Q1 2021 Earnings Call

Company Participants

- Gary S. Guthart, Chief Executive Officer
- Jamie Samath, Senior Vice President, Finance
- Marshall L. Mohr, Executive Vice President & Chief Financial Officer
- Philip Kim, Head, Investor Relations

Other Participants

- Amit Hazan, Analyst
- Bob Hopkins, Analyst
- Larry Biegelsen, Analyst
- Matt Taylor, Analyst
- Richard Newitter, Analyst
- Rick Wise, Analyst
- Tycho Peterson, Analyst

Presentation

Operator

Ladies and gentleman, thank you for standing by, and welcome to the Intuitive Q1 2021 Earnings Release. At this time, all participants are in a listen-only mode. Later, there will be time for questions. Instructions will be given at that time. (Operator Instructions) As a reminder, this conference is being recorded.

I would now like to turn the conference over to our host, Philip Kim, Head of Investor Relations. Please go ahead.

Philip Kim {BIO 22131870 <GO>}

Good afternoon and welcome to Intuitive's first quarter earnings conference call. With me today, we have Gary Guthart, our CEO; Marshall Mohr, our Chief Financial Officer; and Jamie Samath, our Senior Vice President, Finance.

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. Our SEC filings can

be found throughout 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 first 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 Jamie will review our financial outlook. 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 first quarter of 2021 was a step in the right direction. In the quarter, we saw a healthy recovery of surgery and use of our products. Strong capital placements continued in Q1 2021 and utilization of installed systems increased through the quarter, indicating a need for our customers to return to surgery.

We're in the early innings of commercialization of two new platforms for Intuitive, while advancing digital enablement of our ecosystem. Our teams are making good progress in all three areas. Overall, we are seeing some pandemic recovery but improvement has been uneven with significant regional variation. Our experience shows that our business rebounds as COVID drops.

Starting with procedures, general surgery in the United States was a source of strength in the quarter driven by bariatric surgery, cholecystectomy and other procedures. Bariatric surgery has been on a multi-quarter growth trajectory, the result of a line development and commercial activities, starting with a capable system using advanced instruments and combined with a focused commercial team. Ventral hernia surgery is recovering. We think ventral hernia tracking behind aligned to hospital inpatient prioritization.

In the U.S., gynecology and urology returned to growth after pandemic related declines. Growth in our second largest market China continued to be strong, with multiple specialties contributing. Lastly, procedures that have long diagnostic journeys such as prostatectomy and thoracic surgery remain below historical levels. Philip will take you through procedural dynamics in more detail later in the call.

On the capital side, new system placements continue to exceed our expectations with United States, all of France and UK standing out in the quarter. We know that new system placements are closely tied to anticipated procedure volumes and system utilization in mature markets. System utilization grew in the quarter on average with significant regional variance due to pandemic differences.

Overall, capital strength indicates anticipation of future procedure opportunity for our customers. A significant number of systems were part of multisystem deals by hospitals and integrated delivery networks, supporting a theme in which customers who know robotic-assisted surgery well, continue to invest with us.

Lastly, the use of leasing and other alternative capital placement models ticked up again this quarter. Marshall will take you through capital placements in more detail later in the call. Surveying our business around the world, our business in China is growing quickly from a small base and we are pleased with the performance of our joint venture with Fosun Pharma. We believe there is significant long-term opportunity in China and remind you that it is currently a quality control market. We expect China to be dynamic and competitive in coming years, and we are investing in the market to bolster our place as a leading provider to the Chinese healthcare system.

In Japan, growth remains healthy, go below pre-pandemic levels. In Europe, our business in France and Germany have performed well considering the pandemic. In the UK, tightly controlled surgery results and in procedure declines, but we've also seen an increased commitment to robotic-assisted surgery in the form of increased capital placements, anticipating return of da Vinci surgery post pandemic. Italy and Spain are rapidly returning to growth after substantial pandemic impacts.

Speaking to our finances in the quarter, procedures recovered nicely in Q1. System placements came in above plan and I&A revenue per procedure was above our expectations, together driving 18% revenue growth over Q1 2020. Product gross margins were strong in the quarter, largely due to above average system ASPs, lower than expected excess and obsolescence charges and higher volumes through our factory.

Other spending was constrained in the quarter driven by three factors. First, travel and associated cost did not recur at pre-pandemic levels. This spend will increase as COVID wanes, and our customers and our staff reach immunity. Second, COVID delayed some work in R&D, leading to some underspending prototypes, we expect these programs to ramp up as COVID wanes in our labs and development programs recovery efficiency. Third, we deferred some investments in infrastructure that were necessary during the pandemic. We think most of these factors will normalize over time and we consider them one-time events related to the pandemic. We are still in the early stages of developing robotic-assisted surgery globally, and we will continue investing in R&D and our regional capabilities to realize these opportunities.

As I mentioned at the start of the call, we are in the early phases of our commercialization efforts for new platform, which we expect to play out over future quarters. Our single port surgery platform da Vinci SP, we performed our first cases in the U.S. and Korea of an important accessory or SP access points, which enables surgery close to the variable and eases assist in surgeon access through the single incision. The access port is an important -- is important in the SP ecosystem, facilitating access and workflow in many procedures in which SP is used.

