Q3 2021 Earnings Call

Company Participants

- Gary S. Guthart, Chief Executive Officer, Member of the Board of Directors
- Jamie Samath, Senior Vice President-Finance
- Marshall L. Mohr, Executive Vice President and Chief Financial Officer

Other Participants

- Amit Hazan
- Larry Biegelsen
- Matt Taylor
- Rick Wise
- Robert Hopkins
- Tycho Peterson
- Vijay Kumar

Presentation

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Q3 2021 earnings release conference call. At this time, all participants are in a listen-only mode. Later, we will have a question-and-answer session and instructions for queuing up will be provided for you at that time. (Operator Instructions)

I would now like to turn the call over to your host, Senior Vice President of Finance, Jamie Samath. Please go ahead, sir.

Jamie Samath {BIO 7313010 <GO>}

Good afternoon, and welcome to Intuitive's third quarter earnings conference call. With me today, we have Gary Guthart, our CEO; Marshall Mohr, our CFO and Brian King, our Treasurer.

Before we begin, I would like to let you know that Philip Kim, our Head of Investor Relations for the last couple of years, has moved on to pursue his next opportunity. We appreciate his contributions and wish him well in his next endeavor. Joining us on the call today is Brian King, who has been our Treasurer for the last seven years. Brian will be expanding his responsibilities to include the role of Head of Investor Relations.

Moving on, 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 Form 10-K filed on February 10th, 2021 and Form 10-Q filed on July 21st, 2021.

Our SEC filings can be found through our website or out 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. I will discuss procedure and clinical highlights, and provide an update of our financial outlook. 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 team performed well in the third quarter in the face of pandemic related headwinds. The rise of the Delta variant and stresses in some hospitals, pressured the demand for surgery. While the supply chain disruption has yet to abate, necessitating redirection of internal resources to continue to meet our customers' demand. Despite these challenges, growth in the use of our products continued in the quarter and capital demand remains robust. New platforms advanced in their commercialization, in their innovation and in their clinical programs.

Turning first to procedures, the increased COVID burden tempered the recovery we saw in the second quarter, particularly in the month of August. The impact of the Delta variant drove procedures in the United States below our expectations at the start of the quarter with run rate, stabilized in the last couple of weeks of September. Adoption continues in the United States, driven particularly by benign general surgery procedures, including bariatric surgery, cholecystectomy and hernia repair.

Trends in malignant procedures remain solid, including prostatectomy, hysterectomy, lobectomy and colon resection. Two trends that have emerged over the past few years are the increased use of da Vinci and benign procedures, and rising use of our advanced instrumentation and targeted procedures. Both are the result of focusing on our customers' needs, and delivering product and economic solutions to match.

Outside the United States, procedure performance relate as a function of regional pandemic impact. In China, growth in the quarter was strong and span multiple specialties, reflecting continued adoption. In Japan and Korea, our procedure business

remains healthy with slight sequential procedure growth Q2 to Q3, despite COVID-related surgery disruption. Germany, the UK and France had reasonable year-over-year procedure growth, and our customers are having success in diversifying procedure categories beyond urology.

Regarding the capital environment, new system placements continue to be robust. The United States had an outstanding capital quarter, if a balanced mix of hospitals new to da Vinci, as well as healthy incremental placements for existing customers and trade-ins of older technology. This performance has been driven by collaboration with U.S. integrated delivery networks, as they thoughtfully manage and expand the capacity of their da Vinci fleets. Elsewhere, China, Japan and Europe had solid placements in the quarter and our placements in Brazil showed strength.

Turning to our newer platforms, our single port system, da Vinci SP had a solid quarter as we pursue additional indications. Placements of our flexible bronchoscopy platform, Ion grew nicely, sequentially, Q2 to Q3, powered by continued strong customer experiences in the field. Our finances were strong again, this quarter though they followed an unusual path, system strength and favorable system cells make stroke strong system revenue. Procedures grew at the low end of our expectations as a result of the Delta variant. Instrument and accessory revenue per procedure moved down modestly as benign procedures continue to make up more of the procedure mix and our extended use instrument program reaches equilibrium in the field.

Our spending grew sequentially and year-over-year as we continue to invest in expanding our new platforms and digital programs as well as build our go-to-market capabilities globally. Our expense growth was again modestly lower than plan, driven by some increase in time to fill open positions in a tight labor market, lower travel-related spending giving the pandemic and some understanding and prototypes. We will continue to invest in programs that fulfilled the mission and built the company.

Turning to our innovation efforts. We develop and deploy technology-enabled solutions to support our customers' pursuit of the Quadruple Aim, better outcomes, better patient experiences, better care team experiences and lower total cost to treat per patient episode. I'd like to take a moment to overview the clinical status of our programs. For our da Vinci system, there are now over 9.7 million lifetime procedures performed with over 28,000 peer-reviewed clinical publications. Da Vinci x and Xi now have over 70 representative clinical uses allowing broad use across multiple clinical specialties from urology to gynecology, thoracic surgery, general surgery and transoral surgery. Tens of thousands of surgeons routinely use our multi-port systems. We continue to invest in our multi-port products, instruments and services to further expand our capabilities and indications, leading surgeons continue to work with us to pursue new learning with several prospective studies ongoing.

