Q2 2021 Earnings Call

Company Participants

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

Other Participants

- Amit Hazan
- Larry Biegelsen
- Rick Wise
- Robert Hopkins
- Tycho Peterson

Presentation

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Q2 2021 Earnings Conference Call. At this time, all participants are in listen-only mode. Later, we will have a question-and-answer session. (Operator Instructions) As a reminder, under this conference is being recorded.

And at this time, I would like to turn the conference over to our host, Senior Director of Finance, Investor Relations for Intuitive, Mr.Calvin. Please go ahead, sir.

Calvin Darling {BIO 17664656 <GO>}

Thank you, good afternoon and welcome, to Intuitive second quarter earnings conference call. With me today, we have Gary Guthart, our CEO; Marshall Mohr, our CFO; and Jamie Samath, our Senior Vice President of Finance; Philip Kim, our Head of Investor Relations will not be joining on today's call, as he's currently on paternity leave following the birth of his daughter.

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 Form 10-K filed on February 10, 2021 and Form 10-Q filed on April 21, 2021. 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 second quarter results as described in our press release announced earlier today, followed by a question-and-answer session. Gary will present the quarters business and operational highlights. Marshall will provide a review of our financial results. Jamie 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'll turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Thank you for joining us today. Our second quarter 2021 performance was encouraging. With use of our systems for procedures growing beyond pre-pandemic levels and healthy capital placements. Looking at the past eight quarters in context, our compound annual growth rate for procedures for the period Q2 2019, through Q2 2021 of 16.5% is approximately the growth we would have expected absent the pandemic. The pandemic has reordered the quarter in which procedures were performed and we believed it has delayed some procedures that are likely to return in the future and may cause a small number of patients to permanently forego surgery. To understand our system placement and capital performance over this period, we look to annual system utilization trends, which have recovered to utilization rates at the high end of our historical averages. Taken together, this combination of a recovery and procedures, and healthy utilization supports our solid capital placement trends and rounds out a healthy commercial recovery year-to-date.

Examining procedure trends more deeply in the United States, procedure growth was strong in the quarter driven by growth and bariatric surgery, hernia repair and cholecystectomy. Both gynecology and urology procedure annualized growth strengthened in the quarter as pandemic pressures eased in the U.S. Annualized U.S. procedure growth rates were returning to historical levels for procedures with longer diagnostic pipelines as patients have started returning to screening and diagnostic testing.

Growth in our second-largest market, China, continued to be strong with multiple specialties contributing. European procedure growth was generally healthy though varied by country. Recovery in the UK was healthy in the quarter as NHS increased access to surgeries broadly. The pandemic is not behind us and additional infection growth made against strained hospital resources and impact our results in the future. Jamie will take you through procedure dynamics in more detail later in the call.

On the capital side, new system placements continue to be healthy with the United States, China, Germany, France and Japan notable in the quarter. We know that new system placements are closely tied to anticipated procedure volumes and system utilization in mature markets. We continue to see significant utilization variance by region due to pandemic differences.

In the quarter, strong trade-ins of older generation systems for our fourth generation products and strengthen multi-system deals continue to support our thesis that customers that know us best continue to invest with us going forward. We also saw an increase in our IDN customers opening new DaVinci and Ion programs in hospitals within their network that did not previously have an intuitive robotics program, indicating their interest in diversifying access to Intuitive programs across their networks.

Looking to our finances in the quarter, procedures recovered nicely in Q2, system placements came in above plan, and system ASP and INA revenue per procedure track slightly above our expectations. Together, driving revenue of $1.46 billion in Q2.

Our pro forma spending grew over 24% from a year ago, representing increased investment in our business. However, our expense growth rate was modestly lower than our plan, driven by pandemic related factors. COVID has delayed some work in R&D and clinical trials, leading to some underspend in programs, prototypes and some delay in hiring. We expect these programs to continue their ramp as our labs and development programs recover efficiency.

Travel and associated costs and support of our field have also not recovered to pre-pandemic levels. Field of marketing costs will tick up if the pandemic lanes. In short, our commercial business has recovered more quickly than our spending due to the different ways the pandemic impacts our customers, our supply chains and our hiring. Marshall will take you through our financial picture later in the call.

Turning to our innovation and commercialization efforts, we are developing and deploying technology enabled ecosystems 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. We are in the execution and launch phase of four efforts. First, we are broadening access to our advanced instruments for da Vinci fourth-generation multi-port systems through pursuit of additional clearances and launches outside the U.S. Second, we are expanding our da Vinci SP offering by broadening its regional and clinical indications and by adding it to its suite of instruments and accessories.

Third, we are launching in refining our flexible diagnostic platform Ion by working with early customers to help us establish high-performing sites and by improving our technology and supply chain capabilities. Finally, we are strengthening our digital capabilities across our ecosystem. Our fully integrated advanced instruments portfolio has been a strong addition to our multi-port ecosystem, allowing for high-quality tissue interaction, controlled from the surgeons console, while optimizing workflow.

