \$3.54 per share for the first quarter of 2016 and \$204 million or \$5.13 per share for the fourth quarter of 2016.

GAAP net income for the first quarter included \$21 million of litigation charges compared with \$2 million in the first quarter of 2016 and \$6 million last quarter. The first quarter charges included approximately \$14 million for the estimated cost of settling product liability claims covered by tolling agreements. We've made substantive progress, resolving over 90% of the tolled cases. The remainder of the first quarter charges is related to a settlement of the dispute over license and supply agreement.

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 in prior periods. The excess tax benefit included in our GAAP results for the first quarter was \$33 million, contributing \$0.85 per share. We've excluded this benefit 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.

We ended the quarter with cash and investments of \$3.1 billion, down from \$4.8 billion as of December 31, 2016. The decrease reflects our \$2 billion stock buyback, partially offset by 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>}

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Thanks, Marshall. Our first quarter procedure growth of nearly 18%, U.S. procedures grew approximately 14% and outside of the United States procedures grew approximately 28%.

Procedure growth benefited from tailwinds from the shift of the timing of the Easter holidays from Q1 into Q2, which had the greatest impact on our European business. Excluding the benefit from these tailwinds, our procedure performance exceeded our expectations during the quarter.

In the United States, both maturing growth procedures such as general and thoracic surgery outperformed our plan. Though difficult to assess, strength in the United States may have been due to a short-term uptick in patients seeking care ahead of any potential healthcare reform.

In U.S. urology, the first quarter growth rate for da Vinci prostatectomy was similar to 2016. We believe that our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market. Earlier this month, the United States Preventive Services Task Force or USPSTF, proposed a change to its 2012 guidance around PSA screening from recommending against screening at any age to encouraging individual patients and physicians to consider PSA screening for men aged 55 to 69. We are pleased to see the USPSTF more closely align its recommendation with guidelines from the American Urology Association.

In U.S. gynecology, first quarter procedure growth sustained trends observed during 2016. Procedure growth in U.S. GYN appears to be driven by consolidation of surgeries towards physicians that specialize in complex 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 remains encouraging. Trends in lobectomies and other thoracic procedures continue to show early stage adoption.

Turning abroad, procedures outside of the United States - procedure growth outside of the United States was approximately 28% in the first quarter, led by the global adoption of da Vinci prostatectomy with solid contributions from kidney procedures, general surgery and gynecology.

As I mentioned earlier, the shift of the timing of the Easter holidays from Q1 into Q2 served as a tailwind in the quarter, likely contributing an estimated 3% to our 28% procedure growth outside of the United States. Procedure growth was led by Europe, China and South Korea. In Europe, procedure growth benefited from the Q1 calendar tailwind but also showed strength on an organic basis.

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.

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In South Korea, procedure growth has driven by a mix of specialties and procedures, in addition to a recent uptick in system placements over the past several quarters. Recently procedure growth in Japan has slowed as dVP penetration has grown above 80%.

During the quarter, the clinical study being conducted to support a reimbursement submission for gastrectomy completed enrollment. Over the past several months, new clinical evidence has highlighted the role of da Vinci in treatment of gastric cancers in Asia.

Case series comparing da Vinci to open or laparoscopic procedures have emerged from both South Korea and Japan. Dr. Yang and colleagues from Yonsei University Health System compared all three modalities of surgery across nearly 1,000 patients in an article published in Annals of Surgical Oncology. The authors found that the da Vinci patient cohort had the highest rate of surgical success compared to open or laparoscopic procedures, while experiencing a reduction in major in-hospital complications, a reduction in positive resection margins and improved lymph node yield.

Dr. Uyama and colleagues from Fujita Health University, published a letter in the Annals of Laparoscopic and Endoscopic Surgery, highlighting prior work on over 500 radical gastrectomies for gastric cancer. The authors found that in exchange for greater blood loss and operating time, da Vinci gastrectomy was associated with a reduction in complications and length of hospitalization compared to laparoscopic gastrectomy. In addition, the authors found the da Vinci patient cohort included a larger proportion of advanced gastric cancers, proposing the da Vinci technology was best for these patients.