We've had very strong customer feedback on the port today. We are also increasing our investments to accelerate new indications in key countries. In the U.S., we have two cleared indications for SP and expect to initiate cases as part of our colorectal IDE this quarter. We've seen strong interest in SP use in various specialties and we're in the process of designing trials for additional patients, including thoracic surgery and other surgical business. Overall, we've received robust customer feedback for SP use under existing clearances.

Turning to our flexible robotics platform, Ion, we installed 14 systems in the quarter. We are recovering from our supply backlog and our meeting demand for Ion procedures at all our installed accounts, while working to fill customer inventory stocking requests and/or internal inventory goals, which we expect to complete around mid-year.

Our PRECISE trial evaluating the ability to reach and diagnose suspicious pulmonary lesions is on track to finish enrollment by Q2 this year. Our Ion clinical performance is meeting our expectations and customer acceptance remains highly encouraging.

In our digital ecosystem enablement, we've broadened access to our mobile surgeon portal, the My Intuitive app, this April as part of our phased launch. My Intuitive is a mobile app that allows surgeons to manage their da Vinci experience into da Vinci systems and as they are training and do their operative data in the form of the camp.

Our Intuitive telepresence program supported 45% of all case observations in Q1 2021 up from less than 5% a year ago, a significant achievement accelerated by the pandemic, improving convenience for our customers and reducing costs for our team. Year-over-year surgical simulation usage in the quarter grew roughly 46% over Q1 2020, validating the power of digital tools.

Finally, our team made significant progress in automating customer facing analytics as part of our robotics program and consulting services which allow our customers to analyze the relative performance of their da Vinci programs, now will retain part of customer engagement at States.

In conclusion, we're seeing adjustments in the health care system that favor our offerings. Increased depreciation of high quality MIS in the current and post-pandemic environment increased openness to digital technologies, increased use of analytics to assess care and increasing sensitivity by health systems to total cost to treat. We have and will continue to position ourselves to perform well in this environment.

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

Key business metrics for the first quarter were as follows. First quarter 2021 procedures increased approximately 16% compared with the first quarter of 2020. It was approximately the same as last quarter. On a day adjusted basis, procedures grew 18% year-over-year. First quarter system placements of 298 systems increased 26% compared with 237 systems for the first quarter of 2020 and decreased 9% compared with 326 systems last quarter.

We expanded our installed base of da Vinci systems over the last year by 8% to approximately 6,142 systems. This growth rate compares with 11% last year and 7% last quarter. Utilization of clinical systems in the field, measured by procedures per system increased approximately 8% compared with last year and decreased 2% compared with last quarter. The impact of COVID on da Vinci procedures varied by region.

In the U.S., COVID resurgence that affected procedures later in the fourth quarter continued well into January. Then as COVID subsided, procedures experienced a steady improvement through February and March. In Europe, the spread of COVID varied regionally and procedure growth rates were mixed with strength in France and a year-over-year decline in the UK.

While there have been COVID hotspots within some of our Asia-Pacific markets, they tended to be isolated and in general procedures performed well. China growth was far higher than other regions, reflecting the severity of the COVID impact on China in the first quarter of last year and the additional system installations over the past year. Philip will provide additional procedure commentary later in this call.

Despite the fact that hospitals are better equipped to handle COVID patients today compared with the outset of the pandemic, resurgences of COVID-19 and its variance, like those currently being experienced in parts of Europe and U.S., have challenged hospital care capabilities and have negatively impacted da Vinci procedures.

In addition, delays in diagnosis and treatment of underlying conditions have continued to negatively impact da Vinci procedures. While there is a backlog of patients, it is unpredictable when those patients will ultimately seek diagnosis and treatment and whether they will be treated surgery.

Jamie will be providing procedure guidance later in this call that guidance is based on our experience in the first quarter in the pace at which vaccines have been and are forecasted to be rolled out. Changes in the spread of COVID and its variance in the pace of vaccine rollout could significantly impact our guidance.

Moving on to capital placements. Placements in the quarter reflected procedure growth, hospitals purchasing systems in preparation for a post pandemic environment and hospitals upgrading in order to access or standardize on fourth generation capabilities. First quarter capital placements exceeded our expectations. We believe that generally COVID has had less of an impact on hospital capital spending capacity and that customers recognized that da Vinci surgery meets their quadruple aim objectives better than other surgical approaches.

Looking forward, we see the following capital revenue dynamics. Procedure growth drives capital purchases in many of our markets, to the extent the COVID impacts procedures, it will also impact capital purchases. Leasing and alternative financing arrangements have enabled customers access to capital. We believe leasing will increase as a percentage of sales over time, which will result in the deferral of otherwise current revenue in the future periods.

The trading cycle has been a tailwind system placements. However, as the installed base of older generation product declines, the number of trade-ins will decline. Macroeconomic conditions created by COVID could regionally impact hospital capital spending. And as we face competition in various markets we may experience longer selling cycles and price pressures.

