Date: 2021-01-21

Q4 2020 Earnings Call

Company Participants

- Gary S. Guthart, Chief Executive Officer
- Marshall L. Mohr, Chief Financial Officer
- Philip Kim, Head of Investor Relations

Other Participants

- Amit Hazan, Analyst
- David Lewis, Analyst
- Lawrence Biegelsen, Analyst
- Richard Newitter, Analyst
- Robert Hopkins, Analyst
- Tycho Peterson, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for your patience in holding, and welcome to the Intuitive Fourth Quarter of 2020 Earnings Release. At this time, all of your participant phone lines are in a listen-only mode and later there will be an opportunity for your questions. (Operator Instructions) Just a brief reminder, today's conference is being recorded.

Now I'm happy to turn the conference over to Head of Investor Relations, Philip Kim.

Philip Kim {BIO 22131870 <GO>}

Good afternoon, and welcome to Intuitive's Fourth Quarter Earnings Conference Call. With me today, we have Gary Guthart, our CEO; and Marshall Mohr, our Chief Financial Officer. 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 or uncertainties.

These risks and uncertainties are described in detail in our Securities and Exchange Commission filings, including our most recent Form 10-K filed on February 7th, 2020 and Form 10-Q filed on October 19th, 2020. Our SEC filings can be found through our website or at the SEC's website. Investors are cautioned not to place undue reliance on such forward-looking statements.

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Please note that this conference call will be available for audio replay on our website at intuitive.com on the Latest Events section under our Investor Relations page. Today's press release and supplementary financial data tables have been posted to our website. Today's format will consist of providing you with highlights of our fourth quarter results as described in our press release announced earlier today, followed by a question-and-answer session. Gary will present the quarter's business and operational highlights. Marshall will provide a review of our financial results. Then I will discuss procedure and clinical highlights. And finally, we will host a question-and-answer session.

With that I will turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Thank you for joining us today. Our fourth quarter capped the year in which the pandemic challenged our customers and our business that highlighted some core strengths for the company, introduced some obstacles to overcome and triggered some changes for us. To put the year and quarter in context, let me first review some of the numbers.

Procedures grew 6% year-over-year for the fourth quarter and 1% for the full year over 2019 resulting in approximately one and a quarter million procedures in 2020. We placed 326 systems in the quarter down from 336 systems in Q4 of 2019.

For the full year we placed 936 systems in 2020 down from 1,119 systems in 2019. Finally, revenue fell 3% in 2020 as the result of delays in surgical procedures as hospitals focused on treating COVID patients. Digging a little deeper, our core business remains healthy. After the first surge of COVID abated during this past summer, our customers returned to more routine use of our systems and solutions.

We believe that the Intuitive ecosystem enabled increased access to and practice of high quality minimally invasive surgery, which may have help hospitals conserve valuable intensive care resources during the pandemic. Despite pressure on utilization of our systems due to COVID, our hospital customers continue to invest in building their Intuitive's robotics programs with additional systems evidenced by a 7% increase in the clinical installed base in 2020.

We saw committed customer strengthening their programs likely due to their analysis of how well the Intuitive ecosystem satisfied their quadruple aim objectives, better outcomes, better care team experiences, better patient experiences and lower total cost to treat per patient episode.

Lastly, we believe our investments in our analytics programs have helped customers routinely analyze their performance, supporting their programmatic insights in the year. Our confidence in our core business and our long-term opportunity remains robust in spite of near-term uncertainty, which is as follows.

First, the pandemic is resurgent in many regions powered now by more contagious variance. While hospitals have better protocols to manage patients today than they did

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earlier in 2020. Our weekly surgical data in December 2020 and continuing today shows another clamp down on surgeries.

Furthermore, we believe diagnostic procedures are slowing in hard hit regions. With diagnostic procedures running significantly below pre-pandemic levels, patients in hospitals will acutely feel the impact through disease progression and the more complex therapies necessary when patients do return for care. This delay in diagnostic pipelines will likely take several quarters to resolve even after the threat of COVID begins to abate.

Second, we know that future new capital installs are highly sensitive to utilization rates. Delayed surgeries will also impact the growth of surgical departments pressuring new system installs until excess capacity is consumed. Third, in countries where the government pays the healthcare bill, budget strain and economic fallout from COVID may impact healthcare spending in new and variable ways in different countries.

Lastly, the trend that started prior to the pandemic for increased data requirements and longer clearance timelines from regulators in the United States and Europe for our industry has continued this year. Taken together, these obstacles make predictions for the next several quarters difficult.

As I mentioned earlier, 2020 has broadly eliminated some longer-term trends in healthcare that validate our thesis. The increased pressure on healthcare systems to conserve acute care resources for the sickest patients may have accelerated investments that enable patients to get the care they need with fast recovery, minimizing consumption of scarce hospital resources, and reducing complications. The compounding value of analyzing real time data and offline healthcare data to drive insights to drive better care has become obvious this year.

Lastly, we saw an acceleration of remote technology used to enable proctoring learning and analysis. I've heard it said that in good times we develop ourselves to become who we want to be. While hard times reveal who we really are. In the year, we set our priorities based on our values. We implemented community relief and customer relief, launched our extended use instruments program, mobilized local and remote training resources to support customers differently and continue to listen carefully to our customers to best understand their needs.

We've seen positive customer response to this approach, which is reflected in our net promoter score. You can find more information on these scores in our JPMorgan Healthcare Conference presentation from this month posted on our website. Over the past several years, we've been building our capabilities in different countries to better serve their healthcare systems. I'd like to take a moment to take you through how we performed outside the United States in the year.

