Company Name: Intuitive Surgical
Company Ticker: ISRG US
Date: 2017-10-19
Event Description: Q3 2017 Earnings Call

Market Cap: 39,982.41
Current PX: 357.46
YTD Change($): +146.07
YTD Change(%): +69.100

Bloomberg Estimates - EPS
Current Quarter: 2.257
Current Year: 8.282
Bloomberg Estimates - Sales
Current Quarter: 847.000
Current Year: 3054.625

Q3 2017 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan
- David Ryan Lewis
- Robert Hopkins
- Tycho W. Peterson
- Larry Biegelsen
- Isaac Ro
- Richard Newitter
- Tao L. Levy
- Matthew Taylor
- Brandon Henry

MANAGEMENT DISCUSSION SECTION

Gary S. Guthart

Business Highlights

Opening Remarks

- As you know, Intuitive is focused on significantly improving surgery and enabling access to our products and services in pursuit of this mission globally
- Performance in Q3 was strong, with continued growth in customers' use of our systems and an increase in system placements
  - Worldwide growth in procedures for the quarter was 15% over Q3 2016
- As we've described on prior calls, we expect growth in general surgery in countries outside the United States to continue to lead performance while procedure growth in mature categories in the United States temper

U.S

- In the quarter, we saw this dynamic, with strength in general surgery in the U.S. and in several countries outside the U.S., lifting growth, while U.S. urologic and gynecologic growth moderated
- Drivers of growth include U.S. inguinal and ventral hernia repair, colon and rectal surgery, and thoracic surgery, as well as urology and gynecology procedures outside the United States

- Procedure performance in Asia showed continued strength, with solid growth in China, Japan and Korea
- Overall, European procedure growth moderated slightly from its H1 2017 performance, with trends varying by country
- Patrick will take you through these factors in more detail later in the call

Capital Placement Performance

- Turning to capital placement performance, Q3 was a strong one, with growth in total placements from 134 in Q3 of 2016 to 169 this quarter
- Customers in the United States again showed strong interest in our systems as capital placements grew q-over-q
- Asia, Europe and other market system placements were roughly in line with prior quarter trends
- Capital placements can be hard to forecast and we expect this lumpiness to continue, given conditions in the market
- Our fourth generation systems, da Vinci X and da Vinci Xi, continued to perform well and account for over 85% of systems placed in the quarter
    - Marshall and Patrick will take you through system dynamics in greater detail

Profitability

- Turning to profitability for the quarter, our Q3 pro forma gross margins rose slightly relative to Q2 and are slightly above our expected range for the year
- This is due to strength in procedures and improvements in our operational efficiency
- Our fixed cost growth met our plan YTD, with increases in R&D expenses, growth in staff in European and Asian markets, investments in clinical trials, and growth in corporate computational capabilities

Pro Forma Operating Results

- Our third quarter pro forma operating results are as follows
- Procedures grew approximately 15% over Q3 last year
- We shipped 169 da Vinci Surgical Systems, up from 134 in Q3 2016
- Revenue for the quarter was $806mm, up 18% from the prior year, which included a release of reserves related to da Vinci X trade-out offers of $21mm
- Instrument and accessory revenue increased to $401mm, up 15%

Recurring Revenue and Pro Forma Gross Profit Margin

- Total recurring revenue in the quarter was $548mm, representing 68% of total revenue
- Pro forma gross profit margin was 71.8% compared to 73.1% in Q3 last year, the difference largely driven by a medical device tax refund in 2016
- Pro forma operating profit was $347mm in the quarter, up 13% over Q3 of 2016
    - Pro forma net income was $324mm, aided by onetime favorability in tax items

- And lastly, we completed our 3:1 share exchange announced last quarter
- Marshall will take you through our finances in greater detail shortly

Operations

- Turning to operations, we believe that substantial opportunity exists to enable more minimally invasive surgery, better outcomes and to expand access to our technologies globally
- Our investments in new products and services are built on this belief
- Starting with our multiport product portfolio, recall that we have built a tiered product offering in our da Vinci systems that responds to our customers' desire for choice in content and price points, while maintaining logical upgrade pathways to our leading ecosystem of robot-assisted surgery products and services

Da Vinci X System

- We continue to bring our da Vinci X system to new regions in the world
- In the quarter, we enabled launch in nine additional countries for da Vinci X and anticipate adding four more in this fourth quarter
- This set of options has been well received by our customers, with da Vinci Xi making up roughly 75% of our new placements, da Vinci X making up approximately 10% of new placements in its limited early launch and with the balance made up by Si technology
- We are also advancing our imaging, instruments and accessories portfolios for our generation four systems: the da Vinci X, da Vinci Xi, as well as da Vinci Sp

Surgical System

- While the robotic arms are the most visible part of a surgical system, it's the performance of the whole ecosystem of robot, software, imaging, instruments and accessories, in conjunction with the OR team in their working environment, that creates a high-functioning program
- Our team is committed to understanding the total surgical environment and its workflow and design products that work seamlessly for our customers
- This has motivated our investment in partnerships and technologies for imaging, stapling, and more recently, in advanced energy, working to develop highly effective and easy-to-use total products