Additional revenue statistics and trends are as follows. Total first quarter revenue was $1.292 billion, representing an 18% increase from last year and a 3% decrease from last quarter. First quarter revenue growth reflected procedure growth in higher than expected system placements. Leasing represented 43% of current quarter placements compared with 32% last year and 37% last quarter. Leasing as a percentage of total sales has and will continue to fluctuate with customer and geographic mix.

However, given hospital (Technical Difficulty) we anticipate more customers will seek leasing or alternative financing arrangements than reflected in historical run rates. 44% of systems placed in the first quarter involve trade-ins, which is lower than the 57% last year and the 49% last quarter. Trade in activity can fluctuate and be difficult to predict.

First quarter system average selling prices increased to $1.65 million from $1.44 million last year and $1.43 million in the fourth quarter. The increase relative to last year reflects a higher mix of systems placed in China in our direct markets relative to our indirect markets, a higher mix of dual console system in a lower proportion of trade-in transaction. The increase relative to last quarter reflects a higher mix of dual consoles and a lower proportion of trade-in transactions.

We recognized $19 million of lease buyout revenue in the first quarter compared with $12 million last year and $14 million last quarter. Lease buyout revenue has varied significantly quarter to quarter and will likely continue to do so.

Instrument and accessory revenue per procedure for the first quarter of $1,950 decreased compared with $1,990 per procedure for the first quarter of last year and $2,060 per procedure in the fourth quarter of 2020. Extended use instruments were introduced in the U.S., in Europe, in the fourth quarter. While we saw increased usage of extended use instruments in these markets, full adoption will occur over the next few quarters as customers burn off lower use product.

In addition, we saw customers begin to adjust their instrument buying patterns to reduce their inventory levels to reflect the additional uses per instrument. Increased usage of extended use instruments in customer buying patterns are the primary reasons for the

decrease in instrument and accessory revenue per procedure in the first quarter relative to prior quarters. We expect this trend to continue over the next few quarters.

While we expect price elasticity associated with extended use instruments to enable greater penetration into available markets that benefit is delayed by COVID and otherwise will take time. 6% of the systems placed in the first quarter were SP systems, reflecting a continued measured rollout of SP. Our installed base of SP systems is now 75, 8 in Korea, 67 in the U.S. Our rollout of the SP Surgical System continues to be measured putting systems in the hands of experienced da Vinci users, while we pursue additional indications and optimize training pathways in our supply chain.

We expect to initiate first cases associated with the U.S. colorectal trial in the next few months. We placed 14 Ion systems in the quarter, bringing the installed base to 50 systems. Ion system placements and procedures are excluded from our overall systems and procedure counts. The supply issues we called out last quarter had less of an impact on Ion placements and procedures this quarter. We expect to have resolve those supply issues this quarter. Our rollout of Ion will continue to be measured while we optimize training pathways in our supply chain.

Procedures under the PRECISE study are expected to complete this quarter. Outside of the U.S., we placed 108 systems in the first quarter compared with 55 in the first quarter of 2020, and 130 systems, last quarter. Current quarter system placements included 59 into Europe; eight into Japan and 23 into China compared with 25 in Europe, 10 into Japan and 9 into China in the first quarter of 2020. 22 of the 59 systems placed in Europe this quarter were in the UK. Placements in many markets like the UK can vary significantly quarter to quarter. While we are pleased with the performance of the UK team, we do not anticipate this level of placements in the UK in future quarters.

Moving on to gross margin and operating expenses. Pro forma gross margin for the first quarter of 2021 was 71.8% compared with 69.7% for both the first and fourth quarters of 2020. The first and fourth quarters of 2020 include higher period costs associated with lower production and higher excess and obsolete inventory charges. In addition, the first quarter of 2021 reflected leveraging fixed costs over higher production levels.

Product and customer mix fluctuate quarter to quarter, which can cause fluctuations in gross margins. In addition, if revenues are pressured by COVID-19 production levels may operate at below normal levels which may result in higher labor costs IN under absorbed overhead and reduced product 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 cost or production delays.

Pro forma operating expenses increased 5% compared with the first quarter of 2020 and increased 2% compared with the fourth quarter of 2020.The fourth quarter of 2020 included a 25 million contribution to the Intuitive Foundation, while there were no

contributions in the first quarters of 2021 and 2020. The increase compared to the prior year reflects costs associated with higher headcount and increased variable compensation, partially offset by lower spending in areas impacted by COVID.

First quarter, spending was below our expectations for the reasons outlined by Gary in his opening remarks. Looking to the remainder of the year, we expect spending impacted by COVID-19 including clinical development in-person training, marketing events and travel cost to increase as COVID's impacts decrease and spending deferred due to COVID and other timing matters to increase. Jamie will provide spend guidance later in this call.

Our pro forma effective tax rate for the first quarter was approximately 20% meeting our expectations. 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 pro forma 2020 -- our first quarter 2020 pro forma net income was $427 million or $3.52 per share compared with $323 million or $2.69 per share for the first quarter of 2020 and $434 million or $3.58 per share for last quarter.