Our flexible bronchoscopy system, Ion continues to build momentum clinically and commercially, with several presentations and manuscripts updating Ion clinical progress at the 2021 CHEST Conference this weekend. As described in yesterday's press release, early clinical trial results pointed outstanding capability allowing for definitive diagnosis of

hard-to-reach lung lesions. Our teams are hard at work building our manufacturing and supply capabilities to meet rising demand.

Our single port system SP as a clinical database of 28 peer-reviewed clinical publications. There are currently several ongoing prospective studies for SP and Korea, and the United States including our IDE trial for colorectal indications. This quarter, we received FDA approval of uniportal thoracic IDE. Broad SP adoption will be paced by additional regional and clinical clearances, which remain our focus for the SP program. Our digital solutions provide data-driven insights to surgeons' operative services and hospital administration.

From virtual reality training to efficiency insights to custom comparative outcomes analysis, these tools are now routinely employed by our customers and our teams to improve programs. Our analytics program supported thousands of customers in the quarter turning to machine learning, our teams are at the leading edge of ML based clinical science for surgery. Through our collaborations with leading academic centers in forming out rhythmic and scientific discovery. Taken together, these programs allow our customers to quantify our collective impact on the Quadruple Aim, core to our mission.

Before turning the time over to Marshall, today, we announced some changes in responsibilities of our Senior Executive team. These changes are the result of structured process over the past few years and they are driven by our need to support, growth and our product lines, commercial reach, operations capabilities and business infrastructure as we scale to meet the global opportunity to advance minimally-invasive care.

Starting January 1st, 2022, our Executive Vice President and Chief Business Officer; Dave Rosa, will take on an important new role of Executive Vice President and Chief Strategy and Growth Officer, leading our efforts to identify and realize long-term business opportunities, continuing to build the value of our integrated product offerings and ensuring our customers clearly understand the value of our ecosystem and creating successful minimally invasive programs.

Henry Charlton, currently General Manager of the U.S. and Europe, will succeed Dave as Chief Commercial Officer, overseeing global commercial sales, regional marketing and commercial enablement. Also, Marshall Mohr will take on an important new position as Executive Vice President, Global Business Services, leading Intuitive's continued growth in information technology and enterprise process, data and systems, and Global facilities. Jamie Samath will succeed Marshall as Chief Financial Officer. They are each outstanding proven leaders and will report to me. We expect them to spearhead our efforts to achieve our mission and continue to position Intuitive as first choice of our customers in the growing marketplace.

I'll now turn the call over to Marshall, who will take you through our financial highlights 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. The information in our earnings release and within our prepared remarks, reflects the three-for-one stock split completed earlier in October. Overall, third quarter procedures grew 20% year-over-year and reflected the impact of Delta variant's resurgence. COVID also impacted third quarter 2020 procedures making year-over-year comparisons complicated.

In the U.S., procedures grew 16% reflecting the impact that COVID resurgence had on hospital resources regionally. The impact of the resurgence was most pronounced in August and early September in regionally, in the South and Southeast. Later in the quarter, as COVID cases began to slow, procedures began to recover. However, it is difficult to estimate the extent to which this resurgence or future resurgences will impact da Vinci procedures. Year-over-year, OUS procedures grew 30% with the impact of COVID varying regionally.

In Europe, COVID had a greater impact in Italy and France, and less in UK and Germany. While there continued to be COVID hotspots within some of our Asia-Pacific markets. Overall, procedures into region performed well. China growth in the third quarter continue to be far higher than other regions, primarily reflecting system installation growth over the past year. Relative to the beginning of the pandemic, many hospitals are able to better manage increased COVID patient hospitalizations. However, staffing shortages and hospital supply chain issues are challenging in some -- challenging some hospital capacities include impact deferrable procedures, including da Vinci procedure going forward. Jamie will provide additional procedure commentary later in this call.

Key business metrics for the third quarter were as follows: third quarter, 2021 procedures increased approximately 20% compared with third quarter 2020 and decreased approximately 3% compared with last quarter. Compound annual growth between the second quarters of 2019 and 2021 was 13.5%. Third quarter system placements of 336 systems increased 72% compared with 195 systems for the third quarter of 2020 and increased 2% compared with 328 systems last quarter.

We expanded our installed base of da Vinci systems over the last year by 11% to approximately 6,525 systems. This growth rate compares with 8% last year and 10% last quarter. Utilization of clinical systems in the field measured by procedures per system, increased approximately 9% compared with last year and decreased 6% compared with last quarter. The compounded annual utilization growth rate between the third quarters of 2019 and 2021 was 3%.

Moving on to capital placement. System placements in the quarter reflected a continued trend of IDN multi-system purchases and were driven by procedure growth, and hospitals upgrading in order to access your standardized on fourth generation capabilities.

Looking forward, we see the following capital revenue dynamics. Procedure growth drives capital purchases in many of our markets. To the extent, that COVID impacts procedures,

it will also impact capital purchases. The trade-in cycle has been a tailwind to system placements. However, as the installed base of older generation product declines, the number of trade-ins will decline overtime. Leasing an alternative financing arrangements enabled customer access to our systems. While the percentage of systems placed under operating leases fluctuates quarter-to-quarter, we believe leasing will increase as a percentage of sales overtime, which will result in the deferral of otherwise current revenue into future periods.

