S&P Global
Market Intelligence

# Intuitive Surgical, Inc. NasdaqGS:ISRG

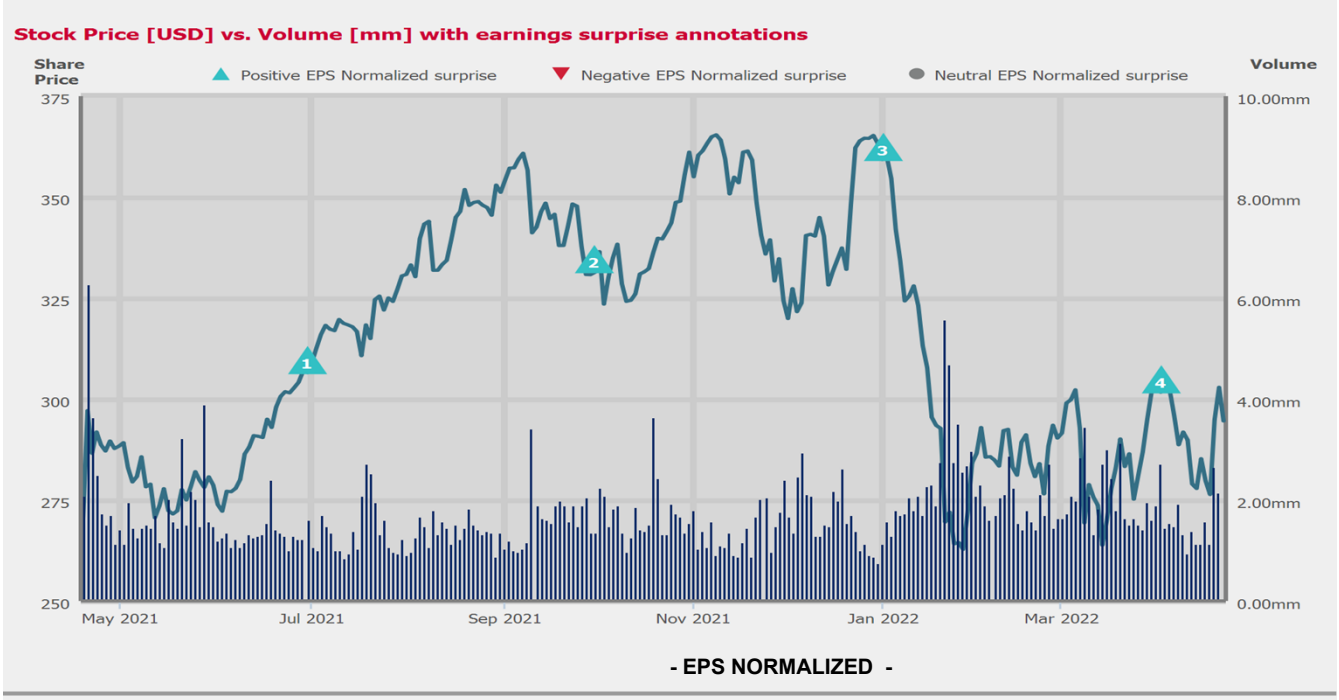
# FQ1 2022 Earnings Call Transcripts

## Thursday, April 21, 2022 8:30 PM GMT

### S&P Global Market Intelligence Estimates

| | -FQ1 2022- | | | -FQ2 2022- | -FY 2022- | -FY 2023- |
|---|---|---|---|---|---|---|
| | CONSENSUS | ACTUAL | SURPRISE | CONSENSUS | CONSENSUS | CONSENSUS |
| EPS Normalized | 1.08 | 1.13 | 4.63 | 1.23 | 4.99 | NA |
| Revenue (mm) | 1425.58 | 1487.70 | 4.36 | 1582.06 | 6434.36 | NA |

Currency: USD
Consensus as of Apr-22-2022 3:43 AM GMT




**- EPS NORMALIZED -**

| | CONSENSUS | ACTUAL | SURPRISE |
|---|---|---|---|
| FQ2 2021 | 1.02 | 1.31 | 1 28.43 % |
| FQ3 2021 | 1.16 | 1.19 | 2 2.59 % |
| FQ4 2021 | 1.28 | 1.30 | 3 1.56 % |
| FQ1 2022 | 1.08 | 1.13 | 4 4.63 % |

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# Call Participants

## EXECUTIVES

**Brian King;Head of Investor Relations**

**Gary S. Guthart**
*President, CEO & Director*

**Jamie E. Samath**
*Senior VP & CFO*

## ANALYSTS

**Amit Hazan**
*Goldman Sachs Group, Inc., Research Division*

**Andrew Christopher Ranieri**
*Morgan Stanley, Research Division*

**Frederick Allen Wise**
*Stifel, Nicolaus & Company, Incorporated, Research Division*

**Lawrence H. Biegelsen**
*Wells Fargo Securities, LLC, Research Division*

# Presentation

**Operator**

Ladies and gentlemen, thank you for standing by, and welcome to the Intuitive Q1 2022 Earnings Release. [Operator Instructions] And as a reminder, your conference is being recorded.

I would now like to turn the conference over to your host, Brian King, Head of Investor Relations. Please go ahead.

**Brian King;Head of Investor Relations**

Good afternoon and welcome to Intuitive's first quarter earnings conference call. With me today, we have Gary Guthart, our CEO; and Jamie Samath, CFO.

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 3, 2022. 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 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. Jamie will provide a review of our financial results, then I will discuss procedure and clinical highlights and provide our updated financial outlook for 2022. And finally, we will host a question-and-answer session.

With that, I will turn it over to Gary.

**Gary S. Guthart**
*President, CEO & Director*

Thank you for joining us today.