I will now summarize our GAAP results. GAAP net income was $426 million or $3.51 per share for the first quarter of 2021 compared with GAAP net income of $314 million or $2.62 per share for the first quarter of 2020, and GAAP net income of $365 million or $3.02 per share for last quarter. The adjustments between pro forma and GAAP net income are outlined and quantified on our website and include excess tax benefits associated with employee stock awards, employee stock-based compensation and IP charges, amortization of intangibles and acquisition-related items and legal settlement.

GAAP net income for the fourth quarter of 2020 and the first quarter of 2021 also included pre-tax gains of $4.7 million and $14.3 million on our investments in private companies, resulting from our purchases of certain technologies. The EPS impact of these gains net of tax was $0.03 per share in the fourth quarter and $0.09 per share in the first quarter. These gains are excluded from our pro forma results. We ended the quarter with cash and investments of $7.2 billion compared with $6.9 billion at December 31, 2020. The increase in cash in the first 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 Philip who will go over procedure performance.

Philip Kim {BIO 22131870 <GO>}

Thank you, Marshall. Our overall first quarter procedure growth was 16% year-over-year compared to 10% growth during the first quarter of 2020 and 6% growth last quarter. Our Q1 procedure growth was driven by 14% year-over-year growth in the U.S. and 23% growth OUS. Procedures in the U.S. recovered steadily after January as COVID cases declined and the associated impact on hospital resources improved.

In the U.S., within general surgery, bariatric, cholecystectomy and hernia were the largest contributors to procedure growth within the quarter. Bariatrics growth remain strong with

positive customer feedback on our advanced instrument portfolio. Cholecystectomy growth was driven by the continued expansion of robotic procedures by general surgeons throughout their total practice. Inguinal hernia growth trailed potential growth in the quarter.

With respect to our more mature procedure categories in the U.S., Q1 gynecology procedures grew double-digits against the prior year growth comparison that was negative due to COVID. While dVP in the U.S. stabilized in Q1 from previous declines, it remains unclear when patients who have been impacted from delays in diagnosis and treatment will ultimately come back. In aggregate, on a worldwide basis prostatectomy in the first quarter, largely stabilized.

More broadly, OUS procedure growth was driven by urology, earlier stage growth in general surgery, gynecology and thoracic procedures. With respect to OUS markets, China procedure growth was strong and benefited from the severe first quarter of 2020 impact of COVID and an increase in the installed base over the past year. China had broad-based growth in all procedure categories.

In Japan, procedure growth moderated somewhat due to restrictions associated with COVID. Procedure growth in South Korea was encouraging with SP utilization continuing to be above exercise. In Europe, France had a solid quarter with broad-based strength in a wide range of procedure categories. The UK remain challenged due to COVID.

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.

A recent article by Dr. Mohamed A Abdul Aziz, Davin Grass and David Larsen with colleagues from the Mayo Clinic published in Surgical Endoscopy provided results from a real world study aims to analyze national trends of conversion during elective colectomy is in addition to MIS utilization trends. Using the ACS National Surgical Quality Improvement Program database for elective laparoscopic or robotic assisted colectomy between January 2013 and December 2018.

A total of 66,652 patients were identified. Overall conversion rates from MIS to open were approximately 42% lower for robotic assisted procedures when compared to laparoscopic procedures, 4.9% versus 8.5%, the rate was also lower for obese patients with a BMI greater than or equal to 36% versus 10.3%.

The authors concluded in part, "this large-scale study identified a decreasing trend in conversion rates over the six year inclusion period both overall and in patients with obesity, paralleling, increased utilization of the robotic platform. Given the potential negative impact of conversion on patient outcomes, individual institutions should consider review of their own conversion data as this may represent an opportunity for quality improvement".

In February of this year, Dr. Amir Bastawrous of those Swedish Cancer Institute in Seattle, Washington and Dr. Robert Cleary of Saint Joseph Mercy Hospital in Ann Arbor, Michigan, published a real world observational study which compared the rates of long-term opioid prescriptions for patients who underwent minimally invasive and open colectomies. This study utilized the IBM market scan research database and analyze 14,887 eligible patients who underwent the colon resection via the open laparoscopic or robotic-assisted approach between 2013 and 2017.

And the one-to-one propensity score matched analysis comparing the MIS and open approaches with over 5,000 patients in each arm, the MIS approach had significantly lower incidence rates of long-term prescriptions of any opioids by approximately 36%, 13.3% versus 20.9%, Schedule II and III opioids by approximately 39%, 11.7% versus 19.2% and high dose opioids by approximately 44%, 4.3% versus 7.7% from 90 to 180 days post operatively.

Looking at the matched analysis between robotic-assisted surgery and laparoscopy with over 1,100 subjects in each group, the robotic-assisted approach demonstrated approximately 45% lower long-term prescription rates of high dose opioids, 2.1% versus 3.8% when compared to the laparoscopic approach.

Furthermore in subgroup analysis, the robotic-assisted approach showed significantly lower rates of long-term prescriptions in any opioids, Schedule II and III opioids and high dose opioids compared to the laparoscopic approach for subjects undergoing a colectomy for non-malignant conditions. The authors concluded in part, "choosing an MIS option in robotic-assisted surgery for some colorectal operations is a modifiable factor that may contribute to less long-term opioid use".

And with that, I'd like to turn it over to Jamie, who will review our financial outlook.