Turning first to Asia. Our business in Japan is moving beyond urology, given reimbursements for a broad slate of procedures obtained in Japan in 2018 and 2020. Government hospitals in Japan have been conserving resources for COVID care and the pandemic has introduced noticeable delays as the health care system reacts to outbreaks.

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In Korea, our business continues to be dynamic with an innovation oriented customer group adopting new products like our da Vinci SP. In China, we saw accelerated customer acceptance of our partnership with Fosun Pharma and our products with growth and procedures and the business overall outpacing our pre-pandemic plans. In 2020, China emerged as our number two procedure market.

Turning to Europe, our team in Germany has had success in engaging larger German hospital groups with increased system placements broadening our market access. Constraints on elective surgery have been implemented assertively in Germany in light of COVID. In Germany, France, UK, Italy, and the Nordics, our goals have been to broaden da Vinci use beyond urology. Progress there in has been hampered significantly by COVID.

Lastly, we see relatively low public sector reimbursements in Europe for benign procedures. Innovations from Intuitive like da Vinci has in our extended use instruments are providing an option for more price-sensitive customers in these markets.

With regard to our innovation and product engines, we spent time walking through our progress at the JP Morgan Healthcare Conference this month and our presentation is available online at our website intuitive.com. I'd recommend to the interested listeners to review of those materials for greater insight into our progress.

Summarizing briefly here, we're making good progress and advancing many elements of our ecosystem, including our advanced instruments, deepening our imaging and informatics programs, including our augmented reality program, Iris, and extending the launches of our new platforms. We grew the install base and procedures for our single port platform da Vinci SP. We're focused on advancing clinical indications for SP in several regions as well as extending its instrument and accessory portfolio. For our flexible robotics platform, Ion, we saw strong clinical results and demand in the year, but manufacturing and supply performance challenges in the fourth quarter as catheter demand outpaced our forecasting models and the need for important quality improvement implementations and COVID quarantines hampered our production.

We are currently shipping Ion product and expect to meet the demand curve in the first half of 2021. Before Marshall takes you through our finances in detail, I would like to touch on our financial strategy. Our operating model withstood the strains of 2020 well, starting with our decision several years ago to shift to greater flexibility and system placement models, the incorporation of sales, leasing and risk shared models allowed us to meet customer's needs during a disruptive time.

Our investments in advanced instruments, including stapling and energy have been fruitful with growing revenues, improving margins and growing customer appreciation for advanced instruments. We've been investing capital in our manufacturing methods to increase quality and lower our costs, which in turn has allowed us to extend the savings to our customers to allow them greater flexibility in deploying our products in more cost sensitive environments.

This has triggered a virtuous cycle that allows us greater volume, which in turn gives us greater ability to invest in higher volume processes. We'll continue to invest in this cycle going forward. We believe we are still in the early innings of a long opportunity to substantially improve their quadruple aim and acute medical interventions using robotics, computing, advanced imaging and informatics. As a result, we continue to invest in our innovation engines to create and pursue these opportunities.

In closing, our priorities for 2021 are as follows. First, we'll support our customer's recovery of surgery during and post-pandemic. Second, we'll focus on outstanding regional performance. Third, we'll advance our priority programs and launches, SP, Ion, imaging and analytics, including new indications and finally, continued expansion of clinical, economic, and analytical evidence base for key procedures in countries.

And I'll turn the call over to Marshall, who will take you through financial matters in greater detail.

Marshall L. Mohr {BIO 5782298 <GO>}

Good afternoon. I would describe the highlights of our performance on a non-GAAP or pro forma basis. I will also summarize our GAAP performance later in my prepared remarks. A reconciliation between our pro forma and GAAP results is posted on our website.

Revenue in procedures are consistent with our preliminary press release of January 13. Key business metrics for the fourth quarter were as follows. Fourth quarter 2020 procedures increased approximately 6% compared with the fourth quarter of 2019 and increased approximately 10% compared with last quarter.

Fourth quarter system placements of 326 systems decreased 3% compared with 336 systems last year and increased 67% compared to 195 systems last quarter. We expanded our installed base of da Vinci systems over last year by 7% to approximately 5,989 systems.

This growth rate compares with 8% in the last quarter and 12% last year. Utilization of clinical systems in the field, measured by procedures per system, declined approximately 2% compared with last year and increased 8% compared with last quarter.

The impact of COVID on da Vinci procedures vary by region. Resurgence of COVID in parts of Europe had significant impacts on procedures including in Italy, UK, Nordics and France. While the impact of COVID on procedures in the Asia-Pacific region, including China, Japan and Korea was far less significant. In the US, fourth quarter procedure growth was impacted by the COVID resurgence resulting in 5% year-over-year growth compared to 7% growth in the third quarter.

Resurgence in US and Europe was more acute and had a greater impact on procedures late in the quarter, a trend that continued into January. The impact of a resurgence can be significant. For example, in California, the fourth quarter COVID resurgence turned a year-

over-year da Vinci procedure growth in October of 8% to a year-over-year decline of 6% in December.

We also believe that reduced diagnosis reflecting patient concern over COVID exposure has impacted certain procedures globally. This has had its most pronounced effect on prostatectomies. Despite the fact that hospitals are better equipped to handle COVID patients today compared to the outset of the pandemic, COVID-19 resurgence is like those currently being experienced in parts of Europe and US have challenged hospital care capabilities and have negatively impacted da Vinci procedures.