In the first quarter, procedure demand for our products was healthy, recovering where COVID receded. Drivers of procedure performance included general surgery in the U.S. and non-urology procedures outside of the U.S., which are our areas of focus. Regardless of the healthy procedure demand, we were challenged by environmental stresses, including regional waves of COVID, staffing pressure at hospitals, component and raw material availability and logistic delays. While it's difficult to forecast how long these headwinds will persist, our teams are working hard to meet the challenge.

In the quarter, da Vinci procedures grew 19% compared to the first quarter 2021. The use of da Vinci in general surgery in the United States grew nicely, led by bariatric procedures, cholecystectomy, hernia repair and rectal surgery. Lobectomy growth was also healthy. Outside the United States, the U.K., China, Japan, Germany and Italy grew above our quarterly average growth rate, but I will note that some countries saw the beginnings of COVID slowdowns later in the quarter, in particular China and Korea.

International use of da Vinci is diversifying beyond urology in several countries with growth in oncologic procedures in thoracic surgery, gynecology and general surgery. In Japan, MHLW increased reimbursement for robotically assisted gastrectomy and added another 8 procedures to reimbursement coverage in April, bringing the total number of covered da Vinci procedure types to over 25 in Japan. In our flexible robotics program, Ion procedures grew approximately 350% in Q1 compared with Q1 2021, reflecting continued strength in adoption and utilization of the platform.

Turning to capital. Our team installed 311 da Vinci systems in the quarter compared with 298 systems in Q1 2021, bringing our total clinical installed base to 6,920 da Vinci systems. Placements varied by region with the U.K. standing out with a strong placement quarter. Capital placements have been historically lumpy and after several quarters of capital strength, we're seeing some near-term softening of our capital placement pipeline in the U.S. Contributing factors may

include a pull-forward of Q1 2022 demand into Q4 2021 due to customer budget utilization at year-end, a reduction in the number of third-generation da Vinci systems available for trade-ins and an overall tightening of hospital finances.

With a 3-year CAGR in procedures of 15% from Q1 of '19 to Q1 of '22 and installed base growth of 11% over the same period, utilization of installed systems continue to climb through the pandemic and in the first quarter. This is increasing the value derived from the existing installed base for our customers and for us. Over the midterm, capital demand in mature robotic-assisted surgery segments is a function of procedure demand moderated by utilization growth. Jamie will give regional capital trends and Brian will give a more detailed procedure review later in the call.

As we exit the first quarter, we continue to invest in global expansion, innovation initiatives and our business infrastructure. Our spending in the quarter was roughly in line with our target. In instruments and accessories, we received Chinese NMPA clearance for our 45-millimeter and 60-millimeter SureForm staplers, our Vessel Sealer Extend and our Endoscope Plus. These products support the utility of our Xi systems for several procedures, particularly general and thoracic surgeries.

Turning to Ion. We submitted our EU medical device regulation application for the platform to allow the entry of Ion into Europe. Our teams are also building production capacity and making improvements to customer workflow, planning software and reprocessing efficiency.

In digital products, the My Intuitive app community tripled year-over-year. It is now available in the U.S., Japan, Germany, France, United Kingdom and Ireland and Switzerland with launches set for Italy, Spain and India in Q2. Building on our Orpheus technology, our teams in Israel and the U.S. have created Intuitive Hub, a unified hardware and software solution for the operating room. Intuitive Hub enables OR teams to capture, edit and share video clips from clinical procedures and collaborate virtually using existing workflows and Intuitive systems.

In the quarter, we launched an upgraded interface to da Vinci systems that allows for automated video capture with integrated procedure annotation for key events, creating convenient video storage and review for da Vinci cases. Customer feedback for this integration has been encouraging. Across the installed base, the number of procedures in which Intuitive Hub was used grew approximately 60% year-over-year.

To our goal of adding Iris anatomical models, we're in conversations with FDA on how best to characterize some of its core AI technology, which will require a resubmission of our 510(k) for the next set of segmented organ models. Finally, the installed base of our virtual reality training simulator, SimNow, grew 33% in the quarter compared with a year ago.

For our single port program, da Vinci SP, we began the launch of our next-generation SP endoscope, which includes our Firefly Fluorescence Imaging technology and has 65% longer life. We also launched our next-generation core SP instruments that can apply higher forces during surgery and are more durable. Feedback on both has been encouraging.

In Japan, we submitted our da Vinci SP for clearance to PMDA seeking broad indications. We continue to pursue additional indications for SP in the U.S., which is important for broader adoption, with an ongoing IDE trial in colorectal surgery and an approved IDE for thoracic surgery. COVID and some site-specific delays have slowed our progress in our colorectal trial. We're working hard to expand the number of participating sites to accelerate its completion.

Stepping back, for 2022, our top priority is to support, supply and train our customers as they navigate a challenging environment. We are also focused on helping general surgeons in the United States adopt our technologies and diversifying our business outside the United States beyond urology and in executing on our new platforms and digital tools.

I'll now turn the time over to Jamie Samath, who will take you through financial matters in greater detail.

**Jamie E. Samath**
*Senior VP & CFO*

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

Overall, Q1 results reflected approximately 19% procedure growth as compared to the first quarter of 2021 and system placements of 311 systems, resulting in an expansion of the installed base of da Vinci systems of approximately 13%. As a result of our procedure and capital performance, Q1 revenue increased by 15% year-over-year.

Key business metrics for the first quarter of 2022 were as follows. Within the 19% procedure growth, procedures in the U.S. increased 16% and OUS procedures grew by 25%. Procedures in the U.S. were impacted in January by the significant number of hospitalizations related to the Omicron variant. As rates of COVID-related hospitalizations declined in February and March, da Vinci procedures recovered quickly. On a 3-year compound annual growth rate basis, first quarter procedures grew approximately 15%.

First quarter system placements of 311 increased 4% from the 298 systems placed last year. The number of systems placed in conjunction with a trade-in of an older generation system declined by 18% from the first quarter of 2021. That decline was entirely driven by the U.S. Utilization of clinical systems in the field, measured by procedures per system, increased approximately 6% compared to last year. Using a 3-year CAGR, first quarter utilization grew 4%.