Da Vinci Sp Program

- In the quarter, we expanded the launch of two additional instruments and accessories for da Vinci X and Xi into seven different countries, and initiated a limited launch of a refined vessel sealer in Europe
- We anticipate that our da Vinci Sp program will complete patient enrollment in surgery for its round of clinical trials this quarter
- As we mentioned last call, four clinical trial sites participated, three in the United States and one in Asia
- Cases in Asia included transoral, urologic and colorectal surgery, while those in the U.S. focused on transoral surgery

Product Validations

- Our teams are finalizing product validations
- We're working to establish manufacturing capability in support of regulatory submissions that enable launch
- We plan to file our first 510(k) for the current Sp design by year end, with follow-on submissions for additional indications thereafter

Flexible Robotics Program

- For our flexible robotics program, we continue to refine product designs, develop our supply chain, finalize our regulatory strategy and initiate testing
- With our partner, we are progressing in building our joint venture in China, with the hire of the first key staff, including the joint venture CEO and CFO

Conclusion

In closing, Q3 2017 was a strong one 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 global region

Marshall L. Mohr

Financial Highlights

GAAP and Non-GAAP Financial Measures

- I'll describe our results on a non-GAAP pro forma basis, which excludes specified legal settlements and claim accruals, excess tax benefits related to employee stock awards, and charges associated with stock-based compensation and 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

Revenue

- Third quarter 2017 revenue was $806mm, an increase of 18%, compared with $683mm for Q3 2016 and an increase of 7% compared with second quarter revenue of $756mm
- Included in third quarter revenue was the recognition of $21mm of revenue deferred in conjunction with the da Vinci X trade-out program we offered to certain first quarter customers
- Excluding the $21mm, revenue would have increased 15% compared with 2016

- We expect the remaining $2mm of deferred revenue under Q1 trade-out program to be recognized by year end

Procedure Growth

- Third quarter 2017 procedures increased approximately 15% compared with Q3 2016, and decreased approximately 2% compared with last quarter
- Procedure growth relative to last year was driven by general surgery in the U.S. and urology worldwide
- The decline in procedures relative to Q2 primarily reflects seasonality
- Patrick will provide more detail concerning procedure adoption

Revenue Highlights

- Revenue highlights are as follows
- Instrument and accessory revenue of $401mm increased 15% compared with last year, and increased 1% compared with Q2 2017, which closely reflects procedure growth
- Instrument and accessory revenue realized per procedure was approximately $1,880 per procedure, compared with $1,870 last year and $1,830 last quarter
- The increases reflect increased sales of our stapling and vessel sealing products and variations in customer buying patterns

Deferred and Systems

- Excluding the recognition of deferred revenue, systems revenue of $237mm increased 15% compared with Q3 2016, and increased 9% compared with last quarter
- The y-over-y increase primarily reflects higher system placements, partially offset by a higher number of operating lease placements and lower average selling prices
- The q-over-q increase reflects higher average selling prices and fewer lease placements

Operating Lease Transaction

- 169 systems were placed in Q3 2017, compared with 134 systems in Q3 2016 and 166 systems last quarter. 20 systems were placed under operating lease transactions in the current quarter, compared with 15 systems in Q3 2016 and 27 last quarter
- As of the end of Q3 2017, there were 134 systems out in the field under operating leases
- We generated approximately $7mm of revenue associated with operating leases in the quarter, compared with $4mm in Q3 2016 and approximately $6mm last quarter
  - We generated approximately $11mm of revenue during the quarter for lease buyouts, compared with $13mm in Q3 2016 and $5mm last quarter

ASP

- Globally, our average selling price, which excludes the impact of operating leases and lease buyouts and revenue deferrals, was $1.47mm, compared with $1.53mm last year and $1.46mm last quarter

- The decrease in ASP compared to Q3 2016 primarily reflects a higher proportion of trade-in transactions, lower-priced systems sold to cost-sensitive market segments and lower pricing offered to customers purchasing multiple systems
- We believe that flexible financing programs like operating leases have positively impacted our ability to grow our installed base
    - While the number of leases is difficult to predict in the short term, we expect the proportion of these types of arrangements will increase over time

Service Revenue

- Service revenue of $147mm increased 13% y-over-y and increased approximately 3% compared with Q2 2017
- The y-over-y and q-over-q increases reflect growth in our installed base of da Vinci systems
- Outside of the U.S., results were as follows
- Third quarter revenue outside of the U.S. of $213mm increased 13%, compared with $189mm for Q3 2016 and increased 4% compared with $205mm for Q2
- Approximately $5mm of deferred revenue recognized in the quarter was outside the U. S. Excluding the deferred revenue recognition, the increase relative to the prior year primarily reflects increased system placements, net of leases, and increased instrument and accessory revenue

International Performance

- Outside of the U.S., we placed 62 systems in Q3, compared with 49 in Q3 2016 and 63 systems last quarter
- Four of the system placements in the current quarter were operating leases, compared with one last year and five last quarter
- Current quarter system placements included 25 into Europe, 14 into Japan, 5 into India, 4 into Mexico and 1 into China
- System placements outside 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