Macroeconomic conditions created by COVID could regionally impact hospital capital spending and as competition progresses in various markets, we will likely experience longer selling cycles in price pressures. Additional revenue statistics and trends are as follows. Third quarter revenue was $1.4 billion, representing a 30% increase from last year and a 4% decrease from last quarter. The compound annual revenue growth rate between the third quarters of 2019 and 2021 was 12%. The year-over-year revenue increase reflected growth in both procedures and system placements. The decrease relative to the second quarter of 2021 reflects lower instrument and accessory revenue, associated with lower procedures, and increased leasing as a percentage of placements.

Leasing represented 41% of current quarter placements, compared with 35% last year and 33% last quarter. Leasing, as a percentage of total sales, has and will continue to fluctuate with customer and geographic mix. However, we anticipate more customers will seek leasing or alternative financing arrangements, then reflected in historical run rates. 40% of systems placed in the third quarter involve trade-ins, which is consistent with the 40% last year and higher than the 38% last quarter.

As customers continue to upgrade to fourth generation capabilities, the population of installed SIs is decreasing, particularly in U.S., where 97 trade-ins were completed in the third quarter, leaving an installed base of SIs of approximately 425 systems. As a result, we expect lower trade-out transactions overtime. Trading activity can fluctuate and be difficult to predict. Third quarter average selling prices increased to $1.57 million from $1.55 million for both the third quarter of 2020 and the second quarter of 2021. Average selling prices will fluctuate with geographic and product mix.

Consistent with historical patterns, we expect a higher mix in systems sold to distributors in the fourth quarter, which carry lower prices. We recognized $25 million of least buyout revenue in the third quarter, compared with $17 million last year and $26 million last quarter. Least buyout revenue is varied significantly quarter-to-quarter and will likely continue to do so. Instrument accessory revenue per procedure of $1,900 decreased slightly compared with $1,910 per procedure for the third quarter of last year and decreased compared with $1,940 per procedure in the second quarter.

The year-over-year change reflects increased usage of extended use instruments, mostly offset by increased usage of our advanced instruments. The decrease from the previous quarter reflects customers continue to adjust their instrument buying patterns to reflect the additional uses per instrument included an extended use instrument. Ten of the systems placed in the third quarter are SP systems. Our installed base of SP systems is now 89; 10 in Korea and 79 in the U.S. We continue our measured rollout of SP as we work on gathering clinical data to gain additional procedure clearances in the U.S. We placed

28 Ion systems in the quarter, bringing the installed base to 98 systems. There were approximately 2,000 Ion procedures completed in the third quarter.

Ion system placements and procedures are excluded from our overall da Vinci system and procedure counts. Our rollout of Ion is progressing well. Outside the U.S. we placed 109 systems in the third quarter compared with 79 in the third quarter of 2020 and 115 systems last quarter. Current quarter system placements included 47 into Europe, 20 into Japan and 17 into China, compared with 39 into Europe, 15 into Japan and 12 into China in the third quarter of 2020. We also placed nine systems in Brazil in the third quarter and now have placed 23 systems in Brazil over the past four quarters.

Moving onto gross margin and operating expenses. Pro forma gross margin for the third quarter of 2021 was 71.3% compared with 70.2% for the third quarter of 2020 and 71.7% last quarter. The third quarter of 2020 included 23 million of service credits issued in conjunction with their customer relief program, higher period costs associated with lower production levels, and higher excess and obsolete inventory charges. The decline in gross margin relative to the second quarter primarily reflects product mix. Product and customer mix fluctuate quarter-to-quarter, which can cause fluctuations in gross margins.

COVID has impacted global supplies of semiconductors and other materials used in our products. While to-date, we've been able to secure supply necessary to ensure fulfillment of customer demand. Our teams are expending significant time and effort to bridge future supply with demand. To-date, we have experienced immaterial component increased, cost increases in freight expedition fees. However, global shortages could result in future supply disruptions as well as delayed development and regulatory activities.

We also expect supply issues to result in higher production costs. Pro forma operating expenses increased 21% compared with the third quarter of 2020 and increased 2% compared with last quarter. The increase compared to the prior year reflects costs associated with higher headcount, increased variable compensation and increased spending in areas impacted by COVID. Third quarter spending was below our expectations due to delays and headcount hiring, and lower spending on activities restricted by COVID including clinical development, marketing events and travel costs. In addition, COVID delayed some R&D work resulting in underspend on prototypes. We expect spending on activities restricted by COVID to increase as the impacts of the pandemic decline. We also expect spending to increase as a percentage of revenue as investments at headcount infrastructure and other support areas catch up to the growth of the business.

Finally, we expect to continue to invest in expanding, and accelerating our ecosystem of products and capabilities. Jamie will provide spend guidance later in this call. A pro forma effective tax rate for the third quarter was approximately 24%. We've recorded expense of $11 million associated with periods prior to 2020, related to guidance recently provided by the IRS associated with stock-based compensation. We expect our pro forma tax rate for the fourth quarter to be approximately 21.5%.