During the quarter, the supply chain environment continued to be challenging and remains dynamic. In Q1, we continued to experience constraints in our ability to meet customer demand. And as a result, on-time delivery performance to our customers was lower than we have experienced so far during the pandemic.

In Europe, recently, we have experienced some geographically limited delays in fulfilling orders for some da Vinci instruments and accessories. These delays were due to a combination of the global supply chain and logistics issues, including our freight forwarder's unanticipated shutdown of its computer system. While these constraints did not have a material impact to our Q1 financial results, risks associated with potential disruption to our manufacturing operations and our ability to supply certain products to our customers remain significant. During the quarter, we also experienced higher logistics costs and manufacturing inefficiencies that impacted our gross margin.

U.S. procedure growth of 16% over Q1 of 2021 reflected continued relative strength in bariatrics, cholecystectomy and hernia repair. In Europe, we experienced strong growth in the U.K., reflecting in part the significant adverse impact of COVID in Q1 of 2021. Procedure growth in the U.K. also reflected strong early-stage growth in hysterectomy, colorectal and thoracic procedures. Procedure growth in Germany and Italy was also strong, while procedure growth in France was adversely impacted by COVID-mitigation measures in the first part of the quarter.

Overall procedure growth in Asia was solid with growth across a broad set of procedure categories. Q1 procedures in China and Korea were slightly lower than our expectations given the impact of the Omicron variant later in the quarter. Procedure growth in Japan was strong, reflecting some recovery in urologic procedures and strong growth in rectal, hysterectomy and thoracic, key procedures that were granted da Vinci reimbursement in April of 2020.

The impact of the Delta variant in Q3 of last year and the impact of the Omicron variant in this past quarter highlight the continued risk of future COVID waves and the associated significant risks to the number of da Vinci procedures that may be performed. Brian will provide additional procedure commentary later in this call.

As Gary indicated, during the quarter, we experienced a softening in our U.S. capital pipeline, which we expect to impact system placements in the near term. In the U.S., we placed 186 systems in the first quarter, lower than 190 in Q1 of 2021, reflecting a decline of 28 systems associated with trade-in transactions, partially offset by increased placements to greenfield customers. The remaining installed base of Si systems in the U.S. is approximately 268 systems.

Outside the U.S., we placed 125 systems in the first quarter compared with 108 in the first quarter of 2021. Current quota system placements included 78 into Europe, 19 into Japan and 9 into China compared with 59 into Europe, 8 into Japan and 23 into China in the first quarter of 2021. We placed 30 systems in the U.K. in Q1 driven in part by the timing of government budget cycles. We do not expect to place similar levels of systems in the remainder of 2022 in the U.K.

Capital performance in Japan was driven primarily by greenfield accounts and some existing customers adding capacity in anticipation of the 8 additional procedure reimbursements taking effect on April 1. System placements in China were moderately impacted by longer logistic cycle times as a result of lockdowns in response to increased COVID cases. As of the end of Q1 2022, there were 55 systems remaining under the current quota in China, which may also be available to competitors that have received local regulatory clearance.

Globally, trade-in transactions represented 35% of placements in the quarter compared to 38% for the full year of 2021 and 48% for the full year 2020. Given the lower number of older-generation systems in the field, we expect the volume of trade-ins to be significantly lower in 2022 as compared to 2021.

Hospitals continue to experience financial and operational pressures as a result of staffing shortages, the supply chain environment and resulting inflation. Since the start of the pandemic in 2020, the impact of COVID has placed a significant

burden on hospitals. The financial pressures our customers have faced have been partially mitigated by government funding, such as the approximately $178 billion of CARES Act and other relief made available to hospitals in the U.S.

The rising interest rate environment increases debt servicing costs and may make access to new debt more challenging. To the extent that hospitals continue to face financial pressures, reductions in government funding and higher interest rates, hospital capital spending may be adversely impacted. In addition, as competition progresses in various markets, we will likely experience longer selling cycles and price pressure.

Additional revenue statistics and trends are as follows. Total first quarter revenue was $1.49 billion, an increase of 15% from last year. Leasing represented 35% of Q1 placements compared with 37% last year, last quarter rather. The slightly lower first quarter lease mix primarily reflected the mix of customers who prefer to purchase systems. While leasing will fluctuate from quarter-to-quarter, we continue to expect that the proportion of placements under operating leases will increase over time.

First quarter system average selling prices were $1.54 million, higher than the $1.45 million last quarter. The sequential increase was primarily driven by a lower mix of bulk buy transactions with large customers and a favorable product mix, in particular a higher proportion of Xi dual system placements in the quarter.

We recognized $16 million of lease buyout revenue in Q1 compared with $26 million last quarter and $19 million last year. Lease buyout revenue has varied significantly quarter-to-quarter and will likely continue to do so.

Instrument and accessory revenue per procedure was approximately $1,870 per procedure compared with $1,940 per procedure in the fourth quarter of 2021 and down 4% from the $1,950 realized in the first quarter of last year. The year-over-year decrease primarily reflects the benefit of stocking orders in Q1 of 2021 associated with the launch of our extended use instruments program in the U.S. and Europe and an unfavorable FX impact from the stronger U.S. dollar. The sequential decline primarily reflects lower stocking orders associated with lower system placements, hospital ordering patterns and a small unfavorable impact from FX.

We placed 34 Ion systems in the quarter as compared to 14 Ion placements in the first quarter of last year. The installed base of Ion systems is now 163 systems, of which 70 are under operating lease arrangements. First quarter Ion procedures of just over 3,900 are up over 4x compared to the first quarter of 2021. Seven of the systems placed in the first quarter were SP systems, including 3 systems placed at customers in Korea. Our installed base of SP systems is now 106.