P&L

Pro Forma Gross Margin

- Moving on to the remainder of the P&L, the pro forma gross margin for Q3 2017 was 71.8%, compared with 73.1% for Q3 2016 and 71.3% for Q2 2017
- The da Vinci X trade-out program had little impact on our margins
- The decrease, compared with Q3 2016, primarily reflects $7mm medical device tax refund received in 2016 and decreased service margins associated with higher scope repair costs
- The increase, compared with Q2, primarily reflects leverage achieved with higher production levels

Pro Forma Operating Expenses

- Future margins will fluctuate based on the mix of our new products, mix of systems and instrument and accessory revenue, our ability to further reduce product costs and improve manufacturing efficiency, and the reinstatement of the medical device tax in 2018
- Pro forma operating expenses increased 21% compared with Q3 2016 and increased 2% compared with last quarter
- The increases reflect our planned investments in product development, specifically, da Vinci Sp, flexible robotics, imaging and advanced instrumentation, and expansion of our OUS markets
- Our operating expenses for 2017 may grow slightly greater than previous guidance, reflecting higher revenue growth

Operating Leverage

- As we have indicated, we are committed to reducing the growth rate of operating expenses in 2018 compared with 2017
- However, as 2017 revenue growth, and in turn, operating leverage, have exceeded our expectations, it is likely we will not create operating leverage in 2018 over 2017 actual result

Pro Forma Effective Tax Rate

- Our pro forma effective tax rate for Q3 was 9.5%, compared with an effective tax rate of 22.7% for Q3 2016 and 29.2% last quarter
- Q3 2017 and 2016 included reductions of $68mm and $16mm of reserves related to the expiration of statutes of limitations on certain tax years
    - Without these reductions, our third quarter 2017 and 2016 pro forma tax rates would have been 28.6% and 27.7%
- Our tax rate will fluctuate with changes in the mix of U.S. and OUS income and with the impact of onetime items

Pro Forma Net Income

- Our third quarter 2017 pro forma net income is $324mm or $2.77 per share, compared with $246mm or $2.06 per share for Q3 2016 and $228mm or $1.98 per share for Q2 2017
- All per share amounts reflect the 3:1 stock split effected in October

Income Tax Reserve

- Recognition of the $21mm of deferred revenue, net of costs and income tax, increased GAAP and pro forma net income per diluted share by approximately $0.09
- The income tax reserve reversal of $68mm increased GAAP and pro forma net income per diluted share by approximately $0.59
- As I indicated earlier, pro forma income provides an easier comparison of our financial results and business trends

GAAP Results

Net Income

- I will now summarize our GAAP results
- GAAP net income was $298mm or $2.55 per share for Q3 2017, compared with $211mm or $1.77 per share for Q3 2016 and $222mm or $1.92 per share for Q2 2017
- GAAP net income included $10mm of net charges associated with legal settlements, compared with no charges recorded in Q3 2016 and $5mm of net benefits recorded last quarter
- GAAP net income for Q2 2017 also included a charge of $6mm associated with purchased IP
  - These costs are excluded from our pro forma results

Tax Benefits

- Beginning in 2017, we are required under GAAP to report the excess tax benefits or deficiencies associated with employees' 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 Q3 was $20mm, contributing $0.17 per share compared with $31mm, contributing $0.27 per share in Q2 2017
  - We've excluded these benefits from our pro forma results
- This amount will fluctuate quarter-to-quarter based on the volume of employee stock option exercises, number of RSUs vesting and the value of our stock

Cash and Investments

- We ended the quarter with cash and investments of $3.8B, up from $3.4B as of June 30, 2017
- The increase generally reflects cash generated from operations
- The accelerated stock buyback agreement we entered into in Q1 will close in Q4
- Based on our current stock price, we will be required either to deliver shares or pay cash to close out the arrangement

Patrick Clingan

Q3 Highlights

Procedure Growth

- Of our third quarter procedure growth, 15%, U.S. procedures grew approximately 12%, and outside of the United States, procedures grew approximately 23%
- Procedure trends were consistent with H1, with growth led by U.S. general surgery and global urology
- During the quarter, in the United States, strength in general and thoracic surgery continued
- Growth in mature procedure categories moderated

- There was one fewer weekday, and we estimate that hurricanes impacted U.S. procedure growth rates by less than 1%

U.S

- In U.S. urology, Q3 growth rate for da Vinci Prostatectomy was similar to H1 2017
- We believe that our U.S. prostatectomy volumes have been tracking to the broader prostate surgery market
- During the quarter, growth in kidney procedures moderated compared to H1

Gynecology

- In U.S. gynecology, third quarter procedure growth was flat compared to the prior year
- Compared to H1 2017, the moderation in third quarter procedure growth was due to benign procedures
- Third quarter U. S. general and thoracic surgery procedure adoption remained strong, led by growth in hernia repair
- Hernia repair continues to contribute the largest volume of new procedures in the United States, with solid contributions from colorectal and thoracic procedures

International Growth

- Turning abroad, procedure growth outside of the United States was approximately 23% in Q3, led by the global adoption of da Vinci Prostatectomy, with solid contributions from kidney procedures, hysterectomies and colorectal resections
- Procedure growth was strong in Asia and variable by country in Europe
- The one fewer weekday compared to Q3 2016 was partially offset by the timing of certain regional holidays

