Q3 2020 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan, Analyst
- David Lewis, Analyst
- Larry Biegelsen, Analyst
- Larry Keusch, Analyst
- Robert Hopkins, Analyst
- Tycho Peterson, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Intuitive's Third Quarter 2020 Earnings Release. During today's conference call, all phone lines are in a listen-only mode. Later on we will have an opportunity for a question-and-answer session. As a reminder, today's conference call is being recorded (Operator Instructions).

At this time, I'd like to turn the conference over to our first speaker, Head of Investor Relations, Philip Kim. Please go ahead.

Philip Kim {BIO 22131870 <GO>}

Good afternoon and welcome to Intuitive's third 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 and uncertainties. These risks and uncertainties are described in detail in our Securities and Exchange Commission filings, including our most recent 10-K filed on February 7th, 2020 and Form 10-Q filed on July 23rd, 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.

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 third 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 third quarter was a productive one with the return to growth in da Vinci procedures amid continuing adaptation to customer needs. In the field, performance varied strongly by region given differences in pandemic impact. Operational performance inside the Company has been strong with remarkable focus and diligence by our teams.

Turning first to global procedures. Q3 2020 procedures grew 7%, compared with Q3 2019. Procedure growth varied widely by country with growth returning to most of the countries we serve with a direct commercial team. US growth was in the mid-single digits and procedure growth in China stood out as particularly strong. Analyzing current global quarterly procedure performance compared with Q3 2019 by clinical category, general surgery is rebounding most quickly, posting double-digit growth with mid-single digit growth in gynecology and modest growth in urology.

Overall, we have seen utilization increasing for our customers, as their resources become available, indicating that surgeons and hospitals are maintaining their commitment to minimally invasive surgery. da Vinci enables access to high-quality minimally invasive care, increasing the number of patients who can return home sooner and decreasing the demand on ICU resources, clearly important in the era of COVID-19.

Currently, two factors are at play at hospitals -- as hospitals treat both COVID and non-COVID patients. First, there were some deferred cases that were scheduled in the spring and summer that have now come back to the hospital for treatment. Second, diagnostic procedures such as colonoscopies and PSA tests have been delayed. It may not be back to pre-COVID levels now. The delay in diagnostic business will delay disease detection and like prostate screening changes in 2012, create a reservoir of patients with more advanced disease. This push-pull of those patients who delayed a scheduled surgery coming back into hospitals now and the delay of disease identification due to diagnostic visit postponement makes hospital patient volumes hard to model for coming quarters. That said, full diagnostic recovery is in everyone's interest and we expect surgery to return to pre-pandemic levels over the mid-term. Philip will take you through procedure trends later in the call.

Given the slowdown in procedures due to the pandemic, we expected weaker capital demand in the third quarter. For the quarter, we installed 195 new systems. This compares to 275 installs in Q3 2019 and 178 installs in Q2 2020. Year-over-year installed base growth was 8% at the end of Q3, after accounting for trade-ins. We know the correlation between system utilization in the form of procedure demand and the need for new capital capacity at hospitals is strong. Many hospitals will seek to absorb existing capacity before installing new capital.

In regions in which da Vinci systems are more common, hospitals may delay adding new systems until utilization recovers. Average globally, we continue to expect a challenging near to mid-term environment for future capital placements as COVID-19 wears on and hospital finances remain strained. Because COVID is impacting locales differently, we see significant variability in procedure growth and new system placement pipelines by region. Marshall will take you through capital placement trends and risks later in the call.

At Intuitive, we're focused on those activities and priorities within our control. Our team in the field, in our labs, in our factories and working in homes and offices is performing well. We adapted our priorities for 2020 to meet the challenge of the pandemic and the needs of those we serve. First, we are focused on the health and well-being of patients, customers, our employees and our communities. Second, we're focused on inventory and supply chain management. So far product availability has been very strong, thanks to the relentless work of our supply chain teams and our partners.

Third, we implemented our customer financial relief program and our extended use instruments program. The timeliness and the design of these programs has been well received by our customers. Fourth, we continue to invest in our high priority development programs, recognizing that high quality MIS is more important in the coming years, not less so. Fifth, we are accelerating activities that help us adapt to the current environment and for which demand is likely to be durable post-COVID. Finally, we have constrained spend, where we believe it is inefficient in the current environment.

With these priorities as our guide, our operational and financial performance served both our customers and our Company well in the quarter. Intuitive commercial and learning teams adjusted their work methods to meet customers where they are, figuratively and literally. Over the years, our teams have built a strong network of capable field trainers, sales reps, surgeon proctors and cloud enabled da Vinci systems. Our professional education and commercial teams engaged this network, implementing onsite digital and regional programs such that customer engagement and training programs are approaching pre-pandemic levels, a remarkable achievement.