In addition, delays in diagnosis and treatment of underlying conditions will also continue to negatively impact da Vinci procedures. Uncertainties in this COVID environment are not predictable. And the vaccine rollout and its impact on controlling COVID spread is also not predictable.

Given these uncertainties, we are not providing procedure guidance at this time. Philip will provide additional procedure commentary later in this call. Fourth quarter capital placements exceeded our expectations, reflecting several factors. In certain cases, hospitals exhausted 2020 budgets and spend capacities. And in some cases hospitals purchased systems in preparation for post-pandemic environment.

We also experienced a higher level of trade-ins of SI systems for fourth generation systems, reflecting hospital desire to standardize their fleet and to avail themselves to fourth generation technology, lower cost extended use instruments. Looking forward, we see the following capital revenue headwinds. Utilization declined 2% year-over-year resulting in excess system capacity at hospitals.

We expect customers to fill existing system capacity before purchasing additional capital. Some of the fourth quarter capital placements reflected hospitals exhausting 2020 budgets as budgetary set for 2021 hospitals could reduce their capital spend particularly as COVID strains hospital profitability.

We expect leasing to continue to increase as a percentage of overall placements. Macroeconomic conditions created by COVID could also impact hospital capital spending. And as we face competition in various markets, we may experience longer selling cycles and price pressures.

Additional revenue statistics and trends are as follows. Total fourth quarter revenue was 1,329 million, representing a 4% increase from last year and a 23% increase from last quarter. Fourth quarter revenue benefited from US customer stocking of extended use instruments and higher than expected system placements. Leasing represented 37% of current quarter placements compared with 35% last quarter.

Fourth quarter placements included some larger IDN transactions where the IDN prefers purchase transactions. Excluding those transactions, leasing as a percentage of total placements would have been several percentage points higher. In an environment of COVID-19 as economic pressures increase, we anticipate more customers will seek leasing

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or alternative financing arrangements than reflected in historical run rates. Approximately half of the systems placed in the fourth quarter involve trade-ins, which is higher than the 40% last quarter and higher than the average over the last couple of years.

Trade-in activity can fluctuate and be difficult to predict. Fourth quarter average selling prices declined to \$1.43 million from \$1.61 million last year and \$1.55 million in the third quarter. The decrease relative to last year reflects a lower mix of systems placed in China and Japan in a higher proportion of trade transactions.

The decrease relative to last quarter reflects a higher proportion of trade-in transactions in a higher mix of indirect market placements. We recognized 14 million of lease buyout revenue in the fourth quarter compared with 17 million last quarter and 34 million last year.

Lease buyout revenue has very significantly quarter-to-quarter and will likely continue to do so. Instrument and accessory revenue per procedure increased to approximately \$2,060 per procedure compared with \$1,910 per procedure in the third quarter of 2020 and \$1,980 realized in the fourth quarter of last year.

The entirety of the increase compared to the third quarter reflects US hospital stocking extended use instruments. We launched extended use instruments early in the quarter in the US and mid quarter in Europe. We will launch extended use instruments in other markets in 2021 and 2022 depending on regulatory requirements.

Going forward, we expect customers to adjust their instrument buying patterns and reduce their inventory levels to reflect the additional uses per instrument. In addition, extended use instruments and lower instrument pricing will result in lower I&A revenue per procedure to Intuitive.

The impact and timing of customer buying patterns and lower per use revenue will likely begin to impact revenues in the first quarter, but will depend on customer inventory practices and procedure volumes. While we expect price elasticity associated with extended use instruments to enable greater penetration into available markets, that benefit will be delayed by COVID in otherwise will take time.

12 of the systems placed in the fourth quarter were SP systems reflecting continued measured rollout of SP and the impact of COVID-19. Our installed base of SP systems is now 69, eight in Korea and 61 in the US. Our rollout of the SP Surgical System will continue to be measured putting systems in the hands of experienced da Vinci users, while we pursue additional indications and optimize training pathways in our supply chain.

We expect to initiate first cases associated with a US colorectal clinical trial this quarter. We placed four Ion systems in the quarter, bringing the installed base to 36 systems. Ion system placements and procedures are excluded from our overall system and procedure counts. Ion system placements were affected by supply chain issues described by Gary earlier in the call.

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We expect to remediate the supply issues in the first half of 2021. Our rollout of Ion will continue to be measured while we optimize training pathways in our supply chain. Procedures under the PRECISE study are expected to complete in the second quarter of 2021. Outside the US, we placed 130 systems in the fourth quarter compared with 140 in the fourth quarter of 2019 and 79 systems last quarter. Current quarter system placements included 54 into Europe, 22 into Japan and 13 into China compared with 54 into Europe, 26 into Japan and 39 into China in the fourth quarter of 2019.

System placements into China In the fourth quarter of 2019 were higher as hospitals accelerated tenders in anticipation of the possibility of higher tariffs. Moving onto gross margin and operating expenses. Pro forma gross margin for the fourth quarter of 2020 was 69.7% compared with 72.2% for the fourth quarter 2019 and 70.2% last quarter. The fourth quarter of 2020 included higher period costs associated with lower production and higher excess and obsolete inventory charges.

The decrease relative to the fourth quarter of 2019 reflects higher period costs associated with lower production, higher excess and obsolete inventory charges and lower system ASPs. As revenues are pressured by COVID-19, production levels may operate at below normal levels, which may result in higher labor costs and under-absorbed overhead and reduced product margins. In addition, product and customer mix fluctuate quarter-to-quarter and could cause fluctuations in gross margins.