First quarter SP procedures grew approximately 36% year-over-year with approximately 50% growth in transoral procedures, a small but high-value segment. Growth of the SP platform will continue to be gated by additional clinical indications and clearances in markets beyond the U.S. and Korea.

Moving on to gross margin and operating expenses. Pro forma gross margin for the first quarter of 2022 was 69.8% compared with 71.8% for the first quarter 2021 and 70.1% last quarter. Pro forma gross margin was lower than last quarter, primarily as a result of higher logistics costs and increased fixed costs relative to revenue as we invest in our infrastructure and manufacturing capacity to serve our long-term needs. While net inventory grew approximately $66 million quarter-over-quarter, there are still a number of components and products that are below our targeted levels.

Pro forma operating expenses increased 26% compared with the first quarter of 2021. The increase in first quarter operating expenses from a year ago reflected an increase in headcount, increased variable compensation and higher customer-facing costs, customer training, travel costs and marketing programs. As of the end of Q1, we had just over 10,500 employees, an increase of 26% from the first quarter of 2021 or an increase of 20% on a 3-year CAGR basis. Of the approximately 2,100 employees we have added over the last year, approximately 900 are manufacturing employees.

Capital expenditures in Q1 were $95 million, primarily comprised of infrastructure investments to expand our facilities footprint, increase manufacturing capacity and automation of certain production lines.

Our pro forma effective tax rate for the first quarter was 23.3%, slightly above our expectations primarily due to certain discrete tax items. Our pro forma tax rate was above the 22.2% for 2021, primarily due to a previous change in U.S. tax law that became effective on January 1, 2022. Our first quarter 2022 pro forma net income was $413 million or $1.13 per share compared with $427 million or $1.17 per share for the first quarter of 2021.

I will now summarize our GAAP results. GAAP net income was $366 million or $1 per share for the first quarter of 2022 compared with GAAP net income of $426 million or $1.17 per share for the first quarter of 2021. 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, amortization of intangibles and gains and losses on strategic investments.

We ended the quarter with cash and investments of $8.4 billion compared with $8.6 billion as of December 31, 2021. The sequential reduction in cash and investments in the first quarter primarily reflected share repurchases, capital expenditures and unrealized losses on interest-bearing investments classified as available for sale, partially offset by cash from operating activities and proceeds from employee stock plans. During the quarter, we repurchased 398,000 shares at an average price of $268 per share for a total expenditure of $107 million.

And with that, I would like to turn it over to Brian, who will discuss clinical highlights and provide our updated outlook for 2022.

**Brian King;Head of Investor Relations**

Thank you, Jamie.

Our overall first quarter 2022 procedure growth was 19% compared to 16% for the first quarter of 2021. The 3-year compound annual growth rate was 15% between the first quarter of 2019 and first quarter of 2022. First quarter 2022 procedure growth benefited by 140 basis points from 1 additional workday in the quarter.

In the U.S., first quarter 2022 procedure growth was 16% year-over-year compared to 14% for the first quarter of 2021 and 16% last quarter. On a 3-year compound annual growth basis, U.S. procedure growth was 13%. In the U.S., first quarter growth was again driven by growth in procedures within general surgery. Bariatrics, cholecystectomy and hernia repair were the largest contributors to procedure growth, while growth in foregut and rectal resection were also strong contributors.

Outside of the U.S., first quarter procedure volume grew approximately 25% compared with 23% for the first quarter of 2021 and 28% last quarter. On a 3-year compound annual growth basis, procedure growth was 20%. In Europe, we experienced strong growth in the U.K., Italy and Germany, partially reflecting the disruption caused by COVID in the first quarter of 2021. In the U.K., procedure growth was strong in general surgery and gynecology categories, supported by early-stage growth in hysterectomy, colorectal and thoracic procedures. Procedure growth in Germany and Italy was also driven by procedures outside of urology with growth driven by colorectal, hysterectomy and thoracic procedures.

Capital placements were also strong in the U.K. with the placement of 30 systems, the highest number of systems placed in the U.K. in a single quarter, driven in part by government funding and the trade-ins of older-generation systems. In Japan, growth in general surgery, gynecology and thoracic continued to be strong with robust growth specifically in benign hysterectomy, gastrectomy and lobectomy. In addition, urologic procedures, specifically prostatectomy and partial nephrectomy, both experienced solid double-digit growth, reflecting a recovery when compared to the prior year, which was constrained by COVID.

In China and Korea, first quarter procedure growth was solid but slightly below expectations as we saw a resurgence in March of COVID infections, regional lockdowns and hospitalizations, which negatively impacted procedure volumes. In China, growth in urology was solid, in particular with growth in prostatectomy, nephrectomy and partial nephrectomy. We continue to see broad-based growth in general surgery, thoracic and gynecology as well. As we enter the second quarter this year, we are seeing the negative impact on procedure volume as a result of continued regional lockdowns.

Now turning to Ion, our robotic-assisted endoluminal platform focused today on minimally invasive lung biopsy procedures. First quarter 2022 Ion procedures totaled just over 3,900 in Q1 2022, an approximately 350% increase over the prior year and 34% over the prior quarter. Ion system placements were also strong, ending Q1 '22 with 163 installed systems, growing approximately 225% over the prior year.

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, Dr. Paresh Shah, along with colleagues from the Robert I. Grossman School of Medicine at New York University and in collaboration with Intuitive, published a real-world body of evidence assessing open conversion rates during minimally invasive surgery using laparoscopic/thoracoscopic or da Vinci robotic surgery across 10 common procedures for benign or malignant conditions. Utilizing the Premier Healthcare Database, this study included over 275,000 adult patients who, between January 2013 and September 2015, underwent a minimally invasive procedure, including hysterectomy, sigmoidectomy, right colectomy, ventral or inguinal hernia repair, partial nephrectomy, lobectomy or low anterior resection.