Across the Company, our teams have prioritized their efforts and practiced fiscal discipline. Based on quality and automation improvements and continued attention, our manufacturing teams are managing our product cost well, leading to strong gross margin performance, while we implemented our customer relief program and our extended use program for Generation 4 instruments. While the pandemic has created near and mid-term uncertainty in the form of competing healthcare priorities and economic stresses, I have high confidence in the need for a high-quality minimally-invasive surgery and therapies in long-term. To deal with the current and future stresses on the healthcare

system, payers, hospitals and surgeons are looking for solutions that improve outcomes, decrease in-hospital resource consumption and lower total cost to treat. In other words, the core pillars of the Quadruple Aim we had set as our goal many years ago.

We have a team that has demonstrated fiscal discipline, particularly in light of the pandemic. Over time, we plan to increase investment in our innovation engines to improve the Quadruple Aim at our customers and to expand our market opportunity. And we will continue to invest in our virtuous cycle of quality and efficiency gains in production that fuel quality improvement, manufacturing cost reductions and pricing flexibility for our customers that can lead to increased volume.

Looking at product operations in the quarter, our advanced instruments and endoscopy programs are producing strong clinical and financial results. Customer adoption of our stapler product line, our vessel sealers and our E-100 Generator has been encouraging. Utilization of these products and their targeted clinical procedures and their re-order rates have been strong. Despite disruptions caused by COVID in 2020, uptake of newly launched products as well as our newest endoscope, Endoscope Plus has also been strong.

As we've said in the past, a great clinical procedure takes the customer, the right system, the right instruments, the right imaging, the right training and the right support. As our Generation 4 ecosystem has matured, customers achieve high utilization rates for our target procedures in Gen 4 accounts.

Our Ion program continues to advance with 11 systems placed in the quarter, many of which are in large teaching institutions. Ion diagnostic procedures are also returning to significant growth. Early clinical studies comparing Ion to existing alternatives in the market both handheld and robotic are beginning to be published and are encouraging, supporting the architectural decisions made early by our design team. While our progress in our PRECISE trial for Ion has been slowed, we are seeing a return to cases as our clinical trial partners come free. Lastly, our team continues to incorporate learnings from customers in improving our system, our manufacturing and our supply chain as we work diligently to support Ion at greater scale.

Turning to our SP system. Its clinical evidence continues to mount and efficacy for the system by surgeons who use it is increasing. Procedures on SP rebounded nicely in the third quarter. I am quite encouraged by the commentary from surgeons on the performance of the system and the potential for it to impact a wider variety of procedures over time. In the United States, we're pursuing expanded clinical indications in a number of areas with our colorectal IDE trials readying initiation. Our system and first clinical case sites are standing by to start the study pending feedback from FDA and barring additional headwinds from COVID-19. If these go to plan, we expect first cases in Q4 of this year or Q1 of 2021.

Our cloud simulation, intelligence and analytics programs are also performing well. We've accelerated our cloud and remote technology efforts this year with the use of our remote case observations and our network simulators ramping quickly. In the quarter, our

network surgical simulators were used over 87,000 times, roughly doubling year-over-year. Our IRIS augmented reality program entered limited launch in Q4 of last year and has recovered well in Q3. Lastly, our customer analytics efforts have been well utilized by hospitals in 2020 and are scaling nicely.

As we finalize our 2021 planning, it's worth reflecting for a moment. The opportunity for improvement in acute interventions, including surgery is a substantial and decades long journey. The fourth quarter of 2020 will mark the 25th anniversary of the founding of Intuitive and the 21st year of clinical use. Looking back at what has been achieved and forward to the important work that remains to be done, we are committed both to our organic innovation and to expanding the universe of bright minds who can improve medicine with the types of science and technology Intuitive pioneered.

To that end, we launched our Intuitive Ventures Group, a part of our futures initiatives, whose mission is to accelerate opportunities at the frontiers of medicine. Intuitive Ventures Group's first fund is $100 million and our team is engaging globally with entrepreneurs having funded some in the quarter. We look forward to seeing what solutions they bring to complex problems.

In closing, our priorities for the next few quarters remain as follows: first, continued strong performance on customer, employee and community safety, while ensuring supply chain stability. Second, continued support of our customers adapted to their specific conditions, we'll support them according to their needs. Third, advancing our priority programs, instruments, accessories, endoscopy systems and intelligence programs and finally, disciplined spend management during this period of change.

I'll now 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 will 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. Key business metrics for the third quarter were as follows: third quarter 2020 procedures increased approximately 7%, compared with the third quarter of 2019 and increased approximately 36% compared with last quarter. Third quarter placements of 195 systems, decreased 29% compared with 275 systems last year and increased 10% compared with 178 systems last quarter.

We expanded our installed base of da Vinci systems over the last year by 8% to approximately 5,865 systems. This growth rate compares with 9% in the last quarter and 13% last year. Utilization of clinical systems in the field, measured by procedures per system, declined approximately 2%, compared with last year and increased 33% compared with last quarter.

Let me walk you through the impact of COVID-19 pandemic on procedures and system placements, and how it impacts our business. Overall, procedures recovered gradually during the quarter to around 90% of pre-COVID levels by the end of the quarter. However, the extent and pace of recovery varied by market. In the US, we reflected several underlying themes. We experienced broader adoption across multiple procedures led by general surgery. For example, we saw significant year-over-year bariatric procedure growth. Partially offsetting broader adoption is the impact of reduced diagnosis and treatment of conditions given patient's concern over COVID exposure, and regional COVID resurgences in regional -- that disrupt elective procedures.