Pro forma operating expenses decreased 6% compared with the fourth quarter of 2019 and increased 11% compared with the third quarter of 2020. The fourth quarter of 2020 include a \$25 million contribution to the Intuitive Foundation compared with the \$5 million contribution in the fourth quarter of 2019 and no contribution last quarter.

Fourth quarter operating expenses continued to reflect reduced spending on activities directly impacted by COVID-19 including marketing events, travel, and in-person training as well as lower variable compensation. These costs will naturally increase as the impact of COVID declines.

We continue to believe we have a unique opportunity to expand the benefits of computer-aided surgery and acute interventions around the world and we'll continue to invest in the business for the long term. During this period of COVID, we continue to invest in product development activities including informatics, advanced imaging, advanced instruments in our lon and SP platforms.

Accordingly you should expect the growth rate of R&D expenses in 2021 to significantly exceed the 2020 growth rate. We expect the growth rate of SG&A expenses to also increase significantly in 2021 compared to 2020. SG&A spending can be categorized as follows.

Investments in OUS markets will increase over 2020 spend as we expand our capabilities and investment in clinical data. Variable compensation will increase over 2020 as we reset goals and targets. Core spending on resources and infrastructure will increase over 2020 to prepare for a post-COVID environment. Spend on activities impacted by COVID like

travel, marketing events, and in-person training will increase as the impact of COVID declines.

Our pro forma effective tax rate for the fourth quarter was 20.7% compared with our expectations of 20% to 21% primarily reflecting the geographic mix of income. Our actual tax rate will fluctuate with changes in the geographic mix of income, changes in taxation made by local authorities and with the impact of one-time items. Our fourth quarter 2020 pro forma net income was \$436 or \$3.58 per share compared with \$426 million or \$3.48 per share for the fourth quarter of 2019 and \$341 million or \$2.77 per share for last quarter.

I will now summarize our GAAP results. GAAP net income was \$364 million or \$3.02 per share for the fourth quarter of 2020 compared with GAAP net income of \$363 million or \$2.99 per share for the fourth quarter of 2019 and GAAP net income of \$317 million or \$2.60 per share for last quarter.

The adjustments between pro forma and GAAP net income are outlined and quantified on our website and include excess tax benefits associated with employee stock awards, employee stock-based compensation and IP charges, amortization of intangibles and acquisition-related items and legal settlements.

GAAP net income for the fourth quarter and third quarters of 2020 also included pre-tax gains of \$4.7 million and \$61.7 million on our investments in private entities resulting from our purchases of certain technologies. The EPS impact of these gains, net of tax, was \$0.03 per share in the fourth quarter and \$0.39 per share in the third quarter.

These gains are excluded from our pro forma results. We ended the quarter with cash and investments of \$6.9 billion compared with \$6.4 billion at September 30, 2020 and \$5.8 billion at December 31st, 2019. The increase in cash in the fourth quarter reflected cash from operations, a reduction in inventory and overall working capital and stock exercises. We repurchased \$34 million of shares in the quarter with an average price of -- at an average price of \$661.10 per share.

And with that, I'd like to turn it over to Philip, who will go over our procedure performance.

Philip Kim {BIO 22131870 <GO>}

Thank you, Marshall. Our overall fourth quarter procedure growth was 6%, compared to 19% growth during the fourth quarter of 2019 and 7% growth last quarter. Our Q4 procedure growth was driven by 5% growth in the US and 11% growth OUS. Resurgence of COVID in the US and Europe impacted our growth rates in the guarter and we saw procedure growth rates decline as the quarter progressed particularly late in the quarter.

With respect to key contributors to growth, overall procedures in China and bariatrics in the US were the largest drivers of procedure growth in Q4. In the US, within general surgery, bariatrics, coli and hernia were the largest contributors to procedure growth

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within the quarter. Bariatrics may be benefiting from certain patients prioritizing weight loss as obesity is a significant COVID risk factor.

In addition, we continue to receive positive reviews of our SureForm 60 stapler, which provides surgeons and optimize robotic toolset and feedback for bariatric procedures. In China, procedure growth accelerated as new systems installed under the quota begin to provide additional capacity for incremental growth. Q4 China procedures had broadbased growth in urology, thoracic, general surgery and gynecology.

With respect to our more mature procedure categories in the US, Q4 gynecology procedure growth was up, reflecting growth in cancer procedures partially offset by declines in benign procedures. On a worldwide basis, DVP procedures in the fourth quarter declined year-over-year and had similar trends as we described last quarter. COVID is impacting the diagnostic and patient pipeline related to DVP.

Now turning to the clinical side of our business. Each quarter on these calls, we highlight certain recently published studies that we deem to be notable. However to gain a more complete understanding of the body of evidence, we encourage all stakeholders to thoroughly review the extensive detail of scientific studies that have been published over the years.

Doctors Clark A. Wilson and Jihad Kaouk from the Cleveland Clinic and colleagues in a paper published urology described their experience evaluating robotic assisted radical prostatectomy with da Vinci SP through an extra peritoneal approach and enhanced recovery protocol for same-day surgery. 60 subjects with organ-confined disease underwent an SP procedure with no patients requiring conversion to another approach.

Median length of stay for all patients was 4.2 hours. 75% of all patients enrolled were discharged on the day of surgery and 96% of patients discharge within 24 hours. When excluding those either with surgery after 6 PM, but with pre-planned admissions due to patient preference or significant comorbidities. The authors concluded a robotic assisted radical prostatectomy with the da Vinci SP system and extra peritoneal approach can be performed safely and reproducibly as a same-day surgery.