These system controlled staplers, vessels healers in energy instruments support a range of procedures from bariatrics to colorectal procedures to thoracic and gynecologic applications. Customer appreciation and recurring use of our products has been growing nicely. In Q2, we launched our SureForm stapling line in India, we launched our force bipolar energy, energy along with our extended use instruments program in Japan and, we launched our secrecy low energy instrument and E100 energy generator in Korea.

Turning to our single port system. We placed 4 SP systems in the quarter, bringing the total install base to 79. As p procedures grew 133% year-over-year with much of that growth coming from the United States. First cases in our SP colorectal IDE trial were completed in the quarter as we seek to bring SP capability to additional procedures. We are also working on a regulatory filings to bring SPD Europe under the European Union's new medical device regulation framework.

Our flexible robotics program first targeted towards diagnostic vancascopy [ph] has had a strong quarter. We place an additional 20 Ion systems in a quarter, bringing the install base to 70. Ion procedures grew six fold over Q2 2022, nearly 1,500 procedures in the quarter, reflecting recovery from the pandemic, the growth and new sites and growth and utilization of existing sites. Our total Ion clinical experience is approximately 4,000 cases today. Clinical trial sites completed enrollment for our precise clinical trial. Finally, our team is making good progress scaling our operations.

Lastly, we continued to digitally enhance our ecosystem. In the quarter, we continued to engage customers and data analytics and opportunity analysis for surgical programs. Cornerstone of our -- your data, your truth analytics efforts. We have continued the launch of our My Intuitive app including launching to first users in Europe. My Intuitive allows surgeons and care team members to access their data to manage their profile, their learning and otherwise interact with Intuitive through an easy-to-use mobile app in the palm of their hand.

Our digital learning programs continue to be an important part of our overall learning initiatives. These programs together trained over 2,200 care team members in the quarter, showing organizational strength and localizing programs and responding with agility the pandemic influence demand. As the phases of the pandemic of all for supporting our team in addressing the opportunities and challenges posed by the pandemic, in the ways we work. Intuitive as manage multiple ways of working for many years, roughly a third of our team works in the manufacturer test and distribution of our products. Another third works closely with customers in the field and the remaining third have traditionally worked in the lab and office environments.

We're taking a first principles approach to return to office environments with our team, bringing back face to face interactions for those tasks best completed in person, while enabling hybrid work environments for accomplished by distributed teams. Most of our offices globally are reopening with this hybrid approach. We anticipate iterating our approach as we learn in a year progresses. As I conclude, that the balance of the year were focused on the following. First, agile and flexible support for our customers globally, as they need, it often addressing the return of surgical patients to treatment. Second, disciplined execution of the launches, including our advanced instruments, SP, ion. Third, driving depth and excellence in regional performance, particularly in Europe and Asia. And finally, the expanding our clinical, economic, and analytical evidence base for key procedures in countries.

I'll now turn the time over to Marshall, to take you through our financial performance 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. COVID had a significant impact on division procedure volumes in the second quarter 2020. That impact was most pronounced in the U.S. and Europe and varied market-to-market complicating year-over-year comparisons. In the U.S., as COVID continued to subside in second quarter of 2021, we saw a lower impact on da Vinci procedures.

Procedure growth in the U.S. was led by bariatric cholecystectomy in hernia procedures. We also believe that growth benefited from some procedures that were previously deferred due to delays in testing and patient concern over COVID. While there is likely some amount of backlog that has not yet been addressed, it's difficult to estimate the extent of the remaining backlog and when it will affect future procedure growth.

In Europe, the impact of COVID in the second quarter of 2021 varied regionally with slower recovery in Italy and France, while we saw early stages of recovery in the UK. While there continues to be COVID hot spots within some of our Asia-Pacific markets, overall procedures in the region performed well. China growth in the second quarter continue to be far higher than our other regions, primarily reflecting the 40% system installation growth over the past year. Jamie will provide additional procedure commentary later in this call.

Hospitalizations of patients due to COVID have negatively impacted DaVinci procedures. To the extent that hospitalizations expand significantly due to COVID, and its variants like currently being experienced in parts of the world, it could negatively impact DaVinci procedures.

Key business metrics for the second quarter were as follows. Second quarter 2021 procedures increased approximately 68% compared with the second quarter of 2020, increased approximately 13% compared with last quarter. Compound annual growth between the second quarters of 2019 and 2021 was 16.5%. Second quarter system placements of 328 systems, increase 84% compared with 178 systems for the second quarter of 2020, an increased 10% compared with 298 systems last quarter. We expanded our installed base of da Vinci systems over the last year by 10% to approximately 6,335 systems. This growth rate compares with 9% last year, and 8% last quarter.

Utilization of clinical systems in the field measured by procedures persistent, increased approximately 55% compared with last year, an increased 11% compared with last quarter. The compounded annual utilization growth rate between the second quarters of 2019 and 2021 was 6%.

Moving on to capital placements. System placements in a quarter reflected procedure growth, and hospitals upgrading to in order to access or standardized on fourth-generation capabilities. Capital placements for the first six months of 2021 were in line with procedure and utilization growth. Looking forward, we see the following capital revenue dynamics. Procedure growth drives capital purchases and 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 placement. However, as the installed base of older generation product declines, the number of trade-ins will decline over time.