The reduction of diagnosis and treatment was most pronounced in prostate cancer. The dynamics that affected the US also affected our OUS markets. In summary, we saw higher procedure growth in markets where COVID spread is lower like China and Japan, compared with markets where COVID impact is greater like the UK and India. While total worldwide procedure rates have improved, it is possible that resurgences of COVID-19 like those currently being experienced in parts of Europe and the US could negatively impact da Vinci procedures. In addition, delays in diagnosis and treatment of underlying conditions could also negatively impact da Vinci procedures. Phillip will provide additional procedure commentary later in this call.

Although capital placements were higher in the second quarter, third quarter placements reflected headwinds we discussed last quarter, including hospitals filling existing system capacity before purchasing additional capital and delayed capital spending, while hospitals revisit their capital budgets given the impacts of COVID-19.

Utilization in the third quarter was 2% lower than the third quarter of 2019, while the second quarter of 2020 utilization was 27% lower than the second quarter of 2019. Going forward, we expect these same headwinds to impact capital placements. In addition, macroeconomic conditions created by COVID could also impact hospital 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 third quarter revenue was $1.078 billion, representing a 4.5% decrease from last year and a 26% increase from last quarter. Third quarter 2020 revenue reflects $23 million of service credits issued in relation to the previously announced Customer Relief Program where we provided service credits to customers as their use of da Vinci systems were lower than pre-COVID volumes.

Total service credits issued under the customer relief program which is now ended, were $82 million. Leasing represented 35% of current quarter placements, compared with 29% last quarter. Second quarter placements included a higher proportion of China placements where leasing is prohibited. Excluding China, we saw increased demand for leasing structures. In an environment of COVID-19 and as economic pressures increase, we anticipate more customers will seek leasing or alternative financing arrangements than reflected in historical run rates. 40% of systems placed in the third quarter involve trade-ins consistent with last quarter. Trade-in activity can fluctuate and be difficult to predict. We recognized $17 million of lease buyout revenue in the third quarter compared with $9

million last quarter and $20 million last year. These buyout revenue has varied significantly quarter-to-quarter and will likely continue to do so.

Instrument and accessory revenue per procedure increased slightly to approximately $1,910 per procedure, compared with $1,900 per procedure in the second quarter of 2020 and decreased compared with $1,980 realized in the third quarter of last year. The decrease compared to last year reflects customer buying patterns partially offset by increased advanced instrument usage. In the third quarter of 2020, we did not experience reduced purchases of instruments that we anticipated in advance of the launch of extended use instruments.

In early October, we launched our extended use instruments in the US. Extended use instruments have 12 to 18 uses compared with our previous 10 use instruments. In addition, we are reducing the price of certain instruments used commonly in lower acuity procedures and/or lower reimbursed procedures. We plan to launch our extended use instruments later in the fourth quarter in Europe and in 2021 and 2022 in other markets, depending on regulatory requirements.

Overall, extended use instruments and lower instrument pricing will result in lower I&A revenue per procedure to Intuitive. For example, had the extended use instruments been available in the lower instrument pricing been in place for all of 2019, revenue for 2019 would have been $150 million to $170 million less than reported and I&A per procedure would have been 7% lower. The impact of these actions on future revenue will depend on procedure volumes, instrument usage and mix, and whether cost elasticity will enable greater penetration into available markets. Beginning in the fourth quarter with the introduction of extended use instruments, we expect that I&A revenue and revenue per procedure will be lower than it otherwise would have been.

Six of the systems placed in the third quarter were SP systems, reflecting both our measured rollout of SP and the continued impact of COVID-19. Our installed base of SP systems is now 58, eight in Korea and 50 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. As Gary outlined, we expect to initiate first cases associated with the colorectal clinical trial by the first quarter of 2021.

We placed 11 Ion systems in the quarter, bringing the installed base to 32 systems. Ion system placements also continue to be impacted by COVID-19. Ion system placements, procedures and related information is excluded from our overall systems and procedure counts. Our rollout of Ion will continue to be measured, while we optimize training pathways in our supply chain. Procedures under the PRECISE study are being completed at a slower pace than anticipated due to COVID-19. Based on the current pace of procedures, we expect the PRECISE study to complete in the second quarter of 2021.

Outside the US, we placed 79 systems in the third quarter compared with 90 in the third quarter of 2019 and 72 systems last quarter. Current quarter system placements included

39 into Europe, 15 into Japan and 12 into China compared with 36 into Europe, 27 into Japan and 10 into China in the third quarter of 2019.

During the third quarter, MOH in China expanded the previous 154 system quota for the period 2016 through 2020 to 225 systems. The timeline for purchasing the 125 systems remaining under the expanded quota is the same as the original quota, which is the hospitals allocated quoted by December 31st, 2020 have two years to complete their tenders. We expect more of the remaining systems to be completed towards the end of the two-year period, and only approximately a dozen systems to be placed in the fourth quarter of 2020. We also anticipate other companies to achieve regulatory approval over the next year or so. If approved, those competitors will share in the remaining quota.