This publication adds the number of early studies around the emerging SP technology demonstrating encouraging results within robotic assisted radical prostatectomy as the same-day surgery and acceptable perioperative functional and short-term oncological outcomes in the hands of experienced surgeons for the appropriate patients.

We look forward to the growth of the body of evidence around da Vinci SP. Lastly I would like to highlight that our Second Annual Sustainability Report will be available after the call on our Investor Relations website.

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

Questions And Answers

Sloomberg Transcript

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Operator

(Operator Instructions) First we go to the line of Amit Hazan with Goldman Sachs. Your line is open.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks very much. Hey, good afternoon, everyone. I thought maybe I'd first go to your comments in general on hospital capital spending and maybe try to reconcile some of them. I think if you go back to last week you cited hospitals with seven plus systems were up strongly and here you are still citing lower utilization is the key headwind. I'm just wondering you otherwise seeing a skewing towards newer customers and just trying to get my hands around. I have to imagine it's complicated and hospital systems are different, but how much more color you can provide around kind of some of these different data points that you provided?

A - Gary S. Guthart {BIO 3429541 <GO>}

Why don't I jump in Marshall and then I'll kick it back to you. Amit, thanks for the question. When we were talking about earlier in the month here, we think there is some budget flushing that happened at the end of 2020. How strong that will be into 2021 that they pull forward spending that would otherwise normally have been in '21.

Hard to say. Having said that, if you look at where we were winning relative to other priorities, even if there is some budget pull forward, large customers were -- that already had robotics were expressing confidence with us, which we think is a positive. The caution we're sending you now in this call is just that over time there'll be in full operation, which is, there is some excess capacity in the field because COVID is suppressing procedures. And at some point COVID will lift and that capacity will be absorbed. Some folks will invest ahead getting ready and being able to work on backlog and others will be conservative and wait till they consume that capacity. Forecasting that is hard. And so that's how we're trying to help you navigate through this, but Marshall please clean up anything that you need to in that answer.

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

No. You hit it perfectly.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. And then as my follow-up and then separate on data and digital engagements to-date again kind of going off of the comment you made last week to hospital analytics and you talked about the 350 hospitals, 690 engagements. I'm just wondering how much more color you can give on that in terms of how much of that is that programmatic variety that you talked about that won't necessarily be monetized versus something that could either improve outcomes or reduce cost and potentially be monetized. Just any color around those early engagements would be helpful? Thank you.

A - Gary S. Guthart {BIO 3429541 <GO>}

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Yeah, thanks for the question. When we're talking about what we shared with you in the talk at JPMorgan. Most of that is programmatic analysis and it's not so much something that we think is going to be revenue generating directly. We think that it eliminates the value of our ecosystem and strong da Vinci programs. And that is a benefit to us. It increases the stick rate. It allows people to see in a verifiable way within their own data sets, the value they're bringing to give them action plans to find opportunity for standardization and other kinds of efficiency improvements.

So it's a high value to the customer and high value to us. Some of the other things that we've shared with you, for example, Iris, those things are something that will collect revenue for. They probably won't become huge revenue arms in and of themselves, but they bring value on a per case basis.

And it's something that we can talk to the customer about in terms of value creation there. They also strengthen the ecosystem. So I think for shareholders who are asking the question. Hey, one is informatics and machine learning create a revenue arm of its own. I'm not sure that's the right question.

I think that analytics and informatics power the ecosystem as a whole. We are pretty agnostic as to how we get paid for that. If we get paid for that through increased utilization, wonderful, that works great. We look at cost to develop those programs and kind of overall their contribution to our financial health, but we don't have to charge for them individually if that's not our customer wants to pay for it. Let me turn it to you, Marshall and any color you want to add.

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

No. I think that's right. I think that we look at it as the opportunity to increase the ecosystem and to expand our base into our accelerate adoption.

A - Gary S. Guthart {BIO 3429541 <GO>}

Thanks, Amit.

Operator

Next we have the line of David Lewis of Morgan Stanley. Your line is open.

Q - David Lewis {BIO 15161699 <GO>}

Great. Thanks so much for taking the question. Marshall I appreciate you don't have guidance and I appreciate your commentary on spending levels for '21, but as I'm sure you appreciate without revenue figures those are kind of hard numbers to put in context. So I was wondering if you help us out a little bit more. I mean is the right messaging here that OpEx growth in '21 is going to go faster than whatever the sales growth rate is or asked kind of same question different way. I mean SG&A for the last several years has grown in line with revenue and R&D has grown kind of 2x revenue growth rates. Are those the type of any of those parameters you would kind of give us any visibility could be super helpful. And then I got a couple of follow-ups.

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A - Marshall L. Mohr (BIO 5782298 <GO>)

It's a good question. And I am as a matter of fact that we aren't given you revenue guidance. So it's hard to put those numbers in context. However it really does come down to the impacts of COVID are really pretty unpredictable. And so if COVID wanes quickly then I think the spend we're talking about might match up better with revenue increase, but I got to tell you the point of my -- the reason I pointed this all out in terms of the increases and expenses that we were able this year we saw a long period where COVID impacted us.

And we, some of the variable expenses, I outlined came in pretty low relative to what they historically had been and those will increase as COVID goes away. But in addition to that, there are other expenses that we will continue to spend the increases there will be increases regardless of what happened to COVID.

I think we want to continue to invest in the R&D areas that I mentioned. And we want to because we see that there is a real opportunity to continue to expand our marketplace and to expand penetration in the long-term. And so we are going to increase those costs. I know I haven't given you what you're looking for, but it's just a very difficult environment to predict revenue and procedures at this point.