Jamie Samath {BIO 7313010 <GO>}

Good afternoon. While there continues to be uncertainty regarding the ongoing impact of COVID-19, given moderating COVID hospitalization trends and vaccination progress, particularly in the U.S., which accounted for approximately 70% of our 2020 procedures, we are reestablishing our financial guidance. In providing this guidance, we know that there are emerging supply constraints in our supply chain, for example, in the semiconductor industry. The outlook we are providing does not reflect any potential significant disruption or additional costs related to the supply constraints.

Our financial outlook for 2021 is as follows. Starting with procedures total 2020 da Vinci procedures grew approximately 1% to roughly 1.243 million procedures performed worldwide. For 2021, we anticipate full year procedure growth within a range of 22% to 26%. We expect 2021 procedure growth will continue to be driven by U.S. general surgery and procedures outside of the United States where we were at earlier stages of adoption.

The high end of the range assumes that COVID cases and the impact on da Vinci procedures to continue to decline throughout the year. The vaccine rollouts continue the

level currently expected by governments around the world and that recovery of patient backlogs will progress. Modeling quarterly results is difficult given the impact of COVID had on 2020 procedures. Therefore, with respect to procedure seasonality, we expect similar quarterly patents of 2019.

With respect to capital, system placements are generally driven by procedure demand, pointing hospitals to establish or expand robotic-system capacity. System placement demand is also the result of customers standardizing on fourth generation technology to trade-ins. Capital sales can vary substantially from period to period, based upon many factors including government healthcare policies, hospital capital spending cycles, reimbursement and government quotas, product cycles, economic cycles and competitive factors. Within this framework, we'd expect 2021 capital placements generally be driven by procedures and the adequacy of existing capacity in the installed base.

During the first quarter of 2021, 43% of systems shipped were under operating leases. We expected the proportion of systems placed under operating leases will vary from quarter to quarter and could continue to trend up in the future.

Turning to gross profit, our full year 2020 pro forma gross profit margin was 68.4%, reflecting the impact of fixed -- higher fixed overhead cost relative to revenue, higher excess and obsolete inventory charges and the customer relief program that was implemented in the second quarter of 2020.

Our full year 2019 pro forma gross profit margin was 71.7%. In 2021, we expect our pro forma gross profit margin to be within a range of between 70% and 71% of revenue. 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, in 2019, our pro forma operating expenses grew 27% and in 2020 given the impact of the pandemic, they grew 3%. In 2021, we expect pro forma full year operating expense growth to be between 18% and 22% reflecting increases in investments in our digital ecosystem, Ion, SP, OUS expansion, higher regulatory-related costs and infrastructure investments to allow us to scale. 2021 spending also expected to be impacted by a return over the course of the year to higher rates of travel increased customer training and a greater proportion of marketing events being held in person and by a variable compensation.

We expect our non-cash stock compensation expense to range between $450 million to $470 million in 2021, compared to $396 million in 2020. We expect pro forma other income which is comprised mostly of interest income to total between $45 million and $55 million in 2021, reflecting lower interest rates relative to 2020.

With regard to income tax, in 2020, our pro forma income tax rate was 22.5%. As we look forward, we estimate our 2021 pro forma tax rate to be between 20% and 21% of pre-tax income. Our 2021 outlook for the pro forma tax rate does not reflect any potential change in U.S. tax rates.

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

Questions And Answers

Operator

(Operator Instructions) First, we're going to the line of Amit Hazan. Please go ahead.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks very much. Can you hear me, okay?

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

We can.

Q - Amit Hazan {BIO 6327168 <GO>}

Great. Maybe putting the first question on just the guide, obviously appreciate that just given all the uncertainty on the procedure side. And so, given that you gave that number, see if you got that further and just give us a little bit more color as to how you got there? We're obviously all kind of trying to figure out recovery back to normal, but also these potential buckets of recapturing backlog of procedure categories for you, particularly in prostate, I suspect? Can you just talk to how you thought about those backlog of patients and that return to normal as you developed this guide for the rest of the year on the procedure side?

A - Jamie Samath {BIO 7313010 <GO>}

Yes. So maybe Amit I'll start with -- this is Jamie. I'll start with the low end of the procedure guidance. So we considered three factors in the low-end. We see the possibility of extended impact of COVID in certain OUS geographies with slower vaccine rollouts and resurgences in some of those geographies. We see that in parts of Europe currently. Secondly, we embedded in the lower end of the procedure guidance, a slower recovery of diagnostic pipelines that have been impacted during the pandemic. And then, third, I mean the low end of the guidance is the possibility of regionalized resurgence of COVID in the U.S. as we raise towards the rollout of vaccines. And ultimately, at some point achieve herd immunity in the U.S.