Moving on to gross margin and operating expenses. Pro forma gross margin for the third quarter of 2020 was 70.2% compared with 72% for the third quarter of 2019, and 62.4% last quarter. The second quarter of 2020 included higher period costs associated with abnormally low production, higher impact of the customer relief program, and higher excess and obsolete inventory charges. The decrease relative to the third quarter of 2019 reflects higher period costs associated with abnormally-low production, the customer relief program, partially offset by product mix.

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 fluctuation in gross margins.

Pro forma operating expenses increased 1% compared with the third quarter of 2019 and increased around 5% compared with last quarter. The increase in third quarter operating expenses compared with the third quarter of 2019 is driven by higher investments in product development activities including informatics, advanced imaging in our Ion and SP platforms, and investment in head counts and capabilities in OUS markets. This was partially offset by reduced spending on activities directly impacted by COVID-19, including marketing events, travel and training, and reduced spending reflecting continued discipline throughout the organization.

Relative to last quarter, spending reflects increases in training and travel, increased spending on product development areas outlined and partially offset by reduced spending. We continue to believe that 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.

Our pro forma effective tax rate for the third quarter was 19.8% compared with our expectations of 20% to 21%. Our actual tax rate will fluctuate with changes in geographic mix of income, changes in taxation made by local authorities and with the impact of one-time items. Our third quarter 2020 pro forma net income was $334 million or $2.77 per share compared with $409 million or $3.43 per share for the third quarter of 2019 and $132 million or $1.11 per share for last quarter.

I will now summarize our GAAP results. GAAP net income was $314 million or $2.60 per share for the third quarter of 2020, compared with GAAP net income of $396 million or $3.33 per share for the third quarter of 2019, and GAAP net income of $68 million or $0.57 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.

Third quarter of 2020 GAAP net income also included pre-tax gains of $62 million on our investments in private entities, resulting for purchases of certain technologies. The EPS impact of these gains net of tax is $0.39 per share. We ended the quarter with cash and investments of $6.4 million compared with 6.1 -- sorry $6.4 billion compared with $6.1 billion at June 30, 2020. Cash generated from operations and stock exercises was partially offset by investments in working capital and our infrastructure. We did not repurchase any shares in the quarter.

Our current thoughts on capital deployment are in the following order: we recognize the hardship that COVID-19 places on our customers and we'll work with customers to ease the burden of lower da Vinci utilization, including providing customers with more flexible financing. We will ensure a secure supply chain and build appropriate levels of inventory to ensure customer supply. We will invest in securing our employees. We will continue to reinvest in the business focused on expanding our market opportunity or accelerating adoption of our products. We will continue to open market repurchase program, consistent with our prior practice.

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

Philip Kim {BIO 22131870 <GO>}

Thank you, Marshall. Our overall third quarter procedure growth was 7%, compared to 20% growth during the third quarter of 2019 and a 19% decline last quarter. Our Q3 procedure growth was driven by 7% growth in the US and 9% growth OUS. US general surgery and China were key drivers of procedure growth in Q3.

In the US, Q3 procedure growth was largely driven by strength in general surgery. Hernia, chole and bariatric were the largest drivers of growth within general surgery in the quarter. Bariatric procedures have been an increased area of focus in 2020 and may also have benefited from certain patients prioritizing weight loss as obesity is a significant COVID risk factor. In China, procedure growth accelerated meaningfully as new systems installed under the quota began to provide additional capacity for incremental growth.

Q3 China procedure growth was strong with broad-based growth in urology, thoracic, general surgery and gynecology. With respect to our more mature procedure categories in the US, Q3 gynecology procedure growth was up low-single digits year-over-year with hysterectomy for cancer volumes growing mid-single digits. Q3 dVH benign procedures were up modestly year-over-year. In the US, dVP procedures in the third quarter declined high-single digits in the quarter compared to a year ago. We believe a constricted

diagnostic pipeline may be impacting dVP volumes as patients may be postponing cancer screening procedures during the pandemic.

On a worldwide basis, dVP procedures in the third quarter declined mid-single digits compared to a year ago. We do not have visibility as to when the diagnostic pipeline returns. Certain states that saw increased COVID cases had lower growth rates. At the end of Q2 procedure volumes in these states slowed and gradually recovered later in the third quarter. We would caution investors that our visibility of COVID outbreaks is limited and that procedure volumes may fluctuate when certain geographies face an uptick in COVID.

Third quarter OUS procedure volume grew 9% compared to 23% growth for the third quarter of 2019. Third quarter OUS growth was driven by continued growth in urology, thoracic, general surgery and gynecology. In Japan, procedure growth moderated versus Q2 due to a slowdown in dVP. Overall, European procedures grew modestly in Q3 as countries recovered from COVID.

In Q3, Germany, France and Italy contributed to year-over-year growth, while the UK declined. However, we would caution that as COVID surges occur in different countries, procedures can be impacted adversely. It is important to note that we do not have guidance and Q3 trends may not be indicative of future results due to potential COVID surges, patient's willingness to have procedures done and a constricted diagnostic pipeline.