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 pro forma net income was $435 million or $1.19 per share compared with $334 million for $0.92 per share for the third quarter of 2020, and $477 million or $1.31 per share for the last quarter. Third quarter 2021 and 2020 included pre-tax gains of approximately $8 million and $62 million associated with investments in companies that resulted from development agreements entered into in prior years.

I will now summarize our GAAP results. GAAP net income was $381 million or $1.04 per share for the third quarter of 2021, compared with GAAP net income of $314 million or $0.87 per share for the third quarter of 2020 and GAAP net income of $517 million or $1.42 per share for the last quarter. We ended the quarter with cash and investments of $8.2 billion, compared with $7.7 billion last quarter. The increase in cash in the third quarter primarily reflected cash from operations and stock exercises. We did not repurchase any shares in the quarter.

And with that, I'd like to turn it over to Jamie.

Jamie Samath {BIO 7313010 <GO>}

Thank you, Marshall. Our overall third procedure growth was approximately 20% compared to growth of 7% during the third quarter of 2020. Q3 procedure growth reflected 16% growth in U.S. procedures and 30% growth in OUS markets. In the U.S., procedures in Q3 were adversely impacted by an increasing COVID-related hospitalizations due to the Delta variant. Procedures were particularly impacted in those states with relatively lower vaccination rates.

As the number of COVID-related hospitalizations peaked and began to improve in September, we saw U.S. procedures start to recover. Q3 growth reflected relative strength in bariatrics procedures, cholecystectomy and hernia repair. In the more mature procedure categories, year-over-year growth in prostatectomy was strong relative to historical averages and benign hysterectomy grew in the low single the low single digits range. Third-quarter OUS procedure volume grew approximately 30% compared with 9% growth for the third quarter of 2020.

Third quarter 2021 OUS procedures were driven by growth in prostatectomy and earlier-stage growth in general surgery, gynecology, kidney cancer procedures and thoracic surgery. China procedure growth remains strong and broad-based as a result of continued expansion of the installed base under the current quota and the addition and training of surgeons new to the da Vinci platform.

Growth in Japan was solid, but was impacted by localized lockdowns, stemming from ongoing efforts to prevent resurgences of COVID. Growth in Korea was also solid, primarily driven by gynecology, urology, and head and neck procedures. A little more than half of the procedures in these three key Asian markets are outside of urology.

In Europe, procedure growth varied by country based on the relative impact of the Delta variant and the impact of COVID-related mitigation measures. Growth in the UK and Germany was solid with procedure growth in France and Italy impacted by reduced capacity for surgery as hospitals reserved resources for potential increases in COVID patients.

During Q3, customers in the U.S. and Europe effectively consumed their remaining inventory of 10 life instruments following the launch of extended use instruments in those regions in Q4 of last year. With this full adoption in the U.S., customers are benefiting from I&A per procedure costs that reduced by approximately, 10% in lower acuity procedures such as cholecystectomy and hernia repair.

In Europe, customers are benefiting from an even larger reduction in I&A costs for targeted procedures. While recent procedure trends are confounded by the various waves of the pandemic, we believe based on customer feedback for the adoption of extended use instruments is having a positive impact on targeted procedures. In our new platform, Ion procedures increased almost four folders compared to Q3 of 2020, driven by a significant expansion of the number of systems of customers and an increase in usage in the existing installed base. Our single-port platform, which is gained by additional regional and clinical clearances showed solid performance with almost 50% year-over-year procedure growth.

Now, turning to the clinical side of our business, each quarter on these calls, we highlight certain recently published studies that we deemed 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.

During the quarter, Dr.Michael Kent from Beth Israel Deaconess Center, Harvard Medical School in Boston, Massachusetts, published results from a landmark multi-center pulmonary open robotic and thoracoscopic lobectomy or PORTaL study in the annals of surgery. This retrospective study sponsored by Intuitive compared lobectomy outcomes associated with open VATS and robotic-assisted da Vinci surgery with over 6,000 cases included in this analysis.

After one-to-one propensity score matching, a comparison of open and da Vinci lobectomies with approximately 800 patients in each group, showed a two-day shorter length of stay and a 9.5% lower rate of prolonged hospital stay, associated with da Vinci lobectomies. The da Vinci cohort also had an approximately eight-minute shorter mean OR time for cases without a concomitant procedure. Post-operative complications were approximately 9% lower with the da Vinci robotic approach.

With regards to the propensity score match comparison of minimally invasive approaches with over 1,700 patients in each group. The da Vinci approach evidenced to 1.1 day short of mean length of stay and a 6.1% low rate of conversion to thoracotomy when compared to VATs. With differences in conversion rates report for each tumor stage in the analysis, the authors conclude in part "in this retrospective multi-institutional data analysis", both

robotic-assisted and VATs lobectomy are associated with improved perioperative outcomes compared to open lobectomy.