China, South Korea, Germany and Japan

- Outside of the United States, procedure growth was led by China, South Korea, Germany and Japan
- Procedure growth rates in China moderated, despite continued strong expansion in system utilization
- System placements remain constrained, pending the issuance of a new quota for civilian hospitals
  - We have no update regarding the status of the quota
- In South Korea, growth was led by gynecology and urology, including contribution from Single-Site use in gynecology
- In Germany and Japan, procedure growth rates in Q3 were similar to H1 2017, led by the adoption of urology procedures
- During the quarter, recently placed da Vinci X systems generated solid utilization
- The systems were largely used in urology and gynecology procedures, with general surgery procedures in the United States

Da Vinci Surgery

- Globally, evidence continues to build in the support of clinical and economic validation of da Vinci Surgery
- During the quarter, an economic analysis studying the impact of da Vinci Hysterectomy in Denmark was published in the Journal of Robotic Surgery
- The work was completed by a team of researchers from Aarhus University and Odense University
- Comparing more than 7,600 hysterectomy patients across open, laparoscopic and da Vinci Surgery, the authors compared the comprehensive cost of care from the year proceeding to the year following a hysterectomy for benign or malignant conditions

Benign Procedures

- For benign procedures, the authors found that da Vinci Hysterectomy was less expensive than either open or laparoscopic procedures
- For less complex malignant procedures, da Vinci Hysterectomy was more expensive than laparoscopic procedures and less expensive than open surgery
- Within this population, the authors determined that the da Vinci patient cohort was more complex than the laparoscopic cohort and largely replaced open surgery at most institutions
- In conclusion, the authors stated, “our study demonstrates that the use of robotic technology for hysterectomy is potentially cost saving from a broad health care perspective”

Calvin Darling

Q3 Highlights

Procedures

- 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 14% to 15% above the approximately 753,000 procedures performed in 2016
  - We are now increasing our estimate for 2017
- We now anticipate full-year 2017 procedure growth within a range of 15% to 16%

System Placements

- In regards to system placements, although the proportion of Q3 systems placed under operating leases was slightly lower than Q2, we continue to expect that over time, the proportion of systems we placed under operating leases will generally trend upwards
- With increasing placements in the cost-sensitive market segments, we expect that our average system selling price will continue to trend gradually lower
- As Marshall mentioned, $21mm of the $23mm deferred in Q1 related to our da Vinci X trade-out program was recognized in Q3
  - We expect to recognize the remaining $2mm in Q4 and close out the program

Gross Profit

- 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 71.5% of net revenue
- We now expect to come in at the top end of the range and anticipate pro forma gross profit margin to be between 71% and 71.5% of net revenue

Operating Expenses

- 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've 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 17% and 18% above 2016 levels
    - We now expect pro forma 2017 operating expenses to grow between 18% and 19%

Noncash Stock Compensation Expense

- We continue to forecast our noncash stock compensation expense to range between $200mm and $210mm in 2017, as communicated on our last call
- We expect 2017 other income to be at the top end of the $35mm to $40mm range forecast on our last call
- With regard to income tax, we now expect our Q4 2017 pro forma income tax rate to be between 26.5% and 28.5% of pre-tax income compared to our previous guidance of 28% to 29.5%

QUESTION AND ANSWER SECTION

<Q - Amit Hazan>: Let me start with your new thoughts on 2018 actually and just hit that to make sure we have it clear. So I think in the past, you're talking about higher OpEx spending this year and then normalizing in 2018. That's how we started the year. What are you thinking about OpEx spending for 2018 in the comments that you made? And historically, high single-digits would've been normal. What do you consider to be the new target?

<A - Marshall L. Mohr>: Yeah. I think what we've said is that we would expect to, as you said, return to normal spending next year, normal being defined as something that's more in line with revenue growth. I think that what we're seeing this year is we're outperforming on the revenue line and we wind up with much higher leverage than we had expected, and therefore, higher profit margins. And so, if we continued our spending – even if we decreased the rate of spending next year or the rate of increase next year, you still wind up with not achieving leverage as maybe we were indicating before. So, it all has to do with where we're coming out this year relative to next year. In total, if you looked at our plans on a two-year basis from last year to next year, it's really pretty consistent with that.

<Q - Amit Hazan>: Okay. And then, just on the installed base in the U.S., it's now three quarters in a row that you got really strong numbers, especially new additions to the installed base. I think it's almost double what we saw last year. So, I think you guys will always point us to procedures as the key leading indicator, but I'm wondering if there's any additional insight as to why it's been so strong so far this year. And how much does that growth in the U.S. installed base improve your confidence for U.S. procedure growth over the next 12 months?

<A - Marshall L. Mohr>: Yeah. You took some of the words right out of our mouth. Procedure growth really does drive placement growth, so we kind of think of it in that order. And procedure growth, we've talked about what that's been. It's been stronger for the last few quarters.

To date, 85% of our system placements have been to existing hospitals, with roughly two-thirds of that to expand the installed base. So, what we're seeing is hospitals growing procedures, having a need for additional capacity, and therefore, buying systems. 90% of the systems we've sold are fourth generation, as Gary had indicated, so Xi and X. And what we see there is that people want to avail themselves of the latest capabilities, including computer-aided setup, optimized advanced instruments and table motion and multi-quadrant access.

So, it's a number of factors that are driving it. It's hard to predict. We don't give you guidance on systems going forward but that's what's driven it so far.