Q - David Lewis {BIO 15161699 <GO>}

Okay. And then just maybe two quick follow-ups. One, easier to answer, the other. Just in terms of volumes, obviously fourth quarter was more similar to third quarter and generally speaking and the message from most corporates last week was that first quarter is going to be you know at fourth quarter if not frankly a little worse. I'm just wondering if you sort of comment on sort of what you're seeing for the procedure environment here in the first quarter. And then just secondarily on the extended use program. Obviously we saw kind of a bolus on revenue per procedure this particular quarter as hospitals didn't change inventory patterns. Are you seeing any evidence I know it's hard in COVID that it's driving higher demand, the extended use program driving higher demand and when would you expect those revenue per procedure numbers to begin to reverse. Is that as early as the first quarter or probably more likely middle part of the year. Sorry for both questions. Thanks so much.

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

Yeah. So your -- the first part of your question was -- Q1 volume. I made the comment that as we went through the quarter the resurgence became more acute and it had a greater impact on procedures. And so I gave you the California example of where you go from growth in October to reduction in December. That should be an indication of the level of sort of impact it can have. And then I made -- I also made the comment that we saw the trends at the end of the quarter continue into January.

So I think you said that other companies are saying that Q1 could be worse. It could be, but again we're not, we're not going to try to predict exactly where it's going to come out, given the uncertainties around it. But it's clear coming into the quarter, it was at the -- at the bottom end of what was going on in Q4. As far as extended use instruments go, we

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launched it in the US in -- at the beginning of the quarter and in Europe in the middle of the quarter.

About three quarters our customers are now acquiring extended use instruments. They're starting to be used on procedures. It's really hard for us to predict exactly when we'll start to see the benefits of those extended use instruments in terms of elasticity and a price elasticity and it's certainly are going to be confounded by COVID.

So I think it will take time. I think it's going to take a while before we start to see that. Sometimes you have to point out benefits to the hospital. You have to sell a little bit and just think we'll be patient about it.

Operator

Next, we have the line of Bob Hopkins, Bank of America. Your line is open.

Q - Robert Hopkins {BIO 2150525 <GO>}

Okay, great, thanks, and good afternoon. Gary, I want to get your opinion on two geographies if okay. First on the US. Just curious, do you think that perhaps by the second half of this year, there is a chance based on everything you're seeing that we could be close to a normal level of surgical procedure volumes in the US or given what you're seeing on the diagnostic side and the slow vaccine rollout that that's more likely to be a 2022 event. And then also I love to get your opinion on China and the durability of the phenomenal growth you appear to be having here of late?

A - Gary S. Guthart {BIO 3429541 <GO>}

Hey, Bob, on the first one, the US, I won't predict for you. But let's talk about the puts and the takes the things that are going to be the push pull about it. Clearly hospitals want to get back to treating patients who are non-COVID patients, there is a demand and the desire to do that.

It takes a couple of things. One is that resources get freed up from treating COVID patients to allow them to treat other things and some of that is ICU resources and a lot of it is staff. So as COVID surges go. So it is access to that set of resources. Your tracking in analysis is as good as ours in terms of looking at how well the vaccine is going to go out and what the COVID numbers might be. So I think that's a large part of it. In terms of the diagnostic pipelines kind of the same thing I think everybody wants to get patients back in to get diagnosed. There's we think a backlog that's been building for surgical patients as the surge happens.

And then you have this longer backlog of folks who have been for going normal checkups whether it's colonoscopies or PSA screening or what have you. That will start coming back in and of course disease doesn't take a holiday. And as a result those things will be more advanced when they're caught. We've seen this before, we've been in this movie when we saw changes to PSA testing recommendations. That will again create a backlog, but it will take longer for it to realize and a longer for it to process through.

I don't think it's going to drive substantive share shifts between treatment modalities. I think it's going to be hard on patients as they go through that and that will provide a headwind for us, and certainly in 2021 and then tailwinds thereafter as those folks are diagnosed and come back into the pipe.

So that's kind of where I see the US. Moving to China, long-term, we're quite excited. Pretty clearly Chinese patients are interested in high quality care. Chinese surgeons are quite interested in robotics and in da Vinci and our partnership with Fosun and the joint venture is going well for us.

So in the near term that feels great. And I think there's a lot of strong underlying interest. As we've talked about before the medical marketplace in China is complicated. Right now systems are under quota essentially managed quota. We see changes occurring in the Chinese regulatory environment over time as CFDA implements new policies and processes. And we see that there are Chinese companies that are interested in this opportunity are pushing hard to field competitive systems.

So we are committed long-term to China. I think it's going to be a strong demand market and a bouncy sometimes turbulent marketplace due to policy changes and some of the central controls that are in place. We'll keep you updated as we get more clarity there.

Q - Robert Hopkins (BIO 2150525 <GO>)

Great. Thank you. I'll leave it at that.

A - Gary S. Guthart {BIO 3429541 <GO>}

Thanks, Bob.

Operator

Next, we have the line of Larry Biegelsen, Wells Fargo. Your line is open.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. I'll just ask one multipart question on Ion. I'm just curious to know kind of the what comes next year. You talked about the PRECISE data completing enrollment I think in the second quarter. Should we assume that we see that data in 2022? Is there any update on Ion in China? And then your competition has talked about indication expansion beyond lung bronchoscopy. Any color or you're willing to share there? And just lastly adding a therapeutic capability to Ion. So basically the road map here on Ion what can we expect maybe going forward here? Thanks for taking the question.