Robotic-assisted lobectomy was associated with additional differences compared to VATs such as a reduced length of stay and conversion rate. In August of this year, Professor Umberto Bracale from the University of Naples Federico II in Naples, Italy, published a systematic review with meta-analysis of transversus abdominis release or TAR for ventral hernia repair, assessing short-term outcomes of the open and robotic-assisted approaches. The meta-analysis combined six studies containing over 800 patients of which just over 200 patients underwent robotic-assisted da Vinci surgery and just under 600 patients under patients, who underwent the open approach. Results of this meta-analysis found that the robotic-assisted approach was associated with a 4.4-day shorter length of stay, 64% lower risk of post-operative complications and 79% lower risk of developing systemic complications.

Readmission and reoperations were comparable between both groups. The authors concluded in part "based on the data from the meta-analysis", the robotic approach for TAR seems safe and feasible, even in more difficult cases. Robotic-assisted TAR shows the common advantages of minimally invasive procedures that improve short-term outcomes with significant benefits in the early post-operative period.

Lastly, as noted in yesterday's press release, preliminary results from the precise study of evaluating outcomes associated with the Ion endoluminal system were presented at the Annual CHEST Conference. This preliminary analysis of 69 subjects showed a diagnostic yield of 83% with a sensitivity of malignancy of 84% to 88% from the biopsy of peripheral pulmonary nodules with a mean size of 17 mm. These initial outcomes regarding the performance of the Ion system are encouraging and we look forward to the full study being published in the second half of 2022.

I would now turn to our financial outlook for 2021. During Q3, we experienced a more challenging supply chain environment with a deterioration in on-time delivery performance from our suppliers. We also saw increased supply chain costs. While this did not have a material impact to our operating results in Q3, the outlook we are providing does not reflect any potential significant disruption or additional costs related to supply constraints.

Starting with procedures, last quarter, we forecast 2021 procedure growth of 27% to 30%. Given Q3 results and the impact of the Delta variant, we are now narrowing our forecast and expect full-year 2021 procedure growth of 27% to 29%. This procedure outlook does not reflect a significant impact from all our staffing shortages or a resurgence of COVID-19. The high end of the range assumes the COVID-19-related hospitalizations in the U.S. continue the recovery that began in September and that COVID-related mitigation measures in OUS markets continue to ease.

Turning to gross profit. On our last call, we forecast our 2021 full-year pro forma gross profit margin to be within 70.5% and 71.5% of revenue. We now expect 2021 gross profit margin to be within 71% and 71.5% of revenue. This range does not reflect any significant

disruption associated with the current supply chain challenges. Our actual gross profit margin will vary quarter-to-quarter depending largely on product, regional and trade-in mix, the impact of product cost reductions and manufacturing efficiencies and competitive pricing pressure.

With respect to operating expenses, on our last call, we forecast to grow full-year pro forma 2021 operating expenses between 17% and 21% above 2020 levels. We are refining our estimate and now expect our full-year pro forma operating expense growth to be between 17% and 19%. We expect our non-cash stock compensation expense to range between $450 million and $460 million in 2021. With regard to pro forma other income, which is comprised mostly of interest income, we expect a range of between $50 million and $55 million in 2021. Finally, with respect to income tax, we expect our Q4 2021 pro forma tax rate to be approximately 21.5% of pre-tax income.

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

Questions And Answers

Operator

(Question And Answer)

(Operator Instructions) We will go first to Amit Hazan with Goldman Sachs. Your line is open. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks, and good afternoon. I want to come back to the supply chain comment first. Just to ask you, how visibility looks for componentary now versus maybe a little bit earlier this year, what lead times look like now? Sounds tighter just a little more color around that, and to what extent have you kind of already been able to either kind of double order or for lack of a better term, I guess or stockpile this year and how viable when option does that remain for you?

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

Yeah, I think -- Amit, it's Marshall. The environment as it relates to supply chain has deteriorated got more difficult over time and as we said, we've dedicated substantial resources to dealing with those shortages and it is not to-date created an issue with us supplying customer demand, but there's a risk, and it's a real risk and so we call it out to make sure that everybody is aware of that.

From the perspective of cost, we try to have some costs increased material costs last quarter. They were not significant and we also incurred some expediting fee associated with freight again, not material. But going forward, we do expect cost -- increase cost and that will probably hit the margin in Q4, Q1. It's hard to predict exactly how much. And so, I think that kind of summarizes it for you. It's a difficult environment right now.

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

I'd just add, I think our supply chain and manufacturing teams are doing great. I think they're working in a tough macro environment and that micro environment will clear up when it clears up.

Operator

Thanks. Our next question we go to Larry Biegelsen with Wells Fargo. Go ahead please.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question, just two for me. One on Ion, Gary and then one on procedures. So the precise data look good. Yesterday -- I guess the question is, do you think the early data suggests your shape sensing technology can lead to better yields and lower product rates versus your main competitor, which is used as a different technology, and how much of a catalyst do you think the data from yesterday will be for Ion? And I just had one follow-up.