Overall, a 5% conversion to open rate for the MIS approach was observed across all procedures with a range of 1% to 24%. Converted to open patients were associated with a 1.8-day longer length of stay, 1.7x greater risk of readmission within 30 days of the procedure and a significantly higher in-hospital or perioperative 30-day total cost, adding approximately $2,900 to the in-hospital cost and $3,400 to the total 30-day cost. The researchers also compared differences in conversions between the laparoscopic/thoracoscopic and da Vinci cohorts. After performing propensity score matching, conversion rates for da Vinci procedures were significantly lower than LAP or VATS across all procedures. The volume-weighted conversion rate for da Vinci was approximately 2.8%, corresponding to a total relative conversion reduction for all study procedures of 58.5% compared to the laparoscopic or the thoracoscopic procedures.

The researchers concluded in part, "From the standpoint of population health or a hospital system, these high-level data indicated that a cumulative effect of conversions can be a significant burden. And that reduction of conversion has major benefits and leads to increased value for the patient, the hospital and society at large. The use of robotic-assisted surgery is associated with a significant decrease in the conversion rate for all 10 operations studied, and a multidisciplinary robotic program encompassing several specialties could result in significantly decreased conversion rates with an improved ability to deliver successful minimally invasive surgery to its patients."

I will now turn to our financial outlook for 2022, starting with procedures. On our last call, we forecast full year 2022 procedure growth within a range of 11% to 15%. We are now increasing our forecast and expect full year 2022 procedure growth of 12% to 16%. This range continues to reflect the uncertainty associated with the course of the pandemic. The low end of the range assumes ongoing COVID and staffing pressure at hospitals and assume some continued choppiness with COVID throughout the year. At the high end of the range, we assume COVID-19-related hospitalizations around the world decline throughout the remainder of 2022, and there are no additional significant impacts from further resurgences. As noted last quarter, the range does not reflect significant supply chain disruptions.

The steep increase in infections and subsequent recovery in the quarter from the Omicron variant in the U.S. and the trend in procedure volumes we have seen exiting the quarter in China highlight the risk to the number of procedures that may be performed. In the second quarter of 2022, our year-over-year procedure growth rate will likely be lower than recent quarters as Q2 2021 results reflected a strong recovery in procedures as COVID began to subside.

Turning to gross profit. On our last call, we forecast our 2022 full year pro forma gross profit margin to be within 69.5% and 70.5%. We are now slightly expanding the range of our pro forma gross profit margin to be within 69% and 70.5% of net revenue. The lower end of the range was updated to reflect the impact on input costs related to supply chain, inflation and some impact from a stronger U.S. dollar. Our actual gross profit margin will vary quarter-to-quarter depending largely on product, regional and trade-in mix and the impact of new product introductions.

With respect to operating expenses, on our last call, we forecast pro forma operating expense growth to be between 21% and 27%. We are refining our estimate and now expect our full year pro forma operating expense growth to be between 23% and 27%. We continue to expect our noncash stock compensation expense to range between $510 million and $550 million in 2022. We expect other income, which is comprised mostly of interest income, to total between $50 million and $60 million in 2022.

On last quarter's call, we forecast 2022 capital expenditures within a range of $700 million to $1 billion. We are now refining estimated capital expenditures for 2022 to be in the range of $700 million to $900 million based primarily on the current timing of planned facility construction activities. With regard to income tax, we continue to estimate our 2022 pro forma tax rate to be between 22% and 24% of pretax income.
That concludes our prepared comments. We will now open the call to your questions.

# Question and Answer

**Operator**

[Operator Instructions] And our first question is from the line of Amit Hazan.

**Amit Hazan**
*Goldman Sachs Group, Inc., Research Division*

Maybe I'll ask my first question on your comments on the U.S. systems side and the capital spending environment. Would just love to have more color on that. And obviously, we're focused on the same numbers that you mentioned, which is just the greenfield unit placements. And if we kind of look back just as context of what we have just over the past 4 or 5 years, those tend to increase by about 10% a year, and it is pretty choppy year-to-year. Just using that as a proxy, how much help can you give us on whether that's a good kind of target for this year for the nontrade-ins in the U.S.? And then just color on what you're seeing here in the near kind of just immediate term that you mentioned, it sounded like a lot of risk factors. And I'm wondering if it's risk factors that you're citing or something that you're actually seeing in your customers delaying planned purchases.

**Gary S. Guthart**
*President, CEO & Director*

Yes. Let me take the second question first and then I'll ask Jamie to step in on, a little bit more on the trade-in side. So what we're seeing now where we're at is a little bit less delay of planned purchases, a little bit less what we're signaling, more around Q4 demand looks strong. Q1 in terms of the early parts of the pipeline process and some of the contracting, some of the later parts, we're seeing in the U.S. just a little bit lower volume.

It may clear itself. It may entirely be that this was just a pull-forward of a little bit of demand and some budget flushing as hospitals got ready for the retirement of some of the government support for COVID. But it's not clear. We don't know yet. We know for sure that we're getting toward the end of the Si trade-in cycle in the United States. So that will soften some of the U.S. capital. And then there's forecasted additional pressures on hospitals and finances. The short answer to that is, we're going to have to see. We'll see if those come to fruition or not. So that's a little bit of where that lays out. With regard to kind of what does the trade-in ratio look like, let me turn it to you, Jamie.

**Jamie E. Samath**
*Senior VP & CFO*

Yes. If I just look back at last year, 2021, there's about 500-ish trade-ins done globally. Of that, about 80% were transactions in the U.S. So you can just kind of get a sense of the degree to which the U.S. has driven the trade-in cycle. As I said in my prepared remarks, as of the end of Q1, there's about 268 Sis left in the U.S. in the installed base. And so you can kind of use those 2 data points to do some estimate of how that will play out over time.

As you start to get towards kind of the end of the tail of remaining Sis, they probably last for a little longer than kind of the average when you're at the middle of the distribution. But that's what I'd say with respect to trade-ins.