Looking forward, during the second quarter, we expect our procedure growth rate outside of the United States to slow as the calendar tailwind becomes a calendar headwind of similar magnitude during $\Omega 2$. As we move throughout the year, we also expect the contributions from China and Japan to moderate until we obtain a new quota and place new additional systems in China and obtain additional procedure reimbursements in Japan.

The first quarter was another quarter with a large number of clinical publications evaluating da Vinci surgery. Of these, I wanted to highlight two additional publications. Dr. Ruan, from Baptist Hospital of Miami, and colleagues, published results from nearly 300 right colectomy patients in the Journal of Surgical Laparoscopy, Endoscopy & Percutaneous Techniques.

Comparing da Vinci surgery with intracorporeal anastomosis to laparoscopic surgery with extracorporeal anastomosis, the authors found that while patients in the da Vinci cohort had longer operating times, they experienced less blood loss, shorter incision lengths and longer specimen lengths.

Other clinical endpoints that trended towards improvements in the da Vinci patient cohort include readmissions, post-operative complications, lymph node yield and zero incisional hernia repairs compared to 7% in the laparoscopic cohort.

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The next publication is from Dr. Leone (25:49) and colleagues from McGill University in Montreal, Canada, published an article in the Journal of Gynecology (sic) [Gynecologic] Oncology on the impact to their hospital from adopting da Vinci surgery for Gynecologic Oncology. The authors reported that the introduction of da Vinci increased the use of minimally invasive surgery from 15% to 76%, increasing the volume of patients treated by 27%. And decreasing inpatient board cost by approximately \$5,000 per patient, despite a higher proportion of patients with complex comorbidities, the authors concluded "organizations are beginning to recognize that the economic implications of introducing a robotics program extend beyond the operating room. It is timely to evaluate the broader ripple effects robotics has on hospital departments outside of the operating room"

This concludes my remarks. I will 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 9% to 12% above the approximately 752,000 procedures performed in 2016.

Now, based upon favorable trends in key markets outside of the U.S., U.S. general surgery growth and solid results in mature U.S. procedure categories, we are increasing our estimate for 2017. We now anticipate full-year 2017 procedure growth within a range of 12% to 14%. We expect the Q2 procedure growth rates, particularly in Europe will reflect fewer operating days than in the previous year.

In regards to system placements, 21 of our 133 first quarter system placements were structured as operating leases. Going forward in 2017, we expect an increasing proportion of system placements to be under operating leases. We have recently expanded our leasing programs in Germany and Korea, and in the U.S., more customers are considering operating lease arrangements to acquire da Vinci capacity.

The average selling price for systems sold outright will vary quarter-to-quarter based upon factors including product, regional and trade-in mix. With the upcoming expansion of our value oriented system offering and increasing placements in the cost sensitive market segments, we expect that our average system selling price will trend gradually lower in 2017.

As we have described, approximately \$23 million of product revenue was deferred in Q1, related to our da Vinci X trade-out program. In future quarters, we expect to defer additional revenue related to da Vinci X trade-out offers that we will make to customers in the U.S. and other markets ahead of the availability of the product. We will recognize revenue at the point the trade-out offers are executed, or when they expire.

Turning to gross profit, on our last call, we forecast 2017 pro forma gross profit margin to be within a range of between 69% and 71% of net revenue. We now expect our full-year 2017 gross profit margin to be in the upper half of that range.

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Turning to operating expenses. As we have described previously, we have accelerated our investments in several strategic areas that will benefit the company over the long run. 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 between 15% and 18% above 2016 levels. We now anticipate coming in at the higher end of that range.

Consistent with our last call, we expect non-cash stock compensation expense to range between \$190 million and \$200 million in 2017 compared to \$178 million in 2016. We expect 2017 other income to be between \$30 million and \$35 million compared to the \$25 million to \$30 million range forecast on our last call. With regard to income tax, consistent with previous quidance, 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.

During Q1, we had \$38.5 million diluted shares outstanding for EPS calculations. As Marshall described, in connection with our accelerated share buyback program, on January 27, we took delivery and retired approximately 2.4 million shares, representing the initial delivery from Goldman Sachs. Based upon the timing of this transaction during the quarter, about 1.7 million shares were reduced from our Q1 share count.

The remaining 700,000 of the 2.4 million share reduction will be realized in Q2, reflecting the full quarter impact. A final delivery of shares under the program, if any, will be delivered at the end of the contract period in November. Beyond the accelerated buyback, our actual Q2 shares outstanding will also be affected by the impacts of employee option grants, share price and other diluted share calculation inputs, as well as any other buybacks.