Leasing and alternative financing arrangements enabled customer access to capital. While the percentage of systems placed under operating leases fluctuates quarter-to-quarter, we believe leasing will increase as a percentage of sales over time, which will result in the deferral or otherwise current revenue into future periods.

Macroeconomic conditions created by COVID could regionally impact hospital's capital spending. And as competition progresses in various markets, we will likely experience longer selling cycles and price pressures. Additional revenue statistics and trends are as follows, total second quarter revenue was $1.464 million representing 72% increase from last year, and 13% increase from last quarter. The compound annual revenue growth rate between the second quarters of 2019 and 2020 was 15%.

Second quarter revenue reflected growth in both procedures and system placements. Leasing represented 33% of current quarter placements compared with 29% last year and 43% last quarter. In the quarter, we completed a number of placements with larger IDN that prefer to purchase rather than lease product. Leasing is a percentage of total sales lag has and will continue to fluctuate with customer and geographic mix. However, we anticipate more customers will seek leasing or alternative financing arrangements than reflected in historical run rates. 38% of systems placed in the second quarter involved trade-ins, which is lower than the 40% last year in the 44% last quarter.

As customers continued to upgrade to fourth-generation capabilities, the population of installed SIS is decreasing. Particularly in the U.S. where 110 trade-ins were completed in the second quarter leaving an install base of SIS of approximately 500 systems. As a result, we expect lower trade-in transactions over time, trade-in activity can fluctuate be difficult to predict. Second quarter second quarter system average selling price has decreased to $1.55 million, from $1.65 million for both the second quarter of 2020, and the first quarter of 2021. The decrease relative to these prior periods reflects geographic mix and volume discounts provided to customers purchasing multiple systems.

We recognized $26 million of lease buyout revenue in the second quarter compared with $9 million last year, and $19 million last quarter. Lease buyout revenue has varied significantly quarter-to-quarter and will likely continue to do so. Instrument and accessory revenue procedure of $1,940 increased compared with $1,900 per procedure for the second quarter of last year, and decreased compared with $1,950 per procedure in the first quarter.

Extended use instruments were introduced into the U.S. and Europe in the fourth quarter in most other markets in the first six months of this year, except China due to regulatory timelines. In the U.S. and Europe extended use instruments were nearly fully adopted in the second quarter. The year-over-year increase in INA -- revenue per procedure, reflects increased usage of our advanced instruments partially offset by the impact of extended use instruments. We believe that globally customers have had not completely adjusted their instrument buying patterns to reflect the additional uses per instrument. Customer adjustment of buying patterns will reduce INA revenue per procedure.

For the systems placed in the first quarter or SP systems reflecting continued measure roll out of SP. Our installed base of SP systems is now 79, 8 in Korea and 71 in the U.S. We completed first cases associated with our U.S. colorectal clinical trial in the second quarter. We placed 20 Ion systems in the quarter, bringing the install base to 70 systems. There were nearly 1,500 Ion procedures completed in the second quarter. Ion system placements and procedures are excluded from our overall system and procedure counts.

The supply issues we called out in the first quarter did not impact Ion placements and procedures in this quarter. Our rollout of Ion will continue to be measured while we optimize training pathways in our supply chain. Outside the U.S., we placed 115 systems in the second quarter, compared with 72 in the second quarter of 2020 and 108 systems last quarter. Current quarter system placements included 63 into Europe, 16 into Japan and 19 into China. Compared with 18 into Europe, 18 and to Japan and 21 into China in the second quarter of 2020.

Moving on to gross margin and operating expenses. Pro forma gross margin for the second quarter of 2021 was 71.17%, compared with 62.4% for the second quarter of 2020 in 71.8% last quarter. The second quarter of 2020 included $59 million of service credits issued in conjunction with our customer relief program. Higher period costs associated with lower production and higher excess and obsolete inventory charges. The first and second quarters of 2021 reflect leveraging fixed costs over higher production levels. Products 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 we carry safety stocks of critical components and are otherwise working to secure supply necessary to ensure fulfillment of customer demand, global shortages could result in higher production costs and production development and regulatory delays.

Pro forma operating expenses increased 24% compared with the second quarter of 2020, an increased 5% compared with last quarter. The increase compared to prior year reflects costs associated with higher head count, increased variable compensation and increased spending in areas impacted by COVID. Second quarter spending was below our expectations due to 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 in headcount infrastructure and other support areas catch up to the growth in 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.

Our pro forma effective tax rate for the second quarter was approximately 25%. In the second quarter we modified the useful life of a deferred tax assets, which resulted in a current charge to pro forma income. However, that charge generated that change generated a long-term benefit of $66 million that is recognized currently in GAAP income, who will be recognized ratably over approximately 10 years in pro forma income.

The charge associated with the deferred tax assets in a higher mix of U.S. income, drove the 25% current quarter pro forma rate. We expect our pro forma rate for the last six months of 2021 to be between 21% and 22% versus our previous guidance of 20% to 21%, reflecting a greater proportion of U.S. income for the year.