I think, Amit, you had a question on greenfields. The way I would think about it in the U.S. is you kind of have your procedure estimates that you can take from our range. You can apply the usual model with respect to utilization. That gives you some sense of how the installed base might expand. And so you can kind of do that calculation. That obviously is a mix of greenfields and incrementals. And I would just reflect in that model then what is the potential risk from what we highlighted with respect to the softening U.S. capital pipeline that we saw in Q1.

**Gary S. Guthart**
*President, CEO & Director*

Just a capping remark on that. Final thought is the core driver in a mature multiport market segment in a country like the United States, the core driver is procedure demand. And we feel like procedure demand is healthy. It's healthy in our target areas. Our major focus is making sure that we can supply the customer with what they need in a way that's high quality and timely. So it's really managing the supply chain. If that goes well and we are successful in closing those gaps, I think capital demand will work itself out. It will play through because it ultimately in those markets is driven by core procedure demand.

**Amit Hazan**
*Goldman Sachs Group, Inc., Research Division*

And the second question, I always hate to ask this question, but I feel like investors want me to at this point in time, just get you to reflect on this. We always believe, as you stated, that you're working on at least one, if not 2, new platforms. We know you have that in the background. We see your R&D spend. That's obvious to everyone. I think the big question is always about timing. And for us, what we wanted to ask is, is this a situation at this point in time where technology just needs more time to incubate, whether maybe what we're seeing is more something that's related to FDA and the process that you go through and how that's evolved. How much color can you give us on just the process for getting new technology to market and where you are?

**Gary S. Guthart**
*President, CEO & Director*

Yes. It's a good question. What I'd say here is a couple. One is, as the technologies have matured and the installed base has gotten bigger, we've made an intentional decision to invest a lot in upgrading the capabilities of Gen 4 platforms that are out there. So the first thing has been that the Xi that somebody purchases today is more capable than the Xi that they had when it was first launched, and we keep doing that.

In part, that's easier, those kind of incremental adds to a platform architecture that's pretty mature are easier for the customer base to absorb. And they also compound utilization. They allow them to get more utility out of the capital they have. They get higher throughput through it, and they do more procedures with it. And in Gen 4, we're not done with that. We have continued to do it, whether it's instruments and accessories or endoscopy or software. And we have some things up our sleeves for that, too.

So that was intentional. We were doing more kind of structural changes early on in that product and we have intentionally moved some things into more incremental changes on Gen 4. We do think that there are bigger structural changes that will make sense. We are working on them. They are interesting. I think they have long-term implications for the surgical market segments we participate in. I'm excited about them. Some of those things are around technology development. Some of them are around manufacturing and supply chain development, and some of them are around clinical pathways and regulatory pathways. So all of those things play out.

I will reinforce what you said. We work on incremental changes. We work on structural changes. And we work kind of multiple generations ahead. And that remains true. We continue to do that. Timing-wise, sometimes a little bit hard to predict perfectly based on both supply chain readiness and how FDA thinks about those things. For us, I want to make sure that every time we make a step that the customers value it, that it's done with them in mind rather than with us in mind. And we continue to have that philosophy and we'll pursue it.

**Operator**

The next question is from Rick Wise from Stifel.

**Frederick Allen Wise**
*Stifel, Nicolaus & Company, Incorporated, Research Division*

Maybe we could talk about, you could expand on your comments on Ion. Just a couple of things you said that I'd be curious to hear more about. Submitted for EU approval, maybe you could give us a little more color on the timing of the opportunity and I'm wondering whether it impacts '22. But maybe you could also talk a little bit about what you've been kind enough to describe in the recent past as sort of an inflection point for Ion. Maybe broadly speaking, what's the feedback you're getting from how the device is using? And maybe talk a little bit about what's next. I mean, it seems more like an execution kind of story at this point.

**Gary S. Guthart**
*President, CEO & Director*

Thanks, Rick. On submission for Europe, we just submitted our dossier. Europe has changed over the framing of their medical device regulation. They call it EU MDR. It's relatively new for the world. As a result, projecting exact timing to get those clearances is a little different relative to historical norms. We don't anticipate it completing in 2022. It's a little bit of, what's the odds game, but we think it's several quarters to finish mostly because it's new for the regulators and it's new for us.

On the point of how is Ion going, it's being driven right now on the single indication of biopsy and bronchoscopy. I think it's driving well because it meets a need. I think alternate technologies, manual and robotic, are less capable. And we see a lot of peer-to-peer word of mouth that is driving interest, and that's backed by data like the PRECIsE trial. So that's been helpful for us.

A lot of our focus here has been developing our manufacturing capacity, continuously improving the product in terms of usability, quality, robustness and efficacy. And the teams are doing a great job and working extremely hard to do all of those things, make sure that we can maintain supply and improve. I'm just delighted with what they're up to. They are both increasing capacity and improving robustness and quality simultaneously. So that's been wonderful, and I think we have room.

We're seeing the combination of Ion bronchoscopic evaluation combined with robotic surgery thereafter. Sometimes people do it on the same day. And that has seen some real value for patients. It's not every part of the patient population, but there are some patients for whom that's a good solution. And we see a lot of excitement. So the tie-through of Ion diagnostics with follow-through treatment is creating patient value. It's shortening the time to definitive answers and then a surgery if a surgery is indicated. So that's been great.

We think Ion as a platform has multiple future indications that it can provide, of clinical value that it can bring, and we are pursuing them assertively in various places. We are not yet publicly describing what those things are, in part because we have some technology to develop, in part there's some regulatory pathways and it's a competitive space. And so we're working down those elements. As we get a little closer, have a little bit better visibility into which ones, when, then we'll be sure to share.