With respect to the backlog, the backlog is accumulated really for three factors, lower diagnostic pipelines, deferred elective surgery as hospital systems get inundated with COVID cases and patient reluctance to undergo surgery during COVID resurgences. These subcomponents we think get recovered over different periods of time. The backlog is actually constantly netting between increases and recovery. So the total accumulated backlog is difficult to predict. The rate of recovery is also difficult to predict, but we expect it to go through into 2022. And so the '21 procedure guidance that we provided reflects our best estimate of the range of the impact of backlog in the year.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. I appreciate that. And I want to come back with a second question, just a topic that's been discussed before, but I just figured in light of COVID to bring it up again, which is this is a question of ambulatory surgery centers and lower acuity procedures generally. I mean especially given COVID, it just seems like there's never been more of an optimal time for Intuitive to discuss and go after this part of the market and we still don't hear you talking about it that much. And I just beg the question of what's holding you back? And we know that the reflect answer seems -- reflects kind of answer seem to be on the reimbursement side and that it may not be optimal. When I think about your advantages that you pitch to hospitals on the marketing side, the surgeon benefit, frankly the outcomes, that seems to be a lot more important and potentially beneficial than where reimbursement lies. So help us out here, why ambulatory surgery centers not a bigger opportunity for you right now?

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

Yeah. This is Gary. We are already in ambulatory surgery environments with our customers of different types, and we see healthy programs there. I don't think we are struggling from the point of view of having a product that can help them or services that can help them or way to have a conversation. I think all those things are in place.

I do believe that over time reimbursement matters, particularly in customers that operate in both environments, hospitals and ASCs. For them, reimbursement matters, if they're going to move a patient, but they get a big difference in the revenue, then they're going to make those decisions. It may change over time, and that what payers ultimately decide to do, and whether they want to create some incentives to help things move into ASCs will be ready.

Long term, I'm bullish on that. I think the environment makes sense, but economics and incentives really matter. It doesn't clear up your question, it reinforces our position.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. Thank you for that. I'll step back in queue.

Operator

Thank you. And next, we go on to the line of Larry Biegelsen. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. Gary, can you please provide more color on the Intuitive telepresence feature that you mentioned on this call? It's the first time I heard you talk about it and that 45% of procedures was a pretty impressive number. Is that through your agreement with InTouch? How is it being used by customers? What are the benefits and how do you see that playing out post-COVID? And I had one follow-up.

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

Yeah. So, you're right. It is the result of the technology and collaborative agreement we signed with InTouch many years ago. We brought a team over as well as some of the technology and have put it in our hands. The use case I was talking about there is the ability for people who are interested in observing a case by an expert to log in online through a secured network, high speed streaming and view that case on da Vinci accounts. And that's an important part of both knowledge transfer from those high volume accounts as well as an introductory exposure for surgeons who are thinking about it. So that has been great.

There are other use cases for streaming connections, video streaming connections into our products that I won't detail now. It's pretty neat. And so prior we had started that, I was believer or we as a company we are believers that those kinds of access, think of it as kind of surgical FaceTime, surgical Skype over a distance that kind of access would be important to folks and the pandemic really accelerated it. So we had the technology infrastructure in place as people started to be more open to the use of digital tools to do the learning and exposure and wanted to stay off the planes and out of cars. We saw it really accelerated, and that's what we've been touching on.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's very helpful. And then lastly, what response you're getting from the extended use program you introduced in Q4 2020? Any changes to kind of the impact that we could see from that and any color yet on demand elasticity? Thanks for taking the questions.

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

Yeah, sure. So we introduced extended use instruments into Europe and into the U.S. in Q4. We did see increased usage of extended use instruments. They still have some level of inventory of shorter life used instruments. And they're burning that off. We also had commented last quarter that we saw stocking orders of extended use instruments and we're seeing some adjustment of their buying patterns to recognize the increased number of uses per instrument. So quarter, as I called out, instrument and accessory revenue per procedure was lower than last quarter and it primarily reflects those factors, the use of extended instruments and adjustments of inventory buying patterns.

I don't think it's exhausted the whole impact. I think if you go back to our previous scripts, you see that we said that had you implemented this in 2019, it would have affected total revenue by about $150 million to $170 million or about 7% of I&A per procedure. And we've only seen a part of that so far. When the rest of it will hit, this questionable will roll out over time as they continue to use those instruments and as we roll it out to other countries.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks, Marshall.

Operator

Thank you. And next, we are going to the line of Bob Hopkins. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Great and thank you and good afternoon. I want to ask a question or a few questions on the -- just the first quarter procedure volume numbers that you provided, because it was obviously a lot stronger than consensus estimates. And so Gary I was just wondering a couple of quick things. Is it safe to assume that the end of the quarter was materially stronger than the beginning and middle of the quarter in terms of procedure growth? And then I was just wondering what stood out to you, Gary, either geographically or by procedure type in the quarter that you think is worth calling out?

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

Thanks for the question. To the first one, we definitely saw growth through the quarter, which was encouraging. In terms of procedure types, I think there is this interesting mix, the prioritization that folks are making as they come back in the hospitals, right? I think is a mixture of patient desire depending on what they think their condition might be for example bariatrics and hospital and surgeons prioritization around urgency for example diagnosed cancers and changes that are challenges to the diagnostic pipeline. I was pleased by U.S. general surgery. I think that that has shown some resilience. A lot of that is benign procedures, and I think that that has been kind of on the upside of our models. So, so far so good.