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

Q&A

Operator

Thank you. And our first question will come from Bob Hopkins with Bank of America. Go ahead, please.

Q - Bob Hopkins {BIO 2150525 <GO>}

Yes, good afternoon. Can you hear me okay?

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

We can.

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

We can.

Q - Bob Hopkins {BIO 2150525 <GO>}

Great. Good afternoon. So, I guess the first thing I'd like to ask about is your announcement on da Vinci X. And it sounds like if you're deferring revenue now that the timing of this is fairly imminent, so is it safe to assume that X will be launching this calendar year?

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

We plan to launch in Europe first and we are in the process of the CE Mark review, we expect that we'll pass through that review in the next quarter or so.

Q - Bob Hopkins {BIO 2150525 <GO>}

And then a couple other follow-ups, in terms of U.S. timing and then Gary, can you just describe this a little bit more, I think you said it was an add-on to Si. I'm just curious, is this technology primarily a lower priced offering, or is it going to be positioned as a tool for new settings or new surgical markets? I just wanted to try to get a better understanding of what the, kind of, new market opportunity that this is addressing?

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

Sure. So, let me describe a little bit of what it is first. It really combines our latest instrument accessory robotic and computing and imaging technology with an Si patient cart chassis. This brings to market advanced upgrade package for Si technology that's lost between the Si and the Xi in terms of its breadth of clinical reach, and it creates an attractive entry point for either an upgrade or a new install. I think that it will do well in places that Si does well today, and adds to it some of the Xi technologies at an attractive economic place. Where that goes in terms of treatment locations, we'll see. I think it will be well received.

Q - Bob Hopkins {BIO 2150525 <GO>}

And then, lastly I guess on da Vinci X, could you just talk about what sort of difference in price point are we talking about here? And what sort of difference in functionality, if it's primarily addressing similar kind of surgical opportunities, I'm just curious as to any sense for what's the ASP difference and the functionality difference, that would be very helpful? Thank you.

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

Yeah, you'll have to wait on ASPs. We aren't announcing it at this time. Just directionally it will be between Si's and Xi's. In terms of capability, again, as we launch, we'll give you additional information in terms of future benefit. It isn't foundational in terms of the types of procedures it can do.

It will make Si's more capable to more comfortably do more procedures. Xi will remain the top of the line. Xi has intraoperative table motion, it has automated help in set-up and optimization in multi-quadrant functions that X will not have.

Q - Bob Hopkins {BIO 2150525 <GO>}

Included launch in the U.S. this year? This is my last question.

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

It is possible, but we haven't yet called the end date in terms of launch timing.

Q - Bob Hopkins {BIO 2150525 <GO>}

Okay, great. I'll get back in queue. Thank you.

Operator

Thank you. Our next question will come from Amit Hazan with Citi. Go ahead, please.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks, hey, good afternoon, guys. Let me just start maybe with the da Vinci Sp delay and just ask for a little bit more color, just specifically what happened to get you to drive that delay? And then also, other than the software upgrade, are you pretty much ready for the 510(k) filing in terms of the clinical results you wanted to have?

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

Yeah. The clinical side has been really good. We're feeling great about our clinical experience and overall product performance. We do - we did learn some things in our trial that we want to make a little easier. It has to do with making it a little bit easier to set up and a little bit smoother and optimized workflow.

We decided that, given the extensive HF, human factors validations, that are required by regulators these days that we'd rather do that sooner ahead of the submission than later. And so, we've made the decision to go ahead and pull that software release forward and do those validations on the newly released software. So I'm not foundationally upset about where we are with regard to Sp. You get out, and you learn. I'd like to take those learnings and put them back into the product and get on with it.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. And then just two quick questions on guidance. First, on the gross margin side, I think I want to try to understand you had another really good gross margin quarter. And your guidance is still kind of a little bit below where we were last year. But it seems like the same drivers are in place, lower cost and new products, managing fixed costs well.