**Frederick Allen Wise**
*Stifel, Nicolaus & Company, Incorporated, Research Division*

Got you. Procedure demand, as you clearly stated, it was healthy this quarter. It feels like it's likely to continue. So hopefully, as hopefully COVID headwinds settle back a little bit around the world, Intuitive always used to talk about the, let's see if I can say this correctly, Gary, the percentage of utilization for average utilization for da Vinci systems. And I'm sort of making this up from memory, but it used to be like when you got to 60% or 65% of da Vinci capacity, it would start to drive new discussions about new systems. Forgetting the specifics of my question, where do you feel like you are with the current installed base utilization? And is that a consideration that we should reflect on as we think about system placements going forward?

**Gary S. Guthart**
*President, CEO & Director*

There's absolutely a relationship between procedure growth and demand and increased utilization on capital, right? And it's inversely related. If you have lower utilization, you sell more capital to do the same number of procedures. We have believed and have pursued assertively that while higher utilization decreases the number of systems that we sell, it increases the utility, the economic value derived by our customers to get higher throughput. And so we put programs in, both in terms of design and workflow as well as consulting services to help them get higher utilization. We've been doing that for years.

It's a number that you can move in a sustained way, but it's hard to move quickly. And I'll turn it over to Jamie shortly. He'll talk a little bit about what the trend line and utilization growth has been. But from an intent point of view, we are happy to see increased utilization even if that pressures near-term capital because it creates better ROI conditions for our customers. And from a pure marginal economics point of view, at Intuitive, the marginal economics work out well for us, too. So it's a win-win even though at the top line in placements it may look like pressure.

So then you had asked the question, kind of what is peak utilization and how do you think about that. I'll also turn that over to Jamie. It has a lot to do with mix and operating conditions in the hospital. It's a little bit less a technology question, a little bit more how they use it. So Jamie, perhaps a little bit on utilization.

**Jamie E. Samath**
*Senior VP & CFO*

If I just go back to pre-COVID for a second, Rick, if you look at 2019, average system utilization grew by 5% over 2018. If I look at recent times and use the CAGR approach to kind of normalize for COVID, last year, on a 2-year CAGR basis

in 2021, utilization grew by 4%. This past quarter on a 3-year CAGR basis, again, back to 2019, grew by 4%. So you can see some relative consistency there.

With respect to looking forward, I think that there is some dependency on the institution, the procedure mix within the institution. General surgery in combination with Xi gives you the opportunity to drive utilization differently than a different procedure mix, particularly given the lower procedure times in some of the benign low-acuity procedures. But it also reflects the number of surgeons that are trained and the commitment of the hospital to drive asset utilization. If you look at the distribution of utilization, today, it's relatively wide. I think there are a number of CFOs in hospitals that on a medium-term basis see opportunities to continue to drive utilization up, and we are supportive of that.

**Operator**

And the next question is from Larry Biegelsen from Wells Fargo.

**Lawrence H. Biegelsen**
*Wells Fargo Securities, LLC, Research Division*

Just one on China for me and one on inflation and supply constraint. So on China, what have you guys seen so far from the lockdowns? And what are your expectations for the second quarter? Do you think you can still grow year-over-year in China? And related to that, Gary, what's the process and time line for the next quota? You're about to finish this quota. Is it possible the next quota could be larger or eliminated entirely? And I have one follow-up.

**Gary S. Guthart**
*President, CEO & Director*

I'll turn those both to Jamie.

**Jamie E. Samath**
*Senior VP & CFO*

Yes. With respect to what we saw in procedures in Q1, as you saw, the COVID cases rises in places like Shanghai. And as the authorities lock down, and they lock down pretty strictly, we saw procedures impacted in March. That's continued so far into April, although it's obviously early. I think that there's risk in procedures in Q2 relative to what you would expect without COVID and those lockdowns.

China is our second-biggest marketplace, but it's still a relatively small proportion of overall procedures. U.S. is still about 70% of global procedures. But certainly, the way things look right now, you have some impact in Q2. What that ends up being really depends on how long the lockdowns last and how long COVID persists in China. I think a separate risk is kind of the impact of logistics and supply chains as we deliver product to China and from a more macro perspective just the port closures and the broader impact that we could see in China given the degree of exports they have just generally across the economy.

With respect to the China quota, difficult to predict. The last couple of times, the quota has been issued in the third year of the quota period, which would be next year. We don't have great visibility into when that might be. And we don't have, honestly, great visibility into what the number would be. I don't think we are expecting or planning on a situation where we are exempt from a quota. But again, we don't have great insights to how that will play out.

**Gary S. Guthart**
*President, CEO & Director*

In general, if the quota is responsive to demand, we think demand is high, and the question is how responsive to that demand is the central government quota when they do it. Sorry, Larry, go ahead.

**Lawrence H. Biegelsen**
*Wells Fargo Securities, LLC, Research Division*

No. I'm sorry to interrupt you. Jamie, on inflation and supply constraints, are you able to quantify the impact on the gross margin that you're expecting from inflation? And on supply constraints, how are you addressing this? A lot of companies are buying forward inventory. And what are your expectations for when it gets better? I know you've talked about hand-to-hand combat. You've used that phrase almost on the last few calls.

**Jamie E. Samath**
*Senior VP & CFO*

Yes. I would just maybe ground the impact of inflation a couple of ways. If you look back at history, our gross margin has been in, let's say, the 71%-ish range versus what we just guided, 69% to 70.5%. And there's really 2 drivers in the gap between our history and that range. One are the investments we're making in fixed costs in infrastructure and manufacturing capacity that's being invested effectively for long-term need. So some of that is ahead of when we will need it. But the lead times require that we put that in place ahead of time.

The second impact is this impact from the supply chain and inflation in the form of logistics costs, higher component prices, et cetera. I can't give you perfect kind of delineation between the 2. I would say, roughly slightly more of that, the impact of that gap is on the fixed cost side. The remainder is in inflation, supply chain impacts.

With respect to how we're managing through the supply chain, there are significant efforts by our operations team just to respond to the whack-a-mole that you described. It's a constant battle of issue resolution. And our #1 goal, as Gary described, is to ensure continuity of supply to customers. So that's where our efforts and focus is.