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 thoroughly review the extensive detail of scientific studies that have been published over the years.

Earlier this year, an article led by Dr. Melissa LaPinska from the University of Tennessee, Knoxville in the Journal of Surgical Endoscopy, provided results from one of the largest matched case series analysis for non-complex ventral hernia repair based on real world evidence, utilizing the abdominal core health quality collaborative. The study compared 1,230 subjects undergoing either robotic-assisted or laparoscopic non-complex ventral hernia repair.

In a propensity score matched analysis with 615 subjects in each cohort, the robotic-assisted approach had a shorter mean length of stay by two days, a lower rate of conversion by over 1%, a lower rate of clinic re-encounters through 30 days by 6% and a lower rate of surgical-site occurrences or infections requiring treatments by 2.4%.

An article with Doctors Ravi Rajaram, David Rice and Eduardo Bruera from the University of Texas MD Anderson Cancer Center in the Journal of Thoracic and Cardiovascular Surgery provided results from a real world evidence analysis using the premier hospital database for lobectomy. This study included patients who underwent an elective lobectomy for primary lung cancer between January 1st, 2013 and September 30, 2015 with the objective to compare post-operative in-patient opioid administration after

robotic-assisted lobectomy compared to open and video-assisted thoracoscopic surgery approaches.

In a propensity score matched analysis with over 2,000 subjects in each cohort, robotic-assisted lobectomy patients used a lower total opioid dose and lower average daily dose assessed through the median morphine equivalent daily dosage compared to patients undergoing either an open or VATS approach from postoperative day one until discharge. In both comparisons, over the same period, open lobectomy and VATS patients were more likely to be administered opioids compared to those undergoing a robotic-assisted procedure, 7.6% fewer robotic-assisted patients when compared to open and 2.6% fewer robotic-assisted patients when compared to VATS. The authors concluded in this study of patients with lung cancer undergoing lobectomy, use of a robotic-assisted approach was associated with less opioid administration in the in-patient postoperative period compared to either VATS or lobectomy.

That concludes [ph] our prepared remarks, we will now open the call to your questions.

Questions And Answers

Operator

Thank you. (Operator Instructions) Our first question today comes from Tycho Peterson with JPMorgan. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, good afternoon. I'll start with the procedures here. You were growing 8% exiting June. And obviously, there's a lot of gives and takes on the second wave and some of the diagnostic headwinds as you flagged. But can you maybe just talk on linearity during the quarter, how is July, August and September and any color on the first half of October? And when do you think the diagnostic headwinds could reverse? How do you think that potentially could play out?

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

Marshall, why don't you jump in and speak a little bit to the linearity question? And we'll talk a little bit -- I'll pick up the diagnostic pipeline side.

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

Sure. Consistent with our last call, the beginning of the quarter was depressed relative to, let's say, middle of June. It slowly or gradually came back during the quarter. There's a choppiness, of course, because it varied region by region, but slowly came back in the quarter and probably reached its peak near the end of the third quarter.

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

On the diagnostics side, I think there's a broad recognition by healthcare providers that it's not in anybody's interest for these pipelines to remain stalled. I think there are efforts

to drive them. That said, in terms of how fast they refill and patient comfort to come in and get these things done, I think all of us are going to have to wait and see. So, we'll keep watching and tracking it. Channel checks show that people are working on it. How fast it converges, I don't think anybody has a great predictor.

Q - Tycho Peterson {BIO 4279327 <GO>}

And then, Gary, on the -- some of the developments from last quarter, the extended use instruments and the pricing adjustment, any anecdotal color you can provide on your customer conversations on how they're thinking about incremental usage? And then you kind of mentioned the regulatory hurdle for the extended use instruments, I assume that's pretty straightforward, but can you just comment on that as well?

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

Sure. On the customer feedback side, we've seen a positive response. There are different market segments, both in terms of the types of procedures that people are interested in using our device for, da Vinci for and also different regions. And those reimbursement dynamics and payment dynamics differ. In places where that has been in greater stress, we've seen really positive engagement and response. We will see as it plays out in time. I think COVID in the early days of extended use will be a confounding factor. The early drivers may be as simple as how folks are treating non-COVID and COVID patients concurrently, but we think as it lays out in time, this is going to be really healthy for us and was not a hard analysis to do to understand the potential value of it.

In terms of regulatory pathways, we don't see real hurdles on the regulatory side. I think there's work to be done in terms of validations. And otherwise, I think that's all well in hand. So, I don't see stresses around regulatory clearances as it relates to extended use instruments.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then just last one on China. You mentioned in your comments with regard to the quota that you may see approval from competitive systems next year. Can you just talk on the competitive environment there? Are you seeing more platforms emerge?

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

For several folks, there are a handful of commercial groups in China that are working on systems of one variety or another, whether they seek to compete with a multiport da Vinci type system or a single port system or an Ion-type system. We see interest in all those things. Ultimately, they'll make it through the regulatory process and get into the market. We see great demand in China. And the increase in the quota, I think, is a reflection of customer interest working its way through the national processes to get additional approval.