So I'm just trying to understand if this is conservatism by you or if you're actually starting to think about some of the maybe da Vinci X product coming through and that's why the guidance is lower? What else is the offset versus what you've been able to achieve over the last five quarters?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. Hey, Amit, this is Calvin. And we're definitely pleased with our Q1 gross profit results and our continued progress to reduce cost and improve efficiency, as Marshall took you through. And as such we did take up our guidance to the upper half of the 69% to 71% range. But you look at specifically at Q1, the gross margin of 72% in the quarter benefited from product mixes. 77% of our revenue is from higher margin recurring revenue, and 23% came from lower margin capital, also during the quarter again we had very few charges associated with field actions, excess, obsolete inventory. So as we look forward into the balance of 2017, we think the margin will be impacted by things including, of course, capital sales comprising a higher proportion of the revenue and that mix factor. There will be some costs start to build up that to support the manufacture some of the new products.

We are assuming a higher field action in o-charges (37:44) more aligned with historic ratios. And then as I talked about in the prepared comments, some directionally lower system ASPs as we expand our value oriented system offering and increase placements into cost sensitive market segments, and of course, the margin will vary quarter-to-quarter.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. And then just lastly for me is on the procedure guidance, so if I'm kind of hearing you correctly putting all the pieces together, you had some selling day impact that you're calling out for the first time really, I'm assuming you, kind of, knew that ahead of time, so I don't know how much that has an impact on our new higher guidance but maybe a comment on that?

And then in addition to that, you talked about strong, kind of, legacy growth but your legacy growth was right in line with where it's been more recently. So I'm just wondering, is the net effect of this that the higher guidance for you comes really from general surgery in the U.S., is that what's driving the higher number?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, there's a lot of factors. Again, overall we're again very pleased with our Q1 procedure results and growth trends and we do expect 2017 procedure growth to continue to be driven by U.S. general surgery and international procedures. We're still very early stages of adoption in these categories. And again, we raised our guidance in the quarter from 9% to 12%, to 12% to 14%, so it's reflecting our increased confidence overall.

But at the end, we feel like our Q1 results were exceptional in the quarter and going forward, we would expect some moderation in growth in Asia, as Patrick took you through as we await additional da Vinci procedure reimbursement in Japan, and sales quota in China, we'd expect moderation in the European growth rate due to the timing of the Easter holiday, slight moderation in U.S. mature procedures which have continued trends as you mentioned but dVP and GYN, we assumed some moderation there. And then just,

the overriding uncertainty and policy direction in the United States and what impact that may have.

Q - Amit Hazan {BIO 6327168 <GO>}

Fair enough. Thanks, guys.

A - Calvin Darling {BIO 17664656 <GO>}

Thanks.

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 a few quick ones. Gary, just starting off with the da Vinci X for a second here, I wonder with the upgrade electronics package in tower on da Vinci X, is it going to be possible to upgrade the X with Sp? Meaning, will that tower work with Sp, so potentially you can bring Sp to a broader marketplace than we initially thought, which we thought maybe was limited to Xi?

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

Yeah, so it's a good point. The answer to that is ultimately yes, that the computational hardware platform and the basics are shared across all three, X, Xi and ultimately Sp. So in addition to giving people a lower entry point on advanced technologies it gives them logical upgrade pathways to advanced technologies.

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

Perfect. Very clear and then Gary, just two more quick ones, one on Sp, does this software upgrade or software pull forward I should say, does that impact the timing of the second and third filings you're forecasting of head and neck in others?

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

It does not appear to.

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

Okay. And then, Gary, the one procedure - we talk a lot about prostate, we talk a lot about hernia lately, but this thoracic procedure or segment has really come into the dialogue the last six months. Can you just talk more about what's happening in thoracic. How much of it is long resection? How much of it is broad category of VAT surgery and anything you can share with us in terms of market size, stage of inflection, because it's sort of emerged from a nice place to a definitive driver? It'd be helpful to get some clarity. Thanks so much.

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

Sure. I think just painting in broad strokes, the opportunity for us in thoracic surgery over time is real. There's a lot of open surgery in that space. These are complex procedures and delicate surgeries. And so, we think that sets up well for da Vinci kind of platform. As we've brought Xi to market with its longer reach, its narrower arms and its set of Xi staplers, that has helped. So we're seeing what would amount to early interest and early growth in that category.

In terms of market sizes and rate of penetration, I'll let Patrick speak to that a little bit. We still think we're early. I would also say that we've got our sales force and commercial team really focused primarily on general surgery. I think we want to support that market really well. But Patrick, take it away.