As the supply chain environment rebalances in whatever point that is in the future, certainly, we will kind of refocus our operations teams to focus on cost reductions, getting our manufacturing efficiencies back to our targets. But that's going to really be a question of when will that be. On the inventory side, you saw us actually increase inventories. I referenced in my prepared remarks almost $70 million sequentially. The mix of that, though, is clearly not perfect. We're replenishing inventory where we can if and as supply lasts. But we have an imbalance currently.

Certainly, if you look at the medium to long term, we're going to look carefully at what levels of inventory we want to hold as one risk mitigation. I think the other thing we'll look at is how do we make ourselves less dependent on sole suppliers.

**Gary S. Guthart**
*President, CEO & Director*

Just a tiny bit of color on that capping sentence. The current situation, it's a little bit hard to predict the future because there's enough moving parts that determining what or forecasting exactly how it will move is probably difficult at this moment. Currently, the number of parts that are under stress has decreased, but the intensity of the stress around a few parts has increased. So the number of things that are a challenge is narrowing, but the ones that remain are more stubborn. And Jamie, your point of, we use various tools, whether it's buying ahead, buying safety stock or redundancy in the supply chain, we'll use any and all of those if we can to help mitigate the risk.

**Operator**

Our next question is from Drew Ranieri from Morgan Stanley.

**Andrew Christopher Ranieri**
*Morgan Stanley, Research Division*

Gary, just for you. I mean, I think Intuitive has like 2,200 U.S. hospital customers. That's more my guess than, I think, what you've ever laid out. But can you maybe talk about what it takes to get the remaining 4,000 hospitals really off the sidelines and using robotics? Just maybe how are you thinking about that in the U.S.? I mean, do you necessarily have to go everywhere? Are there really kind of still opportunities to get into the high-volume surgery centers, hospitals given some of the commentary about the trade-in cycle dynamics and your push for some higher utilization of the systems?

**Gary S. Guthart**
*President, CEO & Director*

I won't speak to the quantitative approach. And perhaps, Jamie, you have a perspective. But just to give you a little bit of a qualitative view, many of the hospitals out there that are greenfields, while they may not have one of our programs today are part of an integrated delivery network that somewhere in the system they have our products and knowledge. The way we work with that is collaboratively with IDN leadership. As they start to understand what the value of the programs are, they will start to move within their own system our products into locations they care about. And so we've seen a really nice move and collaborative expansion with our customer base into those spaces.

Increasingly, we have conversations about moving into different sites of care, especially as benign general surgery procedures and some other procedures that are benign and often done in smaller ambulatory environments become more

prevalent in our workspace, we see that improving over time. So we think we can follow our customers where they want to go.

There is the concentrating effect of robotics and capital investment. It is capital investment. When that happens, it does concentrate regionally those patients and procedures into centers of excellence. We think that's good for our customer to get higher utilization. We think it's good for surgical outcomes because they get more practice. So I think it's a combination of the 2. I don't think we just look at it and think we have to go to where every patient is today. We do think consolidation helps and works, but it will expand from where it is in this moment. Jamie, I don't know if you want to add anything to that.

**Jamie E. Samath**
*Senior VP & CFO*

The only thing I would say is the remaining greenfields tend to be, this is not always the case, but tend to be more in the rural setting, smaller number of beds. So what I think we've seen over the last 3, 4 quarters, as Gary described, is actually increases in the number of placements of greenfield accounts. These are hospitals, as Gary said, that are within existing IDNs. And that's largely a function of the success and experience those IDNs have had with benign procedures, particularly in general surgery, which tend to be a higher mix in these rural hospitals. And so they see the opportunity for effective robotics programs in that setting, whereas before maybe there was more skepticism or the financial picture was more challenging. We'll do that carefully and in conjunction with our IDN partners, and it has to be one that makes economic sense for us and for the customer.

On the ASC side, we have a relatively small but growing installed base. Our procedure growth at ASCs in the U.S. is accretive, but that's probably because the number of systems that we have at hospitals or ASCs is relatively low. Those ASCs generally are ASCs affiliated in some way with our IDNs. That kind of gives us greater confidence in those accounts.

**Gary S. Guthart**
*President, CEO & Director*

Drew, I'll give you a fast follow-up here at the end.

**Andrew Christopher Ranieri**
*Morgan Stanley, Research Division*

All right. Just on Japan, you talked about adding 8 more procedures, you're getting reimbursement for 8 more procedures. Can you maybe just put that in context of how you expect that ramp to maybe look like versus the prior wave of reimbursed procedures in Japan?

**Brian King;Head of Investor Relations**

Drew, this is Brian. I guess I would say, really, the opportunity for adoption on those 8 newly reimbursed procedures, it's a bit difficult, I'd say, to estimate at this time, right? I mean, if you were to take procedures like colon resection as an example, it's highly penetrated by LAP today. So I think adoption of da Vinci will actually be dependent on, say, demonstrating clinical and economic benefits, which I think is going to take some time. And I think it's going to take some time to develop our training and proctoring capabilities and really to establish key opinion leaders. So I think it's just going to take some time. It's really hard to estimate how quickly da Vinci will adopt locally.

**Gary S. Guthart**
*President, CEO & Director*

A little color on that. I think over the midterm we're really excited about it. Over the near term, it takes more. Thank you, Drew. That was our last question.

In closing, we continue to believe there's 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. At Intuitive, we envision a future of care that is less

invasive and profoundly better, where diseases are identified earlier and treated quickly so patients can get back to what matters most.

Thank you for your support on this extraordinary journey. We look forward to talking with you again in 3 months. This concludes the call.

**Operator**
Thank you. And ladies and gentlemen, that does conclude our conference for today. Thank you for your participation and for using AT&T TeleConference Service. You may now disconnect.