<Q - Amit Hazan>: Yeah, and I'll sneak in one quick one on physicians trained. I'm just curious, so basically, in general surgery specifically, if you've got a sense of roughly how much of your growth is being driven by new physicians being trained and how much is just kind of an improvement in the same-store sales, so to speak, and how much runway we might have left for kind of new surgeons trained in general surgery as a driver.

<A - Patrick Clingan>: Yeah. Hey Amit, it's Patrick. We see a pretty balanced growth across both new surgeons who are starting da Vinci general surgery for the first time, as well as those who continue to expand their practice by either doing more patients within the existing procedures that they've been performing, as well as adding new procedures to the list that they had been performing over time.

<Q - David Ryan Lewis>: Gary, I had one quick question on some pipeline dynamics and I may come back to the cost after that, but just two things. You reiterated the Sp regulatory timing end of this year. Is there a good estimate for us full commercial launch for Sp first quarter 2018? And the second part of that question was, just on flexible catheter. You talked about the regulatory pathway. But can you give us any sense of 510(k) PMA, we've been assuming 510(k), and whether there is any commercial timeline that you could share?

<A - Gary S. Guthart>: Sure. So on Sp, we don't know exactly the launch date, just given what questions we might get back from FDA. So, we have that and as well as finalizing some of the supply chain work we want to do. But we're working hard and solving the problems that we think we need. So, I don't have any additional update for you on the Sp commercialization ramp. We'll report to you when 510(k) goes in and what we think about it.

On the flex side, likewise, what we've described in the script. We're making good progress on developing the technologies and finalizing our regulatory approach. We believe it's a 510(k). We'll find out. FDA has a say on all of that, but our plans are such that it's 510(k). We have not set a launch date yet for public consumption.

<Q - David Ryan Lewis>: Okay. And then, just coming back to spending, either for Gary or Marshall, the thing about 2017 was you wanted to invest at a greater level because you had a lot going on in the pipeline. By our math and your guidance for next year for flat margins is consistent with our model, but it basically implies about $1B in R&D and combined SG&A, which is a nice big round number. Can you give us any sense of the spending [indiscernible] (34:24)? I think investors are totally comfortable with increased spending if they think that spending is going to generate a high return. So, the kind of things you're working on for next year and why that level of spending is necessary. Thanks so much.

<A - Gary S. Guthart>: Sure. It's a good question. As Marshall said, we haven't really changed our view of what kind of spending is required in 2018. Just a little bit of a math of 2017 changes relative to what the total operating margins look like. With regard to what we're investing in, we go from essentially a single platform in the field and multiport da Vinci to Sp, which is a new patient side, plus accessories and instrumentation, as well as flex catheter, which we think is really important.

So on the R&D side, you've got kind of a broadening of platform lanes. And we think those are important because they don't get developed in a year. They take both technology development as well as technique development and all the commercialization steps that you all are well aware of. So, that's kind of one side.

The flip side is a set of investments around making sure that we can support the scale of the business in the multiport space and that has to do with making sure your factories are right and you've invested in plants and equipment and you get the advantages of scale as you grow. And we've started to see that at the gross margin line, the improvements and

performance above some of our earlier expectations are the result of some hard work in manufacturing efficiencies, which, I think, I would be supportive of or [ph] I may show oversight (35:58). I think it makes a lot of sense. Those are really the investment priorities.

There's a little bit in there about data generation in local markets to support the needs of our customers in the markets in which they operate, be it clinical data or economic data, so that picks up – that rounds out kind of the investment profile. Probably not a surprise to you at all.

<Q - Robert Hopkins>: So, the first question I wanted to ask is for Gary. I noticed, obviously, that TransEnterix got an FDA approval. And what struck me as interesting is they got approval for 23 different indications, 23 different types of surgeries, some without data. And I was just curious, does this suggest that FDA might be willing to approve multiple indications and could this potentially advance some of your timelines for the different indications that you're looking at for Sp and some of your other technologies?

<A - Gary S. Guthart>: Yeah. Fair question. So, the first thing is the use of kind of a one set of data to get additional procedures. That's something that was discussed with FDA in their workshop a couple of years ago and has been employed by us and by others. So, the idea that there are some procedures that are the kind of the key data generators that create an umbrella for other procedures is not a surprise to us, something that we have worked with FDA on and we're not surprised that others are likewise using it.

I think with regard to what evidentiary requirements are, which is a little bit underneath your question, the issue there is that how FDA views this is what you asked for in terms of labeling and claims and the relative evidence to support that are linked. And whether this signals a change in FDA's posture, you really have to read the specifics of the labeling as well as what the submitted data was.

We will do that carefully when it comes out and we'll assess whether their posture has changed or not. But on its surface, just reading what you've seen so far or what we've seen so far, A, we're not surprised that there are a set of procedures and kind of the devil is in the details as to how they viewed it.

<Q - Robert Hopkins>: Okay. Fair enough. So, we'll follow-up after we get more details there. And then, I apologize, Marshall, just one more on the 2018 comment. I assume, from the comments and some of the math, that what you're implying here is a double-digit level of increase in OpEx in 2018. Is that a fair assumption?