Our actual tax rate will fluctuate with changes in the geographic mix of income changes in taxation made by local authorities and with the impact of one-time items. Our second quarter pro forma net income was $477 million or $3.92 per share compared with $132 million or $1.11 per share for the second quarter of 2020. In $427 million or $3.52 per share for the last quarter.

I will now summarize our GAAP results. GAAP net income was $517 million or $4.25 per share for the second quarter of 2021 compared with GAAP net income of $68 million or $0.57 per share for the second quarter of 2020 and GAAP net income of $426 million or $3.51 per share for the last quarter. The adjustments between pro forma and GAAP net income are outlined and quantified on our website. We ended the quarter with cash and investments of $7.7 billion, compared with $7.2 billion last quarter. The increase in cash in the second quarter primarily reflect a cash from operations in 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>}

Good afternoon. Our Second core procedure growth was 68% compared to a decline of 19% and during the second quarter of 2020, which reflected a significant adverse impact from the COVID-19 pandemic. The compound annual growth rate between the second quarter of 2019 and the second quarter of 2021 was 16.5%.

In Q2, U.S. procedures grew 77% year-over-year, which equates to 16% on a two-year compound annual growth rate basis. Our U.S. markets grew 51% year-over-year or 19% on a two-year compound annual growth rate basis. In the U.S. Q2 procedure results were positively impacted by a continuing recovery from COVID-19, including we believe a number of procedures that have been previously defer. Q2 growth was driven by particular strength and benign procedures including Bariatrics, hernia repair, cholecystectomy and benign hysterectomy, reflecting in part we believe a partial catch up in these procedures related to the previous deferral of elective surgeries.

General surgery growth in the U.S. was strong, in addition to the positive impact from patient backlogs reflected did increasing access for surgeons to our fourth generation technology. In the U.S. procedures that are dependent on diagnostic pipelines also grew will be at lower rates as compared to benign procedures. Colorectal growth was strong with solid growth in malignant hysterectomy, thoracic and prostatectomy procedures. Based on market data, we believe that diagnostic pipelines in the U.S. began to recover from the impact of the pandemic in March, with a lag in the recovery of associated procedures.

Second quarter, OUS procedure volume grew approximately 51% compared with 7% decline for the second quarter, 2020 and 23% growth last quarter 2nd 2021 OUS, procedure growth was driven by growth in prostatectomy procedures and earlier stage growth in kidney cancer procedures, general surgery, gynecology and thoracic. China procedure growth remain strong and broad-based. As a result of continued expansion of the installed base under the current quota, growth in Japan was solid but was impacted by a relatively slow rollout of vaccines and the impact of localized lockdowns as a result of ongoing efforts to prevent resurgence of COVID-19. In Europe, procedure growth vary by country based on the relative impact of, and recovery from the pandemic. Growth in the UK was strong with a slower recovery in France, Italy, and Germany.

Now turning to the clinical side of our business, each quarter on these calls, we highlight certain recently published studies that we deem to be notable. However, to gain a more complete understanding of the body of evidence, we encourage all stakeholders to thoroughly review the extensive detail of scientific studies that have been published over the years. During the quarter, a group from the Tang Seng Hospital, Naval Medical University in China published a meta-analysis in BMC cancer, comparing robotic-assisted drastic surgery versus video-assisted drastic surgery or vats. For long lobectomy or segment ectomy in patients with non-small cell lung cancer. The meta-analysis combined 18 studies across different countries containing over 11,000 patients of which just over 5000 received da Vinci robotic-assisted drastic surgery and just over 6,000 received vats. The results of the meta-analysis found that robotic-assisted thoracic surgery compared to vats and associated with among others, the following significant findings. 50.4 milliliter is lower blood loss, 50% lower chance of conversion to an open procedure, a 1.1 day short of stay in the hospital and 10% less chance of patient experience to post-operative complication. The authors concluded quote, the results revealed that robotic-assisted surgery is a feasible and safe technique compared with vats in terms of short-term and long-term outcomes.

In May of this year, Dr.Karl LeBlanc, from our lady of the medical center in Baton Rouge, Louisiana published results from a multicenter study comparing short-term outcomes for incisional hernia. Published in the hernia journal and titled robotic-assisted laparoscopic and openness incisional hernia repair early outcomes from the prospective hernia study, the study contains 371 patients, the underwent an incisional hernia repair procedure across 17 institutions within the United States, between May 2016 and September 2019. Of those patients 43% were in the DaVinci Robotic Cohort. 35% in the laparoscopic cohort, and 22% in the open cohorts. In reporting the results, adjusted using a propensity weighted approach, the authors noted that during the 2 to 4 weeks standard of care visit period. Fewer patients reported the need to take prescription pain medication for the robotic cohort as compared to the laparoscopic and open cohorts. 65.2% for the robotic cohort as compared to 78.8% for the laparoscopic cohort compared to 79.8% for the open cohort. Conversion rates to open surgery were lower in the robotic group compared to the laparoscopic group, 0.6% as compared to 4.9%.