So we feel like we're in a strong position competitively. We think that there's a real market there that's really gated and limited by the quota system. And we expect others will enter the market, seeing the value it has. And we've oriented our teams to make sure we're meeting customer needs better than others do.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. Thank you.

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

Thanks, Tycho.

Operator

Next we have a question from David Lewis with Morgan Stanley. Your line is open.

Q - David Lewis {BIO 15161699 <GO>}

Good afternoon. Just a few here for me, Gary. So it's pretty clear procedure trends normalized across the quarter, and you've seen that J&J saw it as well. You talked about these various forces exhausting backlog, hospital capacity, improving diagnosis. Is it reasonable to expect slow and steady improvement going forward, but at a more modest rate? That's sort of the message we got from J&J. I'm just wondering if you'd comment on that. So we get improvement, but that improvement is going to be more measured going forward.

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

I hesitate to characterize it just because I don't know what the future holds for COVID outbreaks and strain. What I can say is that hospitals are handling the concurrent needs that they have a little bit better. I think they have protocols that they feel good about. I think they have access to resources and things like PPE that early on, they didn't. That gives us some comfort that barring a massive influx that they can manage both size of patient need.

What that plays out like in the future -- sorry, capacity is better. It's also clear that they want to do minimally-invasive surgery and high-quality, minimally invasive surgery and they have an interest in using our products gives me comfort. What the weather does, what the COVID pandemic does, I think, is harder for Intuitive to have direct insight into.

Q - David Lewis {BIO 15161699 <GO>}

Okay. But it sounds like on an apples-to-apples basis, all things being normal, the system continues to improve. Obviously, you're not in control of exogenous factors.

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

I think that's fair.

Q - David Lewis {BIO 15161699 <GO>}

Okay, very fair. And just on extended use, two questions from me. Marshall, for you, I thought I heard, I apologize if I misheard. The customers did not change buying patterns in the third quarter. I'm just sort of curious why do you think that was? And are you more confident, obviously, that will change in the fourth quarter?

And then, Gary, if I said to you, extended use is going to do one or two things, it's going to bring more general surgeons and more types of procedures into the mix or it's going to stimulate a significant amount of sort of Gen 4 platform demand, what do you think is sort of the bigger trigger, a bigger factor here near term?

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

So we announced, in July, the program for the very intent that maybe hospitals might want to take advantage of managing their inventory levels. They do what they do. I can't answer the question as to why their buying patterns were what they were. I think that as far as going forward, there will be a hard cutover. You're not going to see hospitals buy a combination of the two, and we're not offering a combination of the two. We're basically cutting it over to the extended use instruments. So that will -- like I said in my script, that will have an impact on Q4, but I think it will be positive from a hospital economics perspective, which is the whole intent of the program, right?

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

Turning to the issue of what do we think it's going to catalyze. First, we think that surgeons have an interest in using our products broadly, and in fact, in procedures that have been traditionally done laparoscopically. Early days of the Company, it was predominantly a substitution of open surgery. It was a way to allow minimally-invasive surgery where open surgery was the norm and MIS by manual means was really difficult. And yet in general surgery, we're seeing a draw -- a pull by our customer base to do with da Vinci procedures that are often done with laparoscopy.

And there's a reason for that. System is ergonomically sound, it allows more complex cases to be done comfortably and repeatedly. And so we see real demand there. And as a result, we feel like as we've gotten scale, as our instrument quality and processes have improved over the years and we've made design changes, we can make it easier for those who want to use it more broadly to do so economically. So we think it's going to stimulate over the long term more demand on that side and a better way to say it perhaps is it's going to reduce barriers. I think customers want to go there and this reduces barriers to them getting there.

With regard to upgrades, I think there are a whole host of good reasons to move -- for a customer to move into a Generation 4 system, Xi or X if they're in a Gen 3 or Gen 2 system an S or an Si. And extended use instruments are just one of the advantages there. So, I think it helps that problem. But I think that if I had to weigh it to, the former is a strong pull in this. Extended use instruments, next-gen imaging, next-gen advanced instruments, next-gen stapling, vessel sealing, those things are great reasons to upgrade from an Si into a Gen 4.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Thanks so much.

Operator

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

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question guys. Similar question on the recovery, but on the system side. Gary, how do you see that playing out over the next few quarters? Any anecdotes you can share about conversations with hospitals? Utilization was down less this quarter than it was last quarter. And I had one follow-up.

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

I've been relatively pleased with the nature of conversations with hospitals around systems and how they view their robotic programs. I think they're being highly rational. I think they view high-quality, minimally-invasive surgery is important going forward. They have a lot more data at their fingertips, a lot of it's supplied by us, to understand and measure the performance of their programs. And they can look out and say, okay, as they -- if they get more comfortable with recovery, does this help them? And largely speaking, yes, they view it as a help. So I think that's good.