Q - Bob Hopkins {BIO 2150525 <GO>}

And then one follow-up just on that also to get a little bit of a better flavor for procedure volumes in the quarter by geography, I'm just curious on Europe, what's your take on how bad are things there from -- for -- in your view, and just curious maybe how far below 16% was Europe in the quarter?

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

Yeah, I won't quantify it for you, but just to give you a little bit of qualitative color, and Marshall please jump in and help. In the UK, we've seen NHS make priority decisions firmly and that reflects what we see in the procedure of performance itself, which has been suppressed. That said, we're also seeing commitments to MIS in the form of capital acquisition and other things that indicate to us that they're rotating toward it. So there it's kind of a mixed conversation.

France and Germany have been surprisingly good despite complexity with regard to the way COVID is rolling out. And then as we look at Spain and Italy, we see it really just follow as COVID eases surgery comes back and we come back with it. Overall, we feel like we have really good leadership teams in place in country, we feel like we're in good connection with the health care systems. I think we're being agile and adaptable to meet their needs, which is really controlling what we can control and that sense I think the company is doing, all right.

Marshall, anything you'd add?

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

I think it was a great color. I think the only other thing I would add is the -- we've talked about in the past that a lot of the procedures were performing urologic and we're in the process in certain countries of pivoting, and we're starting to see some adoption in GYN and general surgeries in some countries, but we still have work to do.

Q - Bob Hopkins {BIO 2150525 <GO>}

Great. Thank you.

Operator

Thank you. And next, we go on to the line of Tycho Peterson. Please go ahead.

Q - Tycho Peterson {BIO 4279327 <GO>}

Hey, thanks. Couple of follow-ups. I'm curious what's baked in the guidance on utilization, given the extended use instruments kind of commentary before. What do you kind of military [ph] utilization for the year?

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

Yes, I think I would refer Tycho back to 2019 patterns in terms of utilization, obviously in the end capital is going to be driven by procedure performance. So I think, I would just refer to seasonal patterns in 2019 as starting point.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then you've commented a couple of times on this call and other calls on the diagnostic pipelines being under pressure. Can you just talk a bit about how they are looking as a leading indicator to some of the more mature procedures dVP in particular?

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

Yeah. Jamie, why don't you take it?

A - Jamie Samath {BIO 7313010 <GO>}

Yeah. We have -- so we have some market data actually for the U.S. What we see is -- and that's through February '21. What we see is most of the diagnostic tests, say testing for example CT scans for lung cancer. We see that those have been suppressed during this period. So we haven't seen them start to recover at least in the data that we've seen so far. And we see that reasonably correlated to the associated procedures to PSA, dVP has been relatively weak during that period. So it is lobectomy. So, so far we haven't seen any evidence of recovery in diagnostic testing at least in the U.S.

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

There were some anecdotes that it's starting to get better in March. We'll see as it plays out. Even after the diagnostic gets done, there is a work up pipeline that has to be done. That said, I don't feel like we have any evidence that it's moving away from surgery. So it appears in those kinds of cases that it's building a backlog that ultimately will flow

through. If PSA testing back in 2012 is a guy that will take several quarters for that to work its way out.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. And then last one on SP, two quick ones actually. Can you confirm you started the IDE trial for colorectal in the quarter. And then, Gary, you mentioned thoracic surgery and other disciplines. I'm just curious if you could talk a little bit about the roadmap, other areas you might go after with SP?

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

Sure. On the SP side on the IDEs, the first cases are scheduled. We have got all the paperwork done in our research institutions that we're working through, at least the first starting ones and we expect that to happen. The first cases have not yet gone through, they should happen here in the next few weeks.

Thoracic, that's the first time we've been telling you that we think that's interesting. There are single port opportunities for thoracic surgery and we are excited by them. We're working through what those trials look like and having conversations with regulatory bodies to get it going. And given the current environment, we'll have concurrent trials for the colorectal and then thoracic. There are a couple of more indications beyond that, for competitive and other reasons, we're not yet ready to describe what those are going to be for us. But SP is a platform and we're excited by it. So as we get closer and those things get closer to being filed as IDEs and trials, then we'll describe them more fully.

Q - Tycho Peterson {BIO 4279327 <GO>}

Okay. Thank you.

Operator

Thank you. And next, we'll go into the line of Rick Wise. Please go ahead.

Q - Rick Wise {BIO 1490589 <GO>}

Good afternoon, everybody. I was hoping we could talk a little bit more, Gary, about Ion. We did a bunch of physician calls a month or so ago and really fantastic feedback. The doctors are telling it's the early signs of higher diagnostic yield, success in complex cases, noticeable functional benefits and features. All that, left me optimistic about the PRECISE trial.

So couple of things, are you optimistic and hopeful of PRECISE? I think, you said, it would be wrapped up -- I should make sure I understand, by mid-year, when might we see the data? All the docs are anxious to see the data. And with some of the logistical issues resolved, could we -- should we expect an acceleration, is it reasonable to think about -- anticipate acceleration in Ion uptake in the second half and into '22? Thanks.

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

Sure. On the issue of the PRECISE trial, Phil, I'll turn to you in terms of timing.

A - Philip Kim {BIO 22131870 <GO>}

Sure. So we confirm that we expect enrollment in this quarter and Q2, and then, you'd have final data readout in the back half of next year '22.