And reoperation rates in the 30 days post procedure were comparable between robotic and laparoscopic, and lower for robotic is compared to open, 0.6% as compared to 3.1%. The authors concluded in part quote, when compared to open the robotic-assisted surgery group is associated with a comparable operative time, shorter length of stay and lower reoperation rate through 30 days. The difference in the number of subjects reporting the need for prescription pain medication favored the robotic-assisted group in both comparisons and quote.

I will now turn to our financial outlook for 2021. We continue to operate in a challenging supply chain environment and of experience longer lead times and delayed deliveries from our suppliers. While this did not have a material impact to our operating results in Q2, the outlook we are providing does not reflect any potential significant disruption or additional cost related to supply constraints. We also know the increasing number of COVID-19 cases in certain geographies associated with the delta variant. The outlook we are providing on today's call does not reflect risks associated with a significant increase in COVID related hospitalizations in relation to the delta variant, or other potential new variants.

Starting with procedures. Last quarter we forecast 2021 procedure growth of 22% to 26%, given the stronger recovery of procedures we have experienced so far, particularly in the U.S. and strengthen U.S. general surgery. We are now increasing our forecast and expect full year 2021 procedure growth of 27% to 30%. The high end of the range assumes strengthen U.S. general surgery, a return to normalize diagnostic pipelines, the vaccines are effective against any new COVID-19 variants. And the vaccine rollouts in early U.S. markets, continuous currently expected by governments around the world.

Turning to gross profit, on our last call, we forecast our 2021 full year pro forma gross profit margin to be within 70% and 71% of revenue. We are now slightly increasing our forecasts and expect full year gross profit margin to be between 70.5% and 71.5% of revenue. Our actual gross profit margin or very quarter to quarter, depending largely on product, regional and trading mix, the impact of product cost reductions and manufacturing efficiencies and pricing pressure. With respect to operating expenses, on our last call with forecaster growth full year pro forma 2021 operating expenses, between 18% and 22% above 2020 levels. We are refining our estimate and expect a full year pro forma operating expense growth to be between 17 and 21%.

Consistent with last quarter's forecast, we expect our non-cash compensation expense to range between $450 million and $470 million in 2021. We expect pro forma other income, which is comprised mostly of interest income to toll between $50 million and $55 million in 2021. With regard to income tax, we expect the range of our second half 2021 pro-forma tax rate to be between 21% and 22% of pre-tax income, slightly higher than the range we provided on the last call reflecting a higher mix of U.S. income.

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

Questions And Answers

Operator

(Question And Answer)

(Operator Instructions) And for our first question, we will go to Tycho Peterson. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, thanks. Congrats on the quarter. I guess, first question on guidance. Obviously, you made some comments about variance and not factoring in kind of increase in. I know, case arises have been largely decoupled from hospitalizations, but can you maybe just talk through the thought process there and how you're thinking about any potential risks in the back half of the year from the Barrett cases.

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

Just -- thanks, Tycho. From the top, I think you said the right thing, which is there's a little bit of a decoupling thus far of infection from hospitalization. The number we're watching closely is hospitalization. Jamie, I'll let you take it, from there.

A - Jamie Samath {BIO 7313010 <GO>}

Yeah, Tycho. We kind of outlined what was assumed in the high end of the procedure guidance from the low-end perspective, the 27% reflected there is greatest summer seasonality that reflects the possibility of an impact Q2 pent up demand for vacation especially for healthcare workers that worked extensively during this period with COVID. It also reflects lower diagnostic pipelines and perhaps some reluctance for patients to visit hospitals, and there is OUS markets continue to be choppy given the -- in many cases, those markets are behind the U.S. for example, and the vaccinations rollouts and that leaves the possibility of continued resurgences and localized lockdowns. That low-end also reflects some impact of resurgence in the U.S., but as you heard in our prepared comments, a significant increase in hospitalizations is not reflected in the guidance range.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. That's helpful. Shifting to the extended use program, you've been out for around six months smaller rollout in Europe in the fourth quarter. Can you talk about kind of next steps to the program here particular geographies you're targeting? And then is the elasticity relative to the extended use program and the pricing adjustments played out relative to your expectations or any color you can provide on that?

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

Sure. We ruled out the extended use instruments in Europe and the U.S. back in the fourth quarter. And then now we have rolled it out to most other markets in the first six months of this year except for China, where there are longer regulatory timelines. It's a short period, but we believe that there is elasticity and we've seen elasticity in markets where reimbursements are very low. And we've received feedback, positive feedback from surgeons who have indicated it, system access has been a key driver for increased procedures and we think that the extended use instruments lowers barriers for purchases of systems.

Having said all of that, it's been a short period since they've had extended use instruments, even though we've seen growth in the procedures that were specifically targeted by extended use instruments. It's hard to discern what is COVID related versus what is not. And so, we'll see over time, we'll be able to measure a little better over time and we'll monitor.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And last one on SP and the last quarter, you kind of brought up the concept of going after thoracic and some additional other areas. Can you maybe just talk a little bit about the roadmap and I think you alluded to adding additional instruments and accessories, so can you talk on the hardware side as well?