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

Yeah, I think that the architecture as a whole, shape sensor, the way it works. The design choices about making a soft catheter that's quite in and can go deep into the long has been really strong for us. And I think the data speaks for itself. You can compare it for yourself. The data that folks using, Ion are producing and in that from Monarch and we feel great about where we are. I think it is catalyzing as we speak. I think that those results are helping us in the market. Our customers are giving us really good feedback. And we continue to invest in operations part of that program as well as the innovation side. We feel really good about it.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for that Gary. And then on procedures, I guess it sounds like most or if not all, major markets are moving in the right direction. I'd love to hear a little bit more color, particularly on the U.S.? And it sounds like, Jamie, and by the way, congratulations on the new role. It sounds like, we should expect normal seasonality in Q4 when we look at 2018 and 2019. The sequential procedure growth was very similar worldwide U.S. and OUS, is it possible that it could be a little stronger, given that we're seeing a recovery? Thanks for taking the question.

A - Jamie Samath {BIO 7313010 <GO>}

Thank you, Larry. By the way, I would say this, what's reflected in the high-end of our procedure guidance is really two things that COVID-19-related hospitalizations in the U.S. continue the recovery that began in September, and that was kind of in the middle part of September that, that recover -- recovery commenced. So there's a progression there that continues through Q4. It also assumes that the mitigation measures in OUS markets, which are typically a little more conservative than we see in the U.S. continue to ease. And those also started to ease in September.

At the low end what we see is a slower recovery in the U.S. from what we saw in Q3 and choppiness OUS, in terms of kind of the on-off of mitigation measures in various markets. And so that range of 27% to 29% that we provided really is just a function of the rate at which we recover from what occurred in Q3 with the Delta variance.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks so much. Yeah go ahead.

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

So a little color on that. I just jumping in and I think there's two things that are going on. One is what will pace us is hospital availability for surgery righted, it's not infection rate it's going to be resource consumption at the hospital and their ability to pivot their resources, both human capital and facilities back towards surgery. As you double-click on that, some of it is regional variants, but some of it is actually just hospital system variance. There is differences in how each hospital is managing. So it's hard to generalize, I think beware of averages.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Got it. Thanks for taking the questions.

Operator

Next question comes from Bob Hopkins with Bank of America. Go ahead please.

Q - Robert Hopkins {BIO 6184955 <GO>}

Well, thank you and good afternoon. Just two follow-up on that on that last question. So for Jamie and Marshall, I guess, therefore, is the procedure volumes that you are forecasting for Q4, is that assuming improving year-over-year growth in Q4 versus the year-over-year growth in Q3 or about the same?

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

Yeah, I think what's implied by the guidance that we provided, the low end Q4 year-over-year growth will be 15% and high end it will be 22%. So you compare that to what we showed in Q3 of '20, and you see kind of the ranges is above and below what we recorded in Q3. And I think again, it just reflects both the year-over-year comparison in terms of the base for Q4 in 2020, as well as the range of scenarios in terms of what actually occurs with procedures in Q4.

Q - Robert Hopkins {BIO 6184955 <GO>}

Okay. Thank you for that. And then just one quick one for Gary. I was struck by your comments in your opening remarks about your multi-port systems now have 70 clinical uses. And I was curious if you could just elaborate on that a little bit is that 70 different surgical procedures or how you're characterizing clinical uses? That's found that an interesting number.

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

Yeah, that's right. It's the number of kind of different procedures that's described in our labeling as to where this might be used in the body or in a sub specialties. So you're looking at urology, there's a handful of different procedures that it can be used for and likewise gynecology, general surgery and as you just walk through that's a set of procedures for which we've engaged the agency and put in our labeling. So they're quite broadly apply.

Q - Robert Hopkins {BIO 6184955 <GO>}

Okay. My model only has 10, so I guess I have some work to do. Thank you.

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

And we're not done. And we're not done, I think surgeons, and we, and regulatory agencies around the world continue to explore where else technologies like ours can go.

Q - Robert Hopkins {BIO 6184955 <GO>}

Thank you.

Operator

Next question comes from Tycho Peterson with JP Morgan. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, good afternoon. I want to see if you can elaborate a little more on the staffing shortage comments. I know this isn't may be fully baked in the guidance. But how much risk do you think this presents? How widespread it is, obviously the very tight labor market, but just something you are seeing across most of your customers or how would you characterize it?

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

You're referring to the customer side.

Q - Tycho Peterson {BIO 4279327 <GO>}

Correct.

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

Yeah, Jamie, why don't you talk a little bit about it.

A - Jamie Samath {BIO 7313010 <GO>}

Yeah, we've had anecdotal inputs from some customers that they're facing staffing shortages. Other customers have said to us that they're able to overcome those risks. And so given kind of the mixed dynamics and the lack of clear evidence on in terms of its

impact on procedures, and what we've said is the remainder of the year, guidance does not reflect any significant disruption from the last staffing shortages meaning that there's no deterioration in that phenomena for hospitals.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then another dynamic you flag was just kind of a selling cycle. Obviously, early days in competitive product on the back of the CE Mark for Medtronic. I'm just curious out of your -- what you're hearing from your sales reps just in terms of early interest potential demos things like that?

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

Yeah, I think with several of the other systems that are on the market and as you say, the most recent one, we see early engagement, those first engagements tend to be a placement of clinical trial sites and training centers and so on. So they're not surprising, they're kind of their early access programs to get into the market. So far there are fair number of claims about what these new systems will do and I think the reality is time will tell, their Gen 1 systems, I think evidence has to be generated to back up those claims. And so far we don't see anything yet that looks like evidenced just the set of claims. So we'll keep serving our customer doing what we can to make sure that they can achieve the Quadruple Aim, and we'll see how other companies do.