A - Patrick Clingan {BIO 16639980 <GO>}

Yeah. If you look at the United States market, there's probably around 100,000 patients who received surgery to-date, split evenly between lobectomies and other types of thoracic procedures for which we think our products can bring value to patients and surgeons. When you look outside of United States, markets are much, much larger, particularly when you look at Asia and China in particular. So we're optimistic about the future, but we're still in very early days. And you're seeing some of the early evidence sets come out comparing robotics to open and even VAT surgeries where they're improving outcomes, and that evidence holds up over time, we think there is a runway for us here.

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

Great. Thank you very much.

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

Thanks, David.

Operator

Thank you. Our next question is from Tycho Peterson with JPMorgan. Go ahead, please.

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

Hey, thanks. I'll start off with just a couple clarifications on procedure expectations. Are you factoring in any impact from the USPSTF guidelines? And then can you comment on hernia ventral versus inguinal, are you still seeing relatively balanced growth rates between the two?

A - Patrick Clingan {BIO 16639980 <GO>}

Hey, Tycho, it's Patrick. From a USPSTF perspective, in 2012 when the original announcement came out, you saw dVP fallings decline over a couple year period. However, since then you've seen our volumes really returned to nearly the level they were

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in 2011, so I think a lot of it has played through that we're pleased to see the statement become more aligned to what the AUA society guidelines are.

From a ventral and inguinal and hernia perspective, we remain encouraged by the trends we're seeing, you continue to see growth in our existing surgeon populations doing more and more procedures, new surgeons coming along and there is a lot of positive energy coming out of society meetings like the American Hernia Society and the SAGES meeting, so we continue to be pleased by the adoption that we're seeing.

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

And then on Sp, I know you suggested the software release wouldn't necessarily impact the timing for follow-on procedures beyond urology. Can you maybe just help us think of when you may have those filings for the follow-on procedures? And also when can we get a readout from the first clinical experience in Australia, is that something that would be published?

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

Okay. So, tear up the things there, one, is Sp and one is our flexible robotics program. Just going to Sp to start, we have not yet settled on submission time lines for the additional indications on Sp beyond urology. We are imminently initiating the transoral surgery trials and then we'll open colorectal trials thereafter. But we have not yet set dates publicly for when we expect those submissions. That said, the software update we're doing vis-à-vis the urology filing should not disrupt the timeline of those two.

With regard to the work that was done in Australia, that was on the flexible robotics platform, they're in patient follow up now, so they're following patients after their treatment for the prescribed amount of time in their protocol. I'd expect them to be presenting publicly in the fall.

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

Okay. Thank you.

Operator

Thank you. We now have a question from Tao Levy with Wedbush. Go ahead, please.

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

Great. Thanks. Good afternoon. So I had a question on the X, on the da Vinci X. Are the instruments similar to the Xi or it's still going to be a different core set of instruments?

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

Good question. The instruments on X are the same family as the Xi, so there are Generation 2 advanced instrument kits, so things like stapling and vessel sealing are Gen 2. They are the same exact instruments, same part numbers as the Xi likewise with the imaging system. So if you're an account that has multiple systems you have Xis and Sis,

then moving to X can standardize your Si base and have one set of instruments and accessories.

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

Got you. And the pricing pathway for an upgrade from an Si to an X outside of obviously the deferral?

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

So not - we haven't published yet what the list price steps are going to be.

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

Got you. Okay. And just lastly, I asked this question last quarter, I'm just wondering if there's any update on the quota from China? Is that still something you expect over the near-term? Thanks.

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

This is Marshall. There really isn't much of an update. As we previously communicated, we are still waiting for quota which would cover the civilian hospitals in China. And we'll keep you informed as we hear.

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

Thank you.

Operator

Thank you. Our next question is from Brandon Henry with RBC Capital Markets. Please go ahead.

Q - Brandon Henry {BIO 18858621 <GO>}

Yeah. Thanks for taking my question. First, can you talk about the dynamic you mentioned of patients coming in for surgery ahead of potential healthcare reform changes and what you heard from surgeons regarding that dynamic? And then, should we expect this similar dynamic to occur in the second quarter? Then I have a couple of follow-ups.