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

Sure. So right now, we talked in the script about adding our work or IDE around colorectal, we're excited about that, that'll play out over the next several quarters as we grew patients and then given that its cancer procedure in some cases. It's a little bit longer follow-up, so that's a multi-quarter conversation. We're doing what we call the procedure development and the trial development around other indications, we think will be an opportunity on thoracic as well, as well as other ones beyond it.

The instrumentation updates, there are other things Imaging updates and software updates that are really all focused around right instruments, right features for the right extension or right expansion. So, our customers are asking us for advanced instrumentation. So energy and stapling and other things we think that is possible as we're making those investments to move that forward. We think we can bring some outstanding imaging capabilities, including fluorescence imaging into that space. And we're building into the broader digital ecosystem for SP.

Our focus right now is not rapid expansion of the install base. Our focus is in clinical capability and productivity of the install base we have. In other words, happy, very satisfied customers and sequential growth and what they can do with this system remains our focus on SP for now.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. Thank you.

Operator

Next, we'll go to Bob Hopkins, with Bank of America. Please go ahead Mr.Hopkins.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great, and good afternoon. So, first question for me is, just trying to dissect your procedure results a little bit more, because it's some really interesting comments that you saw strength in benign cases, some catch-up cases and then on to your compounded basis, you kind of where you thought you might be pre-pandemic. I'm just curious from what you see out there is just broadly reflective of what you think is going on in the marketplace for surgical procedures or is this simply and primarily just a something about the pandemic accelerating the use of DaVinci and robotic surgery broadly?

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

I'll speak to my impression but I'll caveat it, it's one person's impression. So, it's not a scientific study, just my view. I think what we're seeing is that the longer diagnostic pipelines have had this kind of double effect from the pandemic. Partly, its delays in getting in and getting tested and starting the journey and then getting in and having a procedure or treatment whatever that might be. So, from a core demand point of view or disease state, that's clearly out there in accumulating and it has to be a processed through.

On the benign side, often the diagnostic pipelines are shorter. You go from an issue to identification to closure more quickly. And I suspect that's most of what we're seeing at least in the United States in terms of that. But I don't have scientific evidence, I think that's anecdotal. Jamie anything --

Q - Robert Hopkins {BIO 2150525 <GO>}

Okay.

A - Jamie Samath {BIO 7313010 <GO>}

I'd just add Rob, as you saw the COVID hospitalization rates in the U.S. come down and marching into Q2 that freeze hospital resources to increase the level of surgery that we do. And we also see I think increased patient confidence as a function of the improving vaccination rates and those two things come together, they also allow hospitals to start to address the backlog that's accumulated. And I think the subset of the benign procedures that have been kind of deferred elective procedures, hospitals can recover those pretty quickly.

Q - Robert Hopkins {BIO 2150525 <GO>}

Okay. And then just one quick follow-up and thanks for those comments. Just to be clear on your answer to Tycho's question, just on the recent spread of COVID in variance and the potential impact on demand and hospitals ability to procedures. Are you starting to see that impact now or is it too early and you're just saying that might happen in the future?

A - Jamie Samath {BIO 7313010 <GO>}

Yeah. We've seen that in some OUS markets. We've clearly seen that in markets like, India, Taiwan has been an impact in terms of, and how they've handled that from a healthcare system perspective. And the resulting impact on our procedures. From a U.S. perspective, I think it's early, and I think we're simply acknowledging the risk. I think the thing that we'd call out is, it's not the code case rates per se to monitor is the impact on hospitalizations. Lockdowns decrease patient mobility and willingness to go get their tests. And then hospitalization diminishes ICU capacities those are the -- the drivers we watch.

Q - Robert Hopkins {BIO 2150525 <GO>}

Makes sense. Thank you.

Operator

Next, we will go to Amit Hazan with Goldman Sachs. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks. Maybe start with Marshall on the first one and then go to Gary for the second one. Marshall, the operating margin coming in at the 43%, I'm just wondering how much we can extrapolate here. We heard your comments, but just kind of thinking a little bit longer term in just the next couple quarters. Where you got COVID, I'm just curious what the net effect there is from the savings and expense perspective in R&D, whether this has made the beginning of you starting to see some leverage off of the 10% you've been up for the last couple years? And then SG&A kind of same kind of question you've been spending a lot there, are we starting to see leverage potentially that could enable a little bit better margins as we think about next year, year after?

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

I think there's elements of our spending have been restrained because of restricted because of COVID and its impact. And I kind of articulated with those word, travel and so forth. And we expect those to come back, as COVID goes away and restrictions on travel and the restrictions on other activities go away. We also -- the business came back faster than we had anticipated. And so, we have some catch up to do in terms of infrastructure and support necessary to support the overall business and so we'll spend there.

And so I think you're going to see, this quarter was extraordinary in terms of the operating profit margin and that will -- it'll be lower in future quarters given what I just described. In addition to that, we still think this is a great opportunity to continue to invest in ecosystem of products and capabilities. At this point in time before, competition really gets any kind of toehold. And so we're going to continue to invest. So I wouldn't start building lots of leverage into your models. I think that would be a mistake.