Having said that, I think they're trying to plan what their finance is going to look like in 2021. Some of them have reasonable visibility, others have low visibility. And so I think they may pace, and we're seeing that pacing. I am not discouraged over the long term. I look out, I think that a combination of analytical prowess and recognizing the value of lower variability, high-quality interventions is quite strong. So it will be hard to predict in the near term. We expect pressure, as Marshall said. I think Marshall is right on it. Having said that, in the long term, as procedures come back, capital will be important. And we keep innovating on our products that catalyzes upgrade cycles.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks. And Gary, Intuitive has historically been almost exclusively an organic grower, investing in early in IP and developing products around that rather than buying companies with commercial products or folding in distribution. Do you expect that to change over the next few years? And is that partly why you announced Intuitive Ventures? Thanks for taking the questions.

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

Yeah. I think we have an interest in and pride in our organic innovation capabilities, and I expect that to remain a pillar and part of our DNA. As we've grown and as I think the market has started to really appreciate here, I mean, the medical market, really appreciate what robotic-assisted surgery and computer-aided surgery can do, I think that a lot of new avenues open, and that provides opportunity for us. We have been -- we're not a not invented here culture. We are open-minded to the very bright people outside. We do a lot of activities and tuck-ins over time. Those may get bigger in time. We may continue to do it.

In general, I'd prefer to bring things in earlier rather than later. On the other hand, if something is interesting, we are open-minded to it. The venture fund and our futures

initiatives, I think, are really recognizing as an interesting ecosystem out there developing. There's a lot of technology lines that can make a big difference in medicine. And we'd like to facilitate that growth.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thank you.

Operator

Next we have a question from Amit Hazan with Goldman Sachs. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Hey, good afternoon, everyone. I wanted to kind of try the angle of talking about new technology and pipeline. Maybe try again kind of from an R&D perspective. I think that's where you've been most comfortable answering it in the past. So ask it in that context. Obviously, R&D spending is kind of growing right through these last couple of quarters despite the pressures. Can you just talk to the biggest buckets of R&D spend and your focus or most focused on these days? And how you allocate those buckets within R&D spend?

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

Yes, I'll start, and I'll ask Marshall to do a little bit more of the comparator. For us, we kind of think about it in three categories. One of them is, what are the kinds of things we can invest and that makes a substantive change in outcomes, not a 2% change but a bigger one. And those things get our attention and drive a set of investments. That's one.

We look out at new ways to get into the body with less damage to healthy tissue and less variability. As you know, we look a lot in ways we can bring more information to the surgeon and to make that information more understandable, whether it's advanced imaging or higher quality imaging or machine learning. All those things are ways to help the decision-making and share the load with surgeons, and we're making substantial progress in that domain.

And we've been talking for several quarters now, perhaps several years, about catalyzing a virtuous cycle of driving volume, driving quality, decreasing the cost to make our products and sharing those savings with our customers, which allows them to take our products into places they'd like to go, and we see that happen as well. So those are categorically where we are thinking.

Marshall, I'll let you take the kind of rough mix question.

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

Sure. From a year-over-year perspective, as I said in my script, the biggest area of investment really is digital capabilities, AI, machine learning and informatics. Then after that would be advanced imaging and our capabilities there, and you've seen us introduce

new scope technologies, but also making investments in other ways to image the anatomy. And then the other two areas I'd call out would be Ion and SP, of course, as we bring those products to market.

Q - Amit Hazan {BIO 6327168 <GO>}

And so maybe just a related follow-up on Iris. Just given you mentioned I think that it recovered well in the quarter. Would love just a better understanding of where you're deploying it and implementation. I mean, there's obviously some very big players in the space that you have to contend with, practically speaking, and work with and partner with it. How you're seeing that develop now? And what we should be thinking about over the next year or two for that evolution?

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

I would just kind of anchor everybody on what Iris is. This is augmented reality program that takes preoperative 3D models, MR and CT scans, things like that, that are typically already done in the workflow of a workup for a patient and making it really easy for the surgeon to have access to that data real time. First, before the case to help them visualize the case and plan; and second to have it in real-time in the console.

So it's kind of a really simple idea. And as you say, and rightly say, doing it well, executing it well is the hard part. We have some really good natural collaboration partners in the space to do that with. You think about -- we don't go out and acquire those images ourselves. They're acquired on other people's devices. Those companies are incented and open-minded about how to help those things progress. And we've had good relationships with them. We have done some really cool proprietary things. We have a brilliant team of scientists and computer scientists who have thought hard about how to make that augmented reality work really well. And it's easy to do a quick prototype, and it's hard to do it in such a way that it's additive to the procedure and doesn't get in the way of the surgeon. That's a lot of what has been going on in Iris since then.

And then if you think about, well, where can that take you inside the body? It's really neat. You think about you're interested in what the vasculature is up to, you're interested in what solid organs are doing, you're interested in where tumor boundaries are. And surgeons getting access to that, thinking through what approach might be, getting advice from the computing system is how that might work and consulting with patients about it. Those things are really good, facilitated discussions. I think we are quite strong relative to what I see out in the market from others and where people are kind of in universities. So our team is really good.