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

This is Gary. I don't think we have deep insight there. There's been a little bit of speculation that there's been some pull forward. We have seen, just in the numbers, a little more buoyance kind of broadly across our procedure base, not just in a single category, but kind of across each category, which leads us to believe there's something environmental going on. I would not say that we have special insight. I think it's a little bit of speculation. We'll know on the future quarters. I cannot predict what will happen Q2, Q3 with regard to how ACA dynamics will occur.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. And then separately on the international side, I think the company breaks out international procedures by prostatectomy, hysterectomy and kind of other bucket. The other bucket is the kind of larger portion of international procedures, but we don't really have a lot of visibility into the underlying trends there. So, can you just spend some time discussing what specific countries or procedures are driving that continued 30% plus growth in the other bucket and your confidence of kind of that rate of growth continuing for the other category going forward? Thanks.

A - Patrick Clingan {BIO 16639980 <GO>}

Yeah. Sure, Brandon. It's Patrick. We continue to see most of our outside of the United States procedure growth being driven by urology, mostly prostatectomy and dVP, but also in kidney repairs, mainly through partial nephrectomies, to which the system tends to be an enabler for population of patients to access partial nephrectomy for kidney cancers. We also do see encouraging signs in general surgery and gynecology, stronger in Asia and in certain markets in Europe where we've already deeply penetrated urology.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. Thank you.

Operator

Thank you. Our next question is from Larry Biegelsen with Wells Fargo. Go ahead, please.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Hi, good afternoon, guys. Thanks for taking the question. First, if I focus on the pipeline, any updates on the new technologies that you're working on, the imaging agent and additional instruments? And I had one follow-up.

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

Imaging trial on the neuroimaging (49:37) agent is initiated so far so good. We're still early in that trial, but we're pleased. Otherwise our imaging programs are progressing against our plan. Your second question was on, I'm sorry, advanced...?

Q - Larry Biegelsen {BIO 7539249 <GO>}

Additional instruments.

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

Instrumentation. We have a portfolio of instruments we're working on. Nothing to really call out in terms of dates for you. We are making progress on expanding our stapler line to be a full line stapling system. But nothing I'd call out for you on this call.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Gary, let me ask one on the competition. So Medtronic has talked about bundling their surgical portfolio to drive sales of their robot. Assuming they have a competitive offering, can you talk about things you could do such as partnering to negate that advantage that they could have? Thank you.

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

The way we think about it in terms of servicing our customer is to allow them to have a minimally invasive surgery program that get the outcomes they want across a broad population of patients and surgeons. We think that our technologies are outstanding and we'll continue to be market leading.

To the extent that they need to augment a robotic system with other products, there are a plethora of other companies that are happy to sell into surgical suites. And I think as long as those are at an economically attractive price point and the products are well accepted, I think we're going to be in good shape.

Q - Larry Biegelsen {BIO 7539249 <GO>}

All right. Thanks for taking the questions.

Operator

Thank you. And our next question will come from Richard Newitter with Leerink Partners. Please go ahead.

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

Hi, thanks a lot for squeezing me in here. Just the first one, coming out of SAGES, we noticed just a palpable kind of acceptance, increased acceptance of hernia procedures in general, multiple kind of podium sessions devoted to it. So I was just wondering, is there that acceptance that you're seeing that we saw, do you guys feel that kind of there's been a notable inflection in the acceptance of kind of hernia, robotic hernia surgery? And would you be willing to kind of give us an updated kind of sense of where we are on the market opportunities within ventral and hernia inguinal, how big they are and kind of where you think that could go from your addressable market?

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

I think in the first part of your question, where are we in acceptance. I think that you're seeing some early exploration and enthusiasm and we're feeling that enthusiasm as well. But as you well know, the surgical population is not of one mind. And I think that we're going to see pro-con debates in hernia for some time, and I would expect that.

And I think it will be challenged and debated and discussed variance by patient population, variance by surgical technique and variance by total economics to treat. That leads to your second question, which is, are we ready to make any changes to our thoughts on estimated market size? And I think it's really too early to try to redraw boundaries there. So summary for us is, so far, so good. I think surgeons are finding real

value and pursuing that value. They're doing what, I think, they should in terms of assessing it carefully and publishing the results and debating which patient groups and subgroups make sense and we'll support them in that effort.