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

Well I have, well I add one bit of color to that. I think when we think about our product cycles, I would just have you look back earlier in the da Vinci experience in that. These are long development cycles. The time you (Technical Difficulty) on your end that market penetration rates that are - they're significant and that is both painful in an opportunity. The painful part is the investment troughs are deep in the early and middle years of those product cycles. And we're early in the Ion product cycle, and we're early in the SP or early mid in SP. So, it takes a while, but once you develop are really capable ecosystem and it has a lot of platform use and in that investment can be recovered over time. So, it's hard to time it out and it doesn't time out over one or two quarters it times out over years.

Q - Amit Hazan {BIO 6327168 <GO>}

And Gary just -- with you just thinking through the my intuitive and what you're doing at the surgeon level. I'm actually curious more what's going on with service and software at the hospital like kind of department of surgery level that I don't know how much of an update you can give us, which is something and what's happening at that level in terms of software tools and services? You're developing trying to increase efficiency to feed cost that kind of thing. How close we are to maybe seeing something that you can monetize this, anything you can talk to there will be helpful?

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

We think about digital as enabling and accelerating a lot of different parts of the ecosystem. So, when we talk about my intuitive, that really is putting the power of interaction and data at the surgeon level in their hands or at the robotics coordinator level in their hands. So, we're excited about that because it gives them fast and easy access. It links into some of the other things you're talking about, we are building tools and capabilities that allow hospital departments and departments of surgery to manage their program and look across programmatics for efficiency, for learning, for outcomes and these things interlink.

So, short answer there is, just kind of a reminder what we're trying to do. We think there's an opportunity to accelerate learning and to drive increased in sight for a surgeon into their own progress, we're doing that, that's combination of my intuitive, plus some of the simulation work that we do, plus some of the machine learning and video analysis work that we do. We think there's an opportunity to look at correlations between surgeon performance and outcomes and that has implications for the kind of imaging we do, has implications for task analysis and training and we're doing those things and those can be aggregated across the surgical platform.

And there's a lot of opportunities for or efficiencies and standardization controlling operating costs, controlling consumables costs, those things are ongoing now. So, several of those things are in the markets, the very first kind of Gen 1, some of them are on Gen 2. Some of them are included in our service contracts, some of them are going to produce basis, some of them are fully included because we feel like they make us more efficient and to make them more efficient. So, we don't really call them out as individual revenue lines. I think they are ecosystem enablers and can result in very high customer satisfaction when done well.

Q - Amit Hazan {BIO 6327168 <GO>}

All right. Thank you.

Operator

Next, we'll go to Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

-- nice quarter. One on procedures, one on competition. So, I apologize for the short-term oriented question, but you're the first large CAP company to report here. So I'd be curious to hear from you on any procedure trends through the quarter in the U.S. and international. And regarding the backlog, how do know there was catch up and why won't that continue for the next few quarters? And I had one follow-up.

A - Jamie Samath {BIO 7313010 <GO>}

Yeah. Just in terms of intra quarter procedure trends, if you're asking Larry month by month, there was nothing noble actually that we would call out. There was the usual impact of seasonality from vacations like Easter, but nothing notable within the quarter. I mean in terms of procedure categories, Bariatrics continue the strength that we've seen for some time. China continued, the strength that we've seen over the last couple of quarters, and U.S. general surgery in particular performed well. So I think those are the key kind of procedure highlights.

What was the second part of your question again, Larry?

Q - Larry Biegelsen {BIO 7539249 <GO>}

Yeah. I mean, how do you know there was catch up from the backlog in Q2? And I guess, why won't that continue -- it doesn't seem like the backlog would be exhausted, just after one quarter?

A - Jamie Samath {BIO 7313010 <GO>}

Yes. It's -- his kind of where we stand with backlog. We don't actually know, how much backlog was resolved in the core, and how much backlog is left? Well, the timing of the recovery of that might be, we have a broad range of estimates frankly, the lack of precision in that estimate is such that is probably not useful for us to share. And so we have some indications that we saw, backlog reflected in the Q2 results but at this point it's just too difficult to estimate and therefore kind of give you any additional color on.

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

Yeah. I hear your question is, asking us how much is left? How much of the catch up is left? There appears to be some. It's hard to have a precise measure on it. I think we're going to have to let it play for another few quarters to see. Add to that, the uncertainty way for possibility of wait for it makes it tough to put a number on for now.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful, Gary. And just on competition, it does seem like the noise is increasing, we could see one large competitor approved in the second half of this year. How are you thinking about competition? Are you seeing any impact thus far? Thanks for taking the question.

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

Yeah. A couple of things, I think all of us know, and we as consumers know the customers like choice, perfectly fair. We've seen a few teams come out and field systems that are alternatives to ours transit tariff [ph] was out a few years ago, CMR has been out and now, Medtronic. A couple of things I'd say, one is, we are focused on making sure that our ecosystem, our products, our systems, and everything goes around it really delivers against the quadruple aim all the way through. It's not just a robot. Building a great robot is a hard first step. You have to do it and right now, I think that remains to be seen how strong those other systems are.