A - Gary S. Guthart {BIO 3429541 <GO>}

All right. Thanks, Larry. Philip, I'm going to turn to you on the PRECISE trial timing and then I'll take it from there.

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A - Philip Kim {BIO 22131870 <GO>}

Yeah. With respect to when you might hear some data, it is a fair assumption to expect to hear something in 2022. We haven't been more specific beyond on that, Larry.

A - Gary S. Guthart {BIO 3429541 <GO>}

With regard to future indications. Right now we're at with Ion. We are -- our commercial teams and our manufacturing operations teams are tightly focused on supplying and performing in the diagnostic bronchoscopy market our first indication. Clearly Ion is a platform technology and we're excited about it.

That said, I'd remind everybody, we are in early innings, all of us. The entire field is in early innings with regard to bronchoscopy. Our clinical results there are outstanding. I think that they are market leading relative to competitors, any other competitors, and we want to fulfill that market.

We want to satisfy those customers that means satisfying them in terms of quality and demand and shipments and so on. We think there are longer term applications beyond bronchoscopy and beyond diagnostics and we're working on those. We are working on ablation technologies and some other things.

We're not ready to speak publicly about where we might go next for a couple of reasons. One is, we're still in the very earliest innings about making bronchoscope a reality and two for competitive reasons, we're not ready yet to describe what we intend to do next.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

In China, Gary?

A - Gary S. Guthart {BIO 3429541 <GO>}

On the China front, we of course have the joint venture with Fosun. We are working through pathways for Ion in China. We think there is a market there. I would advise folks that the Chinese regulatory system and CFDA handles GEN 1 products pretty differently than FDA does in the US. And as a result of you want to see a little greater maturity in your product line before you go broadly there. So we're working through that with our JV and also with the Chinese regulators when we have some timelines for you, we will describe them, but we remain active and interested.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Thanks so much.

Operator

Next, we have the line of Tycho Peterson, JPMorgan. Your line is open.

Q - Tycho Peterson {BIO 4279327 <GO>}

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Hey, thanks. Gary you mentioned no kind of shift in treatment modalities. So I assume the deceleration doesn't imply any kind of share loss to laparoscopic, but as we think about coming out of the pandemic. The other side of it is you have a normal technology for monitoring, proctoring, and analysis. Are there structural changes here you think coming out of the pandemic that could drive faster adoption of robotics?

A - Gary S. Guthart {BIO 3429541 <GO>}

I believe so. Now this is you know we will -- the right answer is we'll see, time will tell, but there are some encouraging anecdotes and there are anecdotes. One is I think folks are realizing that a lot can get done without jumping on planes and that's true for surgeons. And one of the things that our teams have done beautifully this year is to more fully digitize and regionalize training that has been great.

So forward deployment of training and greater use of digital tools that will continue. And I think the acceptance of that is increasing. It's also accelerated remote proctoring as you've said. So I think that has been a positive for us and something that we had. Thankfully, we made some investments in part of the pandemic.

The second part is, I think that people are seeing changes in resource consumption. Days in the hospital, ICU time, patient comfort at being housed in hospitals in the pandemic has declined. And I think that will be durable. I think even after COVID rates start to drop. I think folks thinking that sitting around a hospital isn't a great idea and using ICU resources when you don't have to isn't a great idea. And I already I think we see that folks are saying hey really high quality minimally invasive surgery done well, by the way, having the analytics back that up is going to be appreciated and maybe an accelerant.

So I am cautiously optimistic that some of the trends we're seeing in terms of what recovery might be are going to be real positive for Intuitive.

Q - Tycho Peterson {BIO 4279327 <GO>}

Another thing you highlighted at the conference was the regulatory requirements and timelines for the industry keep increasing. I know that's something you've been talking about for a while, but as we think about the road map here for SP, the IDT, IDE trial for colorectal. As the timelines gotten pushed out further in your view, given the regulatory burden or is just kind of in line with what you've been talking about for a while?

A - Gary S. Guthart {BIO 3429541 <GO>}

Yeah, I think, we're starting to see the contours of the regulation side in the US stabilized. So it's stabilizing at a requirement level that's greater than it was in year's past, but I don't think it's continuously moving, that's been good. I think the thing that's challenged some timelines for us and others is COVID. If your clinical trial sites are having to manage COVID as well as whatever your clinical trial is that can put pressure on you. That's kind of a near-term thing.

I think longer term, the question of what does this do if clinical trial requirements and general data requirements in the US and Europe for computer-aided systems and

Company Ticker: ISRG US Equity

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robotics have become greater. What does that imply and it probably implies a couple of things. One is that systems in the market are likely to stay in the market a little longer because it's just extended timelines for innovation.

I think the other thing is that it probably re-sequences when you see different products, where in the world because some healthcare systems are clearly being notable -- are allowing innovative products into their systems a little more quickly and other ones are becoming a little less. So for a company like us you'll see increased investment in head count and in resources for clinical and regulatory staff and you'll see a reordering of where we go with new innovations over time, you probably see for the industry platforms sit a little longer that probably benefits incumbents a little more than it does in surgeons.

Q - Tycho Peterson {BIO 4279327 <GO>}

Great and then one last one on the extended use rollout. You did Europe recently US last quarter. Is there a next step in the process? Are you going to do it in Asia and any reason the elasticity would be different and any geographies in your view?

A - Gary S. Guthart {BIO 3429541 <GO>}

Marshall, why don't you take that first.

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

Sure. The rollout into other parts of the world will depend on the regulatory timelines. As you could imagine in China, it will take a long time and some of the other markets, it might be a little bit quicker. I don't have a complete roadmap of every country. But, yes, Asia-Pac is absolutely on our mind and we'd like to get them out to our direct markets in Asia as soon as possible.