How that grows over time? What parts of the body we approach next? We have a road map, we're working through it. We think that surgeons and hospitals will value it. We're developing the evidence in Iris 1.0, this first launch to really build the value and to lay that road map. So far, we have really passionate advocates, both inside and outside the Company. So so far, so good.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks very much.

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

Thanks, Amit.

Operator

Thank you. Our next question comes from Larry Keusch with Raymond James. Please go ahead.

Q - Larry Keusch {BIO 1504587 <GO>}

Great. Thanks. Good afternoon, everyone. Just -- you mentioned some of this in the prepared comments, but just sort of curious sort of how you're thinking about as you look across your procedures, where do we stand with backlog and those that have actually been completed? And at this point, how are we starting to work through that backlog and really into new cases? Or just -- I'm trying to get some sense of how you think that backlog is working its way through?

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

I think we're coming at it from three different ways, and we have no great insight to share with you. I wish I had better insight. I don't know that if somebody gave you great insight that I would believe it. Having said that, with that as a lovely setup, Phil, if anything you would like to add, please jump in.

A - Philip Kim {BIO 22131870 <GO>}

No. I mean it's clear in our prepared comments, we talked about how there are patients that are being deferred -- that are deferring treatment right now, and that's clearly a detriment to the patient. And so we do see -- we have worked through some of the backlog, as Gary alluded to in the script, but there still are patients that are clearly deferring treatment and still are to be worked on.

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

We're in close contact with our customers to the extent that we can help them provide assurance to patients to make sure that they stay attending to their health care. If we can partner with others to make that easier, we do. And we've had some of those opportunities. Largely, I think this is -- the main owners of this process are the health providers themselves, and we stand in support of them. What makes it so hard to model is that no region, no hospital, no country fits a single pattern. And so you're integrating across a wide spot.

Q - Larry Keusch {BIO 1504587 <GO>}

Okay. Great. And then just the second question is, again, you talked a lot about sort of the benefits of the extended use of the instruments and the lower pricing of the less complex instruments. And certainly, all that makes sense. I think one part of the equation that

people are looking to get some color on is, so how do you look at that price elasticity? And what does that do potentially to the TAM? Presumably, in part, the analysis was done to kind of figure out what the right price for the instruments are. So just wondering if there's anything incremental to add on how you are now thinking about the TAM expansion with sort of the changes that you made to the pricing?

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

Yeah, perfectly fair question. Clearly, we think that there's greater demand at different price points, given both the types of procedures that people want to do and given the regions. What that TAM looks like over what period of time, I don't think we're ready to update with you on this call. We do think over time and as we move into next year, we'll have greater visibility in terms of what's actually happening versus what our models are, and we'll start to share with you a little bit more of what our models look like.

Q - Larry Keusch {BIO 1504587 <GO>}

Okay, terrific. Thank you.

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

So operator, just one more caller, please.

Operator

Thank you. That question will come from Bob Hopkins with Bank of America. Your line is open.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. And good afternoon and thanks for taking the question. I'll just ask one given the lateness of the hour. Gary, I thought I heard you comment that you expect procedures to return to normal sometime in the mid-term. And first, did I hear you correctly? And I'm just curious how you kind of define mid-term. And then lastly and maybe most importantly, I'm just curious what gives you that confidence because there are some people that are beginning to think that maybe some of these COVID issues could have sort of a lasting impact on procedures in terms of patients or logistics within hospitals. So just curious if you could add a little color to your mid-term comment.

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

Yeah, fair. I haven't anchored it on a particular time horizon. I think, frankly, it's exactly as you've really outlined in your question. It's -- what's implied in your question is, I think, as COVID is either tamped down or concurrently managed well, it's in the healthcare system and patient's interest to make sure that people aren't sitting with undiagnosed conditions or suffering with diagnosed conditions that are being untreated.

I think health systems globally, health policymakers and leaders of these institutions are trying to make sure they serve their constituencies well. And to me, the definition of mid-term is when they come over the hump of being able to manage that set of backlogs and

the flow of patients, that may mean managing it within a COVID context or maybe that COVID impressions start to drop and they have more room.

So you can imagine it plays out in a couple of different ways. So long as hospital systems are fully in reactive mode with regard to COVID, I think we're in the near term. So I'd define mid-term as when folks are not in pure reaction that -- when they can manage things concurrently. And we see that executing well in some countries where COVID exists, it's not growing out of sight, and they can manage that pretty well. And where that happens, we see a return to managing surgical patients pretty well. So it's one that starts to happen in more and more countries. How long does that take? I don't really know. And what exactly the catalysts are? Well, it depends on COVID management policy.

Q - Robert Hopkins {BIO 2150525 <GO>}

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

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

Okay. Thanks, Bob. Well, that was our last question.

In closing, we continue to believe there is a substantial and durable opportunity to fundamentally improve surgery and acute interventions. Our teams continue to work closely with hospitals, physicians and care teams in pursuit of what our customers have termed 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. 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 with you again in three months. This concludes today's call.

Operator

As stated, that does conclude our conference for today. We thank you for your participation and for using AT&T teleconferencing. You may now disconnect.