Q - Tycho Peterson {BIO 4279327 <GO>}

Maybe last one, we have a sell side always get the question about, a new system for you guys. It feels like that's picked up a little bit lately. You're putting up good system numbers. I'm curious, in your view is that something the market needs right now? What do you want to say, if anything at all about the appetite for another system from you guys or anything you may be working on?

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

Well, first thing is that we think there's room for innovation on all the platforms we have. So whether it's multi-port and in Gen 4, we continue to innovate. We've done a lot of sequential innovation on Gen4, so our x and XI are different. We continue to invest both in incremental opportunities and in deeper, bigger opportunities on multi-port and as we're ready to roll those out, you'll hear about it.

We brought to market SP, we continue to innovate on SP and get sequential products and clearances globally for SP and likewise Ion, which is having great success early in its first indication, but we think it has opportunities deeper in the body and in different locations in the body, which will proceed and describe over time. So yeah, I think you should expect continued innovation from us.

As to whether we think that we're in immediate need of something, we're innovating at a pace where we think we can bring things that matter to the Quadruple Aim, not so much an idea of what's our retail strategy, but more can we do something that changes Quadruple Aim or otherwise improves the customer experience and that's what we're focused on.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. Thank you.

Operator

Next question comes from Rick Wise with Stifel. Go ahead please.

Q - Rick Wise {BIO 1490589 <GO>}

Good afternoon, everybody. One focused question and then a larger picture one. Gary, when you in your opening comments you mentioned that extended life instruments, if I understood you have reached, I think your report was equilibrium. I just want to make sure I understood what you were implying that suggests that the initial phase of adoption has happened and we're going to see better growth X sort of an initial stocking ASP impact. And is there a second round of instruments this has been so successful? How should we think about all that?

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

Well, with regard to what I meant by equilibrium, it was really that, that initial stocking orders and the transition from old arrangements to newer has largely taken place, but I'll let Jamie answer that more carefully than I just did.

A - Jamie Samath {BIO 7313010 <GO>}

Actually, I think that's right, Gary. There's a period of time when as we launched extending da Vinci instruments customers in the U.S. and Europe in particular were ordering those instruments rate higher than their usage, as they consume that 10 life in instruments that took some time to get into parity. And so you saw in the end a positive benefit to Ion a per procedure in Q1 and Q2. Q3 for those regions that largely came to parity.

We did launch extending da Vinci instruments later in Asia or in some of the rest of the world countries. And so, they are still kind of working their way to parity. So there'll be small downward pressure on Ion per procedure, holding everything else equal as they get to parity, looking forward.

Q - Rick Wise {BIO 1490589 <GO>}

Got you.

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

The second half of your question, just to finish it. You talked about, are we done? Is that if for these kinds of ideas and extended use instruments in da Vinci actually these were designed and process investments that we made to pursue. What we think of is the virtuous cycle. The idea that if we can improve quality and lower costs for our customers that they can use our products and more in different procedures, and we're not done doing that. It may not look exactly like what we've done in the past. There are other things that we think we can do with it. Allow them high value systems at different price points or

high value instruments at different price points. So that line of reasoning has not exhausted itself.

Q - Rick Wise {BIO 1490589 <GO>}

And Gary, just one last big picture question. Obviously, you've created two new senior leadership roles here for Marshall and for Dave Rosa, maybe just if you could just flush out your thinking, is it simply and it would be enough that Intuitive has gotten so large and complex and the future is so bright. You just need more senior leadership focused leadership or what are you charging? What are you expecting? What should we expect from Marshall and Dave in coming years? Thank you.

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

Thank you for that question. Over the last few years, we've had an expansion of business and expansion of opportunity both are happening. On the business side, we want to make sure that we serve our customers at very high quality quickly in local regions, where we can and that we take advantage of a lot of the systems and enterprise data that we have to help drive the business and help our customer, and that's something that Marshall has been doing and I've asked him to double down on that to make sure that we can really take advantage of our global scale and serve our customers in our business really well at that scale and it's an opportunity and it's real work.

The flip side is, I have never been more positive about the long-term opportunity for companies like ours that can master the kinds of things that we have to do to help minimally invasive care and interventions. And so there's real opportunity there and I'd like us to get there quickly to have the agility and focus to be able to open new ideas and new architectures, and new markets and I can think of nobody more qualified to lead that effort than Dave Rosa, who has visited just about all parts of the company started off as an engineering scientist and has done many things for us. So we're really trying to get the advantages of scale to help our global customers and also be agile and capitalizing on growth opportunities as we see.

Q - Rick Wise {BIO 1490589 <GO>}

Thank you so much, Gary.

Operator

Next question comes from Matt Taylor with UBS. Go ahead please.