Even then it's not enough, instruments and accessories, training programs, support staff, analytics capability, publication, scientific publications, demonstrating what you've done. The analytics and evidence-based build are all I think important. So I encourage those folks on the call, it's likely to be a comparison of ecosystems in delivering of quad aim over time. That said, other teams are out, they're all calling on customers. They're giving their power points about what they think is going to happen next and some other things, and our posture to that has been, it may delay some sales as we may have some competitive conversations and tenders and we'll lose some.

What we've seen though is that what happens with the power points and what happens a year later, it's different and that if it hasn't delivered against the quad aim, if these systems can do some cases well, but not all cases well or they have stability issues or other things that worse than pretty quickly. We also find that our economic offerings with da Vinci X and EUP. We have we have choices that we -- ourselves can offer our customers. So, I think all of you on the call, you should expect increased alternatives for the customer base. I think the noise levels will go up. I think our customers will take their time to evaluate new things as they go. We're okay, we're not frightened of that. We think we stand up pretty well to those comparisons, and we're ready to help them pursue their hands as it proceeds.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks so much.

Operator

Next, we're going to the line of Rick Wise with Stifel. Please go ahead, sir.

Q - Rick Wise {BIO 1490589 <GO>}

Hi. Good afternoon, everybody. Hi, Gary. Maybe just at the beginning of your comments, I was struck that you emphasize that da Vinci utilization rates are, if I understood you correctly at the high end of historical averages. Gosh, that's awfully encouraging sounding. It just wondered are you suggesting or should we be thinking that we could be in the front of a new wave of capital acquisition, but again capital or released because of the need to add additional systems to accommodate the expanding number of procedures?

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

The reason I've mentioned it early is, I think when we had pretty strong capital quarters the last few. One of the things we want to look for is, are we building unused capacity into the field that where procedures softer that would install us out. And so, we watch that number because we know it's highly sensitive and we're pleased. Again, if you look across that two-year period, try to look through the pandemic kind of ups and downs. What we're seeing is that procedure demand is there. And the capital to support that demand has not run ahead of the procedure demand.

In fact, our commentary is a little bit the opposite that these are being highly utilized. That's great. That says that we're not putting out more capital than folks need. Even though it's been healthy capital quarters, it means, our customers are getting good benefit out of what you're using those systems for. Jamie and his commentary said that a lot of those procedures are benign procedures. Many of them are shorter duration than longer or more complex disease states. That means that utilization will go up kind of naturally that mix moves toward a higher utilization next. All of that to me indicates that the business feels in balance.

I'll caution that what the next couple of quarters or next four quarters looks like in terms of hospital access to capital and their decision-making capital is always lumpy. It has been -- just so really speaking backwards looking so far so good.

Q - Rick Wise {BIO 1490589 <GO>}

Got you. Gary, separate topic, I've had the privilege of seeing intuitive developed, the use of robotics in multiple clinical indications over the years. And recently, we had a series of very encouraging conversations and the adoption Bariatrics, very encouraging. And basically still under penetrated, big opportunity, doctors talking to us about further expansion of utilization. And I'd just be curious to since you all are calling it out to repeatedly as an important in front of growth driver. Where are we now in your view in that? I'm sure multi-year or long-term adoption process. What's left to do for maybe a product or procedure, or instrument point of view where are we going with this one? Thank you.

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

Let me start with why I think it's adopting and I'm going to turn to Jamie as to the where are we, what inning of base margin I'll let Jamie take that. On the Y side, it's -- Bariatrics has been a little different than other procedure for us, it's highly penetrated laparoscopic indication in the United States. Having said that, it's a difficult procedure for surgeons to perform it's physically demanding. And as we've said in the past, if we can bring the right system, with right instruments, right imaging, in a right usability to right ease of use. We think that surgeons will care and we've seen both good clinical outcomes but also high surgeon satisfaction and better ergonomics.

I think that's what's been driving our our success in the early market. It's taken getting the advanced instruments together as a set, getting our workflows, in our clinical pathways, right? And I think that's been powerful to date. And Jamie, it's too kind of where we are.

A - Jamie Samath {BIO 7313010 <GO>}

Yeah. Just a couple of comments, so Bariatrics obviously has been highly laparoscopically penetrated, historically, from a market perspective about 60% initial so sleeves about 15% are revisions. In terms of our underlying numbers we're growing up a little faster rate in the revision section, sleeves and bypass grow about the same rate. I think the product ecosystem with XI with a 60 millimeter stapler is in good shape, and we're getting good feedback from surgeons in that regard. It's a physically taxing procedures as Gary described. And so, we see that as a benefit also with to respect feedback from surgeons. In terms of penetration or adoption, we're in the early to mid-innings kind of ranges what I'd say in the US market.

Q - Rick Wise {BIO 1490589 <GO>}

Got you. Thank you very much.

A - Unidentified Speaker

Okay. Well, thank you. And our moderator, 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 to treat. 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.

Operator

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