<A - Marshall L. Mohr>: Well, we'll provide you guidance when we get to next quarter. We're not ready to commit to what the increase would be. It's just that as we sit here today, we would imagine that we would not be adding leverage to the model.

<A - Gary S. Guthart>: Our spend in 2017 is, today, has been right where we thought it would be. Revenue has come in pretty well and our margins and other costs have been where we expected them. And so, it just changes the profitability relative to what we were thinking nine months ago.

<Q - Robert Hopkins>: Yeah. I mean, that's really the basis for the question. I'm trying to get at, what percentage of this is really could be associated with just increased confidence in the outlook for revenue growth next year?

<A - Marshall L. Mohr>: Yeah. So, we'll get to the guidance for you in the next quarter.

<Q - Tycho W. Peterson>: Hey, thanks. First question on dVP. I want to make sure I heard this right. I think you said Q3 volumes in the U.S. similar to H1. If that's right, that seems to be a contrast to what you talked about of moderating to low single-digit growth just a month ago. So, can you clarify that?

<A - Patrick Clingan>: Yeah. I guess, Tycho, to clarify, the comment on dVP was the growth rates were very consistent with H1, but the category of urology moderated compared to H1, so inclusive of other procedures like kidney procedures.

<Q - Tycho W. Peterson>: Okay. And then, thinking a little bit ahead on Sp as we think about the initial urology rollout, this is really about improved clinical outcome maybe vs. market expansion, I guess. Can you maybe just talk as

to how you think about that factoring into this option cycle? And since this is kind of a new approach in terms of getting FDA approval by procedure, how does that play into the mix in terms of how much of this is going to be in upsell to the installed base vs. potential market expansion, if you will, when you do roll it out for urology?

<A - Gary S. Guthart>: Yeah. In the early parts of the rollout, we expect to do that in a measured way and the beginnings will be around clinical publication and evidentiary building of evidence. We think that has multispecialty implications. And so, part of this will be the follow-through and get multispecialty indications with FDA and you see some of the trial data doing that. I don't know that Sp harkens a different regulatory pathway for FDA. You had implied that in your question and I'm not sure that I agree with that implication. So far, it doesn't look like a foundationally different way to communicate with FDA.

With regard to the question of how much of this is kind of working backward into the existing procedure base we do in pursuit of better outcomes and how much we'd expand opportunity, I think we're going to see some of both and it's a little bit early to size exactly which. I have been impressed by surgeons' interest in both categories, both improving what they do already as well as being able to approach techniques and applications they have not yet done. So, I think that's what we're excited about. It is the potential to do both. And I'd just say stay tuned there as we get more experience and put this in the field.

<Q - Tycho W. Peterson>: Okay. And then, just lastly, on, I think, about clinical data readout, two weeks from now, you have the data coming out at CHEST. Any preview you can give us for those that don't want to go to Toronto?

<A - Gary S. Guthart>: No, no, no, I cannot.

<Q - Larry Biegelsen>: Maybe I'll just start with the flex catheter, and then, I had one on competition. So, the data at CHEST, is that going to be enough for 510(k) clearance in the U.S.? Will you have to do another trial for 510(k) clearance?

And on the last call, you're asked about how your flex catheter system compares to Medtronic superD [superDimension]. There is another robotic system being developed in the field that we hear is similar to yours. Is that a fair characterization? I'd be curious if you had any comments on that. I have one follow-up.

<A - Gary S. Guthart>: Okay. So on the sufficiency of data, thus far, to date, vis-à-vis 510(k) clearance, don't know yet. So, we'll see. I can't give you a positive or a negative indication.

With regard to other folks working on flex approaches that are robotic, we have heard likewise indications that people are interested in pursuing that. Very little publicly available out there and we won't speculate as to what their plans are ahead of whatever their public releases are. But we remain vigilant. And I guess my major point on this one is the way you'd satisfy your customers best is by understanding their needs and being really conversant in what they want and what the technologies are. And so, I worry a lot less about what others are doing and a lot more about what we're doing. And our team is highly focused in satisfying customer need in that space and we feel good about where we are.

<Q - Larry Biegelsen>: Thanks, Gary. And then, just for my follow-up on the competition, I guess I'll ask one broad question on the TransEnterix approval. Just comments, Gary, from a technology or an IT standpoint and potential for this elongating – the selling cycle in the U.S.? Thanks for taking the questions.

<A - Gary S. Guthart>: With regard to other systems that are coming or have come out, our experience goes back pretty far. So, we have lived through the pathway of hybrid surgical approaches, some robotics, some manual, three-armed systems, some things integrated, some things not integrated. We have lived through that and its our customers who have really taken us to the position we're in with integrated systems, things that work very well together.

Simple examples, if you have a manual stapler and you're using robotic system, the surgeon has to often – almost always, scrub in and scrub out because it's unusual for a physician's assistant to fire a stapler. So, the workflow of getting up and sitting down is really challenging. The challenge of integrating multiple different technologies from multiple different vendors at the OR is a headache and they tell us that. We'd like this all to work together as if it was designed with a whole thought. We didn't choose those things out of the blue. And so, with our own systems, with

systems we competed against 20 years ago, we have kind of seen this. And so, I think that customers will think that through and evaluate it.