Q - Matt Taylor {BIO 16863940 <GO>}

Hey, thanks for taking the question. I was hoping maybe Marshall, you could talk a little bit more about the supply chain issues from the standpoint of just helping us get visibility or understand how close you are to the edge there and meaning you keep calling out this risk that exists, but it sounds like you've been doing a really good job of managing things so far. Is there any benchmark numbers you can give us to help us understand what the lead times are on some of these key things that could get disrupted or the likelihood that

it will happen is it getting better? Or is there a real risk of you not being able to ship some kind of product, is I guess the core of the question.

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

Well, I don't think I can say it's getting better. I actually think that it's a difficult situation and will continue for some time. If you think about the one that's been talked about the most of semiconductors, you've seen it in the auto industry as an issue and computers, and if you had to order any homegoods that contained chips, you would know that there's a problem there. That will take a long time to remedy. It takes a long time to build fabs. It takes a long time to produce product. And so, I think that'll go well into next year or the predictions that we're hearing.

I think, Gary told you, our team has done a marvelous job so far. So I think there are issues on a regular basis and the issues so far our team has been able to resolve those. I don't have any statistics to provide you and how often or what it means. I would just say that some -- anecdotally, some lead times have extended, beyond six months, that's not all product and it's not -- an average you should apply to everything. But in some cases it's pretty long. And so I think you -- it's a problem we highlight as just to make sure that you're aware of the risk.

Q - Matt Taylor {BIO 16863940 <GO>}

Okay. Thank you very much.

Operator

And we have a follow-up question from Amit Hazan with Goldman Sachs. Go ahead please.

Q - Amit Hazan {BIO 6327168 <GO>}

Oh, thank you for that. Yeah, so I thought maybe just to follow-up on this budget question with just a little bit more on just inflationary headwinds generally. And Marshall, just how you're seeing labor costs growth today versus kind of early in the year or more normal times and raw material cost growth versus normal -- more normal times? And it just had for us to start thinking about these things along with what you commented on the supply chain for next year. Is this qualitatively as we start to think about where operating margins might go?

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

We've seen some cost increases. Again, they haven't been that significant and frankly, our teams are -- have done a marvelous job of sort of with efficiency and effectiveness to offset those increased costs. But we're hearing from suppliers that they're going to raise their prices and so we're saying that, hey, we expect that costs will go up more. Not sure, I want to say that the inflation word has hit us and is here to stay, but we are seeing some suppliers raise cost.

Q - Amit Hazan {BIO 6327168 <GO>}

Thank you.

Operator

Our next question comes from Vijay Kumar with Evercore ISI. Go ahead please.

Q - Vijay Kumar {BIO 17881836 <GO>}

Hey, guys. Thanks for taking my question. Gary, maybe two quick ones for you. The PRECIsE study, 83% diagnostic resolution. Could you -- is that good enough Gary? I mean, certainly when the headline numbers when you look at other studies, it's a good number, but I'm just curious. Is this the point where the market awakens to these numbers? And should we see an inflection in adoption of Ion? And just one quick one on 3Q. I know you called out the Delta, but was there any labor shortage impact in 3Q itself, because historically, we haven't seen the pandemic impact where in period over outperformed peers. It just perhaps a little excessive in 3Q, was there something else going on? Thank you.

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

Okay, on the first one on terms of diagnostic yield you had said 82%. And I guess what I advise everybody is, there's a couple of numbers that are important and they stay linked together. And that is what is the size of the lesion, and then what's the positive diagnostic rate ability to definitively diagnosed. That's what the Interventional pulmonologist are looking at.

So the bigger the lesion, if its three centimeter lesion, your diagnostic yield rate is going to go up, your definitive -- it's easier to hit. So you got to look at both numbers. It's not a single metric. So 82% for smaller lesions is leading as far as I can tell for end of bronchial approaches for that approach. Some folks can get to higher yield rates, but they're hitting bigger targets. So you need to look at both and that's what I encourage you to do.

The second thing that I advise you is that, there are other ways to examine or get a biopsy, they are tend to be outside the body, CT-guided needle biopsies, and those outside the body CT-needle, guided needle biopsies have high success rates at gathering the tissue, but they have a lower safety profile than the end of bronchial approach.

So there's kind of a third dimension, which is, did you get the tissue you needed to get a definitive diagnosis, how big was the lesion you were trying to target and what was the complication rate? And we think that Ion is really good at managing all three of those relative to competitive approaches and we're seeing a nice up tick as a result. And is that a tipping point? We'll see, so far so good that's we had expected. This kind of performance that that's what we were targeting and we're pleased to see it being borne out over multiple sites and multiple customers and we think that's going to be helpful.

With regard to your second question, you were talking a little bit about, are we seeing an unusual or more aggressive slow down because of delta than perhaps others? What I'd

encourage you to think about there is, where in the world everybody is exposed and where they're seeing their growth. So in our case, we have a certain regional profile and where our procedures are being done. Other companies may have much bigger exposure to say, markets or countries that have a lower impact having to do with delta. Frankly, I think it's as simple as that, but time will tell on that as well.

So let's go ahead and conclude that was our last question. In closing, we continue to believe there's a substantial and durable opportunity that primarily 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 and surgery and acute care is foundationally human. It falls 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 speaking with you again in three months.

Operator

Ladies and gentlemen, that does conclude your conference call for today. Thank you for your participation, and for using AT&T teleconferencing. You may now disconnect.