As far as the impact on elasticity. We did two things in United States if you recall. We modified the -- we obviously launched extended use instruments, which lower the cost of care for hospitals, but we also simultaneously lowered the price of a few select instruments that are used typically in a more benign lower acuity procedure or benign lower acuity procedures like cholecystectomy, benign hysterectomy and inguinal hernia.

And then in totality then the use -- that if you look at instrument set that might be used in -- cholecystectomy then the cost is competitive with other minimally invasive approaches. In each country, we have modified the pricing differently and we're targeting those procedures that are pressured by reimbursement.

So you can't kind of peanut butter spread the comment of what elasticity will do in the United States will happen in the other countries, but we are targeting specified procedures in each of those countries where reimbursement is stressed and we believe we provide value and we'll see, we believe that will create some elasticity in each country. It will just vary in terms of magnitude.

Q - Tycho Peterson {BIO 4279327 <GO>}

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Okay, thank you.

Operator

Next we have the line of Richard Newitter of SVB Leerink. Your line is open.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi, thanks for taking the questions. If I could just start off on the competitive landscape. Gary, any comments you can offer on internationally any competitors that are on the market and what you're seeing out there relative to kind of what you would have expected. And then in the US just in light of some updates from mainly competitor J&J recently this fall provided an update on the feature set. And any thoughts you would care to offer where they're going to be trying to compete particularly on kind of extra robotic arms et cetera?

A - Gary S. Guthart {BIO 3429541 <GO>}

Sure. Just on the -- just speaking to the international side. The first thing I'd remind everybody is, it's not really a robot versus robot question for customers. It's really robotically enabled ecosystem that drives outcomes versus the robotically enabled ecosystem that drive different outcomes. That is -- it's programmatic versus programmatic. So each of these when they come out, you kind of look at it and say, okay, what's the robot capable of. Did they have the instruments and accessories, the imaging systems, the advanced tools that are required.

Some of this offering analytic capabilities, training capabilities and so on. And you see a pretty different skill set and capability out of each of these ecosystems. And that's true as well for some of the bigger competitors that are domestic. So that's how we think about it and I think that's how customers by and large will think about it.

So there always be some customers who are interested in trialing and seeing what's capable a lot of something new. So I'd expect that. Nothing architecturally that I've seen of any of them including the most recent announcements has surprised me. I think we've seen a lot of these ideas. We've trialled personally a lot of them inside the company.

And so I think time will tell. We have made the trade-offs. We've made for a reason based on evaluation, building product and kind of scientific method. And I think that customers will evaluate those trade-offs over time. We've also seen the idea that some of the bigger players want to bundle that they're going to put all these things together maybe lower the price of capital and try to throw some other things and see if they can entice folks.

And I think the way I'd ask customers and shareholders to think about it is bundling make sense if the underlying products are commodities, if everybody is selling to apply to other paper and one brand is not that different than the other, it's all fine, but that's not where we are.

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Robotic systems and the instrumentation and the imaging systems are not commoditized. And, as a result, there'll be strong differences in how they're used and what the outcomes are. In that regard, I think that's what we'll point our customers too and our sales force to understand as these different things come out.

Q - Richard Newitter {BIO 16908179 <GO>}

Got it. If I could just have one more follow-up on the capital environment and the discussions that you're having. As you talk to the institutions as they think of their 2021 budgets. I'm curious, one, are they kind of thinking of a two-year budgeting process or is it any difference in the way they've approached their budgeting in the past in the way to COVID and then maybe two is the -- what signs that they're going to look forward to kind of get back to you to have confidence to go and make the purchase with the uncertainty that still exists? Thanks

A - Gary S. Guthart {BIO 3429541 <GO>}

Marshall, why don't you kick off that answer and I'll add a little when you're done.

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

Yeah, I think the first part of your question, what are they doing from a budget perspective. I don't have enough insight to be able to answer the question. Well -- we said that we believe that they'll go through a reset of course for 2021. I don't know they'll have the same level of spending they did. We believe that there is financial pressure on the hospitals on a number of the hospitals as a result of COVID. So there is possibility that 2021 budgets will be less, but will be smaller than they were in 2020, but I don't have great insight to them.

A - Gary S. Guthart {BIO 3429541 <GO>}

Yeah, I think the thing I would point to that I think is kind of a economics question for everybody is just going to be something we look at is, they will make their estimates as to how fast folks will return and whether they want to accelerate, so that they have capacity available for dealing with the backlog. I think that will differ by hospital.

So some folks will have the capital capacity to lean in and see this as an opportunity to deepen their exposure or their presence in market. Others will feel conservative and will want to wait and see. So I do not think it's going to be a one size fits all in terms of how they do their financial planning. That was our last question. So I'll conclude from here.

In closing, we continue to believe there is a substantial and durable opportunity to fundamentally improve surgery and acute interventions. Our time -- our teams continue to work closely with hospitals, physicians and care teams in pursuit of what our customers have turned the quadruple aim, better more predictable patient outcomes, better experiences for patients, better experiences for their care teams, and ultimately a lower total cost of care.

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We believe value creation in surgery and acute care is foundationally human. It flows from respect for and understanding of patients and care teams their needs and their environment. Thank you for your support on this extraordinary journey. We look forward to talking to you again in three months.

Operator

And ladies and gentlemen that does conclude the presentation for this afternoon. Again, we thank you very much for all of your participation and for using our teleconferencing services. You may now disconnect.

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