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

On the issue of -- you had said, how we're feeling about it. I think we are reading and hearing what you are reading and hearing also in terms of talking to our customer about the ability of Ion to deliver on its promises to reach into the lungs to get to diagnostic yields that folks have not seen with other technologies and to work in complex cases. So I'm feeling enthusiastic and bullish on it.

With regard to ramp, we are expecting Ion to continue to ramp through the year and into next year. I don't see a step function change. I think it's a sequential ramp as we go and that's because it's an interesting and sophisticated technology. So a lot of what we're working on is making sure that we can get the manufacturability where we need it, getting supply chain stability, quality and predictability, where we need it, iterating our design for manufacturing and working on additional indications because it's a platform.

And we are doing all four of those things, but I don't think, our investors, because of the way these things work, should expect that you flip a switch and it just goes to the next level. I think that it will climb each quarter and that's what we're working on. That meets our expectation and our experience in these kinds of platforms.

Q - Rick Wise {BIO 1490589 <GO>}

Thanks very much.

Operator

Thank you. And next, we go into the line of Richard Newitter. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thanks for taking my -- hi, thanks for taking the question. Just one on operating expense guidance. Thanks for the full year outlook. Just could you give us any sense of the quarterly pacing or would it be safe to assume the 2019 cadence commentary for procedures that are quite OpEx still?

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

Yeah, I think you should see, sequentially, operating expenses, generally increase across the rest of the year. It's really going to be a function of the extent to which COVID continues to impact our ability to incur travel, accelerate customer training and marketing events in person. But generally, I would expect it to ratably increase across the balance of the year.

Q - Richard Newitter {BIO 16908179 <GO>}

Got it. And just, same kind of topic here, on geographic investments and expansion that you started to get more aggressive on pre-pandemic, especially India, just in light of what's been going on in that region, specifically with the COVID problem. Should we be thinking of some of those initiatives postponed even further out, according to the order those things that resume in as early as this year? Thanks.

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

Yeah, I'm sorry, I had a little bit of a hard time hearing you with regard to the referenced trial, so I'll go ahead and re-ask the question, if you would.

Q - Richard Newitter {BIO 16908179 <GO>}

Sorry, my connection is on. But just India, can we think of reinvestment in that region starting now or in light of COVID and the situation there as something in 2022 and beyond? Is that part of the spending in geographic expansion you referred to?

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

Yeah. So with regard to India, clearly current -- the current situation there is such that current procedures are impacted. As I've said, I think that the long-term commitment -- with the long-term commitment we have to market is intact. Our teams are making really nice progress of building footprint and relationships to hospital systems. And so I expect as COVID starts to become managed there a little bit more forcefully then -- and it starts to recover, we'll see a recovery on our side. It has not -- it has not had us -- a retreat. Other places around the world whether it's Japan or China or Europe, we continue to be interested and committed, so not just India but others as well. And then, if you'd just ask your last question then, we'll go from there. Rich, any follow-ups? Operator, one more question, please.

Operator

Next, we go into the line of Matt Taylor. Please go ahead.

Q - Matt Taylor {BIO 16863940 <GO>}

Hi. Yeah. Thank you very much for taking the question. I guess it was good to see that the strong return of capital spending and you're talking about customers looking forward to prepare for volumes committed to robotic surgery, do you think that there was a little bit of a bolus of kind of pent-up spending that came through in Q1 or do you think this is the start of a new pattern of purchasing based on your backlog and what you're seeing with your orders?

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

Matt, this is the subject of fearsome debate amongst us at the company. Marshall, why don't you share your opinion?

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

Well, I'll give you a few different dynamics to consider as we go forward. It's always hard to project out based on one quarter results, I guess we've had a couple of quarters that have been decent. Is there -- was there -- I think a part of your question was, is there pent-up spending? I would just say, I don't know if there's pent up spending, but I would say that clearly the hospitals had more capital to spend than we had anticipated. And as they -- and what's really driving and -- they're spending on da Vinci capital is procedure growth. Procedure growth is the number one thing that drives capital, but also the trad-in cycle and the desire to access fourth-generation product, including the extended use instruments we mentioned earlier. And then, finally, I think that you also have them getting ready for the post-pandemic environment and just a general recognition that da Vinci surgery meets their quadruple aim objectives better than other approaches.

Q - Matt Taylor {BIO 16863940 <GO>}

Right. Okay, guys. Thanks. I'll leave it there. Appreciate it.

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

All right. Well, thank you. Okay, well, that was our last question. In closing, we continue to believe there is a substantial and durable opportunity to fundamentally improve surgery and acute interventions. Our teams continue to work closely with hospitals, physicians and care teams in pursuit of what our customers have termed the quadruple aim, better and more predictable patient outcomes, better experiences for patients, better experiences for their care teams, and ultimately, a lower total cost of care. We believe value creation in surgery and acute care is foundationally human. It follows from respect for and understanding of patients and care teams, their needs and their environment. Thank you for your support on this extraordinary journey and we look forward to talking with you again in three months.

Operator

And that does conclude our conference for today. Thank you for your participation and for using AT&T conferencing service. You may now disconnect.