You had asked, could it delay sales cycles, and the answer to that is yes, it can. In the near term, now we are facing some of these concepts and competitive systems in Europe and customers are evaluating these things in making decisions. I think they make them based on pretty good basis. And so, it may cost some short-term ripples but we'll be ready to engage those conversations with hospitals.

And again, I think we didn't end up where we are by accident. That's true in our IP portfolio as well. And one of the things about being the market leader is you have to solve these problems first and you get to patent them and we have. So, that's something that's an asset for the company as we go forward.

<Q - Isaac Ro>: Just a quick question on China. You guys mentioned that procedure growth decelerated even though utilization per instrument went – or per system went up. Can you just talk a little bit about whether or not we should be thinking about your existing installed base sort of hitting full capacity utilization until we get more of an update on the quota system?

<A - Patrick Clingan>: Yeah. Isaac, I think we've been surprised by the levels of utilization that we see across many of the civilian hospitals within China. And to date this year, they've surpassed levels we thought that we would start to see faster slowdown there and you're starting to see the law of large numbers catch up, but still strong growth in utilization.

So, I think the short answer is we're not sure exactly where the ceiling is because the demand for robotic surgery in China is large and they continue to find ways to efficiently maximize the time they have on the robots each week.

<Q - Isaac Ro>: Okay. And then, just a follow-up on the new areas of investment for 2018 as it relates to your comments on operating leverage. Can you comment, maybe even just qualitatively, on some the biggest areas of new investment that are incremental to the underlying programs you already had planned? Just trying to get a sense of where those resources are being deployed?

<A - Gary S. Guthart>: The way to think about it in terms of the, just so you know, on kind of the R&D product pipeline side, the peak-in platform investment is several quarters before launch, those things peak. And then, they stay at that peak for a couple of quarters as you process through all the launch activities and then you start to come off that peak. And so, you have two platforms that are heavily in design and moving toward commercialization, and that's the bulk of the delta.

With regard to some of the other spending, that tends to be in little bit smaller increments and it's around things that give us manufacturing optimizations. As procedure growth has continued to go and we get additional scale, a lot of the cost in the production and handling of our systems comes down to manufacturing process. And as scale changes, we have an opportunity to tweak what we do to get lower cost. And I think that helps everybody. I think it helps Intuitive. It helps our customers and allows us to take advantage of scale. That's a really good thing. And so, where we see those opportunities, they're pretty easy to evaluate and we move forward on.

<Q - Richard Newitter>: I have two quick ones. Just you've mentioned in the past and you, again, Gary, highlighted some of the imaging developments and advancements that you've been working on. Can you give us a sense as to what the timing might be on the integration of some of those into your current platforms?

<A - Gary S. Guthart>: Sure. So, you think of imaging as kind of having three elements of it. There's the hardware part, the optics, the electronics, the physical stuff. We are consistently improving those things and launch them as either improvements or as upgrades periodically, and you sort of think of those as having life cycles of multiple quarters, six to eight quarters.

There are software improvements, image processing, image integration, those kinds of things, we also launch those. These are either as upgrades or as in conjunction with other opportunities, and those go out also on a kind of a yearly or every other year basis. And then, there's molecules, targeting agents. The molecules are viewed by the world as drugs and those go on drug timelines which are long.

So, we're progressing but it doesn't look like stasis. It is continuously improving our gen four imaging as we speak. The gen four scopes of today are better than the scopes of two years ago. The gen four software is better today than it was years ago and we continue to progress on the molecular front.

<Q - Richard Newitter>: Okay. And on the molecular, there's no concrete timeline?

<A - Gary S. Guthart>: No. Given some of the trial activity that has to go on, we have not yet published what we think the long-term timelines are, in part because we're in conversation with the agency about how they want to view these diagnostic markers in surgery and that creates in a lot of uncertainty as to what the forecast models would be.

<Q - Richard Newitter>: Got it. And then, just one follow-up, you've mentioned the moderation in EU or European procedures in Q3. Can you just elaborate on that a little bit?

<A - Patrick Clingan>: Yeah. There was moderation in certain markets, not in all. We still had strong growth in some like Germany. It was in a handful of markets, some I would characterize as slowdowns in some of the benign procedures where reimbursements are tight and other markets where you've had high levels of penetration in urology, dVP, dVPN, where the emerging procedures are still small and not able to influence growth rate.

<Q - Tao L. Levy>: Maybe we can start with the impact from hurricanes and I guess the one less surgery day in the U.S. So theoretically, if you had all that back in the quarter, I mean, are we talking about another 2% potentially on that U.S. growth, and do you expect to capture some of that business, at least from the hurricane? Is that more of a delay that you can pick up in Q4?

<A - Patrick Clingan>: Yeah. Tao, it's really hard to calculate these things because certainly, there are some patients who need surgery right away, who come back faster and others that can defer longer. What you can look at is just what happens in those markets during those periods of time and give best estimate. Our best estimate in the U.S. is that the hurricanes caused somewhere less than 1% impact to the U.S. growth rate. And the one fewer weekday had some effect as well just because you have one less Monday through Friday, but really hard to be precise about exactly how much it impacted business. Overall, the U.S. didn't feel dramatically different though compared to prior years, particularly in the areas of general surgery and thoracic surgery.