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

That's helpful. And then just a follow-up on the ACA kind of - some of the dynamics that might be playing out in the market place. I'm just wondering on the capital side and on the decision maker side of the equation at hospitals and institutions, any updates on what you're hearing from customers on kind of their willingness to invest in innovation like robotics?

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

I think on the one hand, in a good way, a lot of people understand the basic value proposition of robotics, are familiar with the kinds of things it can do. So that has led to, I think, meaningful conversations that are data driven and effective. I think on the margins right now the ACA has injected some caution on the part of capital buyers. So on the positive side, I think robotics, the value it can bring is pretty well understood. On the negative side, I think, on the margin, at the outside, it's been - ACA uncertainty has been a slight negative.

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

Thank you.

Operator

Thank you. Our next question is from Rick Wise with Stifel. Go ahead, please.

Q - Rick Wise {BIO 1490589 <GO>}

Hi, good afternoon, everybody. Hi, Gary. Just a big picture question first, I mean, I would assume you'd think that the opportunity for robotics in surgery is underpenetrated. I'm just sort of fascinated with the several times you've mentioned, you, Marshall, Calvin had mentioned that average selling prices will trend lower because of new products and mix here. Just stepping back from those specifics, how do we think about the opportunity for a lower priced system perhaps driving increased penetration? I mean, is this the next leg in robotic market penetration, and does da Vinci X and Sp, should we think about that more specifically as one of the next big opportunities as opposed to just a procedure or a geography, if you see what I'm getting at?

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

I'll answer a little simpler question than you asked. I think we have been in close contact with our customers, particularly those outside the United States, and have been listening carefully to what the kind of procedures they want to do, what the reimbursement environments are in their countries, and what kind of capabilities need to match that procedure set and reimbursement set and we think X fits that bill. And as a result, I think that it will be well received. I don't think it's limited to a single country.

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I do think that we believe, and I think our customers believe, that total cost to treat is the right economic measure, the better outcomes followed by economic analyses to look at total cost to treat, and to the extent that your technology offering can match that so that you get both great outcomes and lower total cost to treat that will drive adoption. How big, how fast X goes? We don't have a crystal ball, but we invested in it based on some conversations and research we think was right. I think that it's going to hit the mark for them, and we will be delighted to report to you in future quarters how it's going.

Q - Rick Wise {BIO 1490589 <GO>}

Yeah. And, Gary, just a follow-on to that. So just to be very clear, I mean, this is not, "just an upgrade for existing Si installed base" if is that, but it's definitely something much broader potentially?

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

You can - if one has an Si, then you can upgrade your Xi to an X. If you have node system and you want to get started then you can buy an X to get started.

Q - Rick Wise {BIO 1490589 <GO>}

Yeah. And you did mention, I know it's small, a table motion this quarter. Just out of curiosity where are we with adoption and the uptake there? Is it going as you expect getting planned?

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

Yeah. At the top level, attach rate of table motion has exceeded our initial expectations and kind of our original business plan for that product. I think with regard to the last quarter, I would imagine, I'll let Patrick about...

A - Patrick Clingan {BIO 16639980 <GO>}

Very solid attach rates with new Xi system sales. We've worked largely through the existing population of customers, so we're not seeing as much on a year-over-year basis as we saw on product launch.

Q - Rick Wise {BIO 1490589 <GO>}

Okay. And just last for me on Fosun. Any milestones we should expect in let's say the next 12 months on the program? And maybe just more broadly, how do we think about this partnership's impact if anything now looking ahead on the broader I Surg Chinese business? And especially given the complex geopolitical situation? Thank you.

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

Okay. With regard to Fosun, I think, I'd focus the audience on really two things. One, is the technical progress of the flexible robotics platform because we think that's a major component. And then the other one will be our activities in building that organization, hiring staff as the organization builds out then we'll announce to you kind of where we are. I gave you an update on where we are in the flex robotics program.

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We are very bullish on the interest in and the value that robotic surgery can bring to China. We have the right partner in Fosun over time. That partnership exists today in the form of our distribution relationship with one of their subsidiaries in Chindex. That will grow into the relationship into a full JV. And we will navigate the international waters as need be. So thank you for the question. That was our last one.

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

This concludes today's call. We thank you for your participation and support on this extraordinary journey to improve surgery and look forward to talking to 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.

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