<Q - Tao L. Levy>: Got you. And then, you mentioned you're going to have, if I heard you correctly, about 13 sort of new countries starting to do da Vinci procedures here in H2. Are these countries being supported directly? Are you using distributors? Are there opportunities where these countries will start to buy multiple systems or are these kind of more one-offs?

<A - Gary S. Guthart>: Hey. Tao, it's Gary. Just a clarification from the script, they're not new countries to us in da Vinci. It is X, da Vinci X availability in those countries, so the ability for us to sell the X system there.

<Q - Tao L. Levy>: Okay. Got you. Thanks for that. And then, just one last one, as you look at the Sp for next year, again, in urology, do you have a sense of how many Sp surgeries have been performed sort of in this kind of clinical evaluation phase and how long will it take before some of the surgeons really start to using the Sp in sort of a more consistent fashion once it gets approved?

<A - Gary S. Guthart>: We'll put out first set of systems after clearance. We're selecting sites that we think have multispecialty potential and once – and that'll be limited at our discretion in the beginning so that we get those sites up and running. I opt them to be highly efficient, so we won't have a huge number. I think the demand will oversubscribe the supply in those early launch quarters. I think that it's a highly capable system. I think once we have clearance, there will be a fair amount of use but it's going to be sequential clearances that help us get there.

<Q - Matthew Taylor>: Great. So, you touched on this before but I guess I just wanted to ask a little bit more directly, if you could give us a flavor for anything that you're seeing kind of broadly in the market with regards to utilization or appetite for capital purchases. I remember a couple of calls ago, you said, hey, with some uncertainty around reform, maybe we're going to see some gun-shy buyers, but that clearly has not been the case this year on capital. So, just any update you can provide on the market and what your customers are saying?

<A - Marshall L. Mohr>: Yeah. You're right. We haven't seen broad impact of potential reform or changes in ACA. The feel of the market is pretty similar over the last few quarters. And as I said earlier, really, what we think is driving the strength of system placements have to do with procedure growth.

<Q - Matthew Taylor>: Great. In the U.S., clearly, that's all about general surgery with some of the slowdown that you're talking about in the mature procedures. And I was wondering if you could provide some more color on areas in general that have kind of sprouted more recently. You talked about hernia for a while, ventral and colorectal. Are there any new areas that you're seeing start to grow as surgeons adapting, begin to use the technology in new ways?

<A - Gary S. Guthart>: We do see new opportunities and surgeons interested in advancing. But before I get there, I think that just from our company's focus, we have not taken the ball off general surgery. I think that the ones we're in are still relatively early in their total adoption. You think about hernia repair and colon surgery and rectal surgery, thoracic surgery. These are major categories. We think that we can bring real value and our teams are really focused there. And I focus you there. I don't think we're past that and thinking there's the next thing.

We do see surgeons asking for additional opportunities. They are not yet material. And so, I think we have a long pipeline. I'm not ready to describe them as opportunities for you yet because I don't know that they'll realize but there is real desire. So, we stay focused on finishing the opportunities that we've started and we're still early.

<Q - Brandon Henry>: Yeah. Thanks for taking my question. Can you talk about the trends you're seeing in the U.S. gynecology market? And then, I think you've mentioned there was a moderation in benign procedures. Can you just talk about what led to that? I have a couple of follow-ups.

<A - Patrick Clingan>: Yeah. Brandon, it's -overall in U.S. GYN, we saw pretty flat growth year-to-year. The deceleration compared to H1 was entirely attributed to benign procedures that declined moderately. Malignant procedures continue to grow in the quarter.

The trend there is, in part, because, A, it's a very low-growth area in general. You see high penetration rates of minimally invasive surgery. And in any given period, you're going to have little movements here and there. So, nothing notable to call out specifically as it relates to trend there in the market.

Yeah, I think we've talked in the past about consolidation trends, right? More cases being done by gynecologic oncologists or other surgical specialists, and that's been a positive trend for us and that's largely continued here in Q3.

<A - Gary S. Guthart>: Brandon, we'll just give you one more follow-up.

<Q - Brandon Henry>: Sure. And then, in terms of new instrumentation, I think you mentioned a refined vessel sealer launch in Europe. Can you talk about a little bit about the refinements made there and when you expect to launch in the U.S.? And then, also, do you have any update on timeline for new stapling technology? I think you mentioned 60 millimeters stapler in the past. Thanks.

<A - Gary S. Guthart>: Yes. The vessel sealer is really a refinement in geometry that allows surgeons to get to spaces that were more difficult than prior. It's kind of a family member of the technology we have today. I don't have the launch date for U.S. in front of me. But we continue to build out our stapling line, as we've talked about in the past. Likewise, we have not projected yet the launch timeline of additional staplers, but we think stapling is important. So, that's kind of where we are there.

Gary S. Guthart

Closing Remarks

Let me go ahead and close

That was our last question

As we've said previously, while we focus on financial metrics such as revenues, profits and cash flow during these conference calls, our organization remains focused on increasing value by enabling surgeons to improve surgical outcomes and reduce surgical trauma

- We've built our company to take surgery beyond the limits of the human hand

And I assure you, we remain committed to driving the vital few things that truly make a difference

This concludes today's call

We thank you for your participation and support on this extraordinary journey to improve surgery, and we look forward to talking with you again in three months.