
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549
FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-30713

Intuitive Surgical, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

77-0416458
(I.R.S. Employer
Identification No.)

1020 Kifer Road
Sunnyvale, California 94086
(Address of principal executive offices) (Zip Code)

(408) 523-2100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ISRG	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The Registrant had 357,236,861 shares of Common Stock, \$0.001 par value per share, outstanding as of October 14, 2021.

INTUITIVE SURGICAL, INC.
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PART I - FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS**

INTUITIVE SURGICAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

<i>in millions (except par values)</i>	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,346.7	1,622.6
Short-term investments	2,741.5	3,488.8
Accounts receivable, net	695.0	645.5
Inventory	584.9	601.5
Prepays and other current assets	359.9	267.5
Total current assets	5,728.0	6,625.9
Property, plant, and equipment, net	1,737.9	1,577.3
Long-term investments	4,131.5	1,757.7
Deferred tax assets	411.5	367.7
Intangible and other assets, net	581.4	503.6
Goodwill	344.3	336.7
Total assets	\$ 12,934.6	\$ 11,168.9
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 120.0	\$ 81.6
Accrued compensation and employee benefits	265.3	235.0
Deferred revenue	348.5	350.3
Other accrued liabilities	293.5	298.3
Total current liabilities	1,027.3	965.2
Other long-term liabilities	447.8	444.6
Total liabilities	1,475.1	1,409.8
Contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of September 30, 2021, and December 31, 2020	—	—
Common stock, 600.0 shares authorized, \$0.001 par value, 357.2 shares and 353.1 shares issued and outstanding as of September 30, 2021, and December 31, 2020, respectively	0.4	0.4
Additional paid-in capital	7,015.1	6,444.9
Retained earnings	4,390.1	3,261.3
Accumulated other comprehensive income	5.3	24.9
Total Intuitive Surgical, Inc. stockholders' equity	11,410.9	9,731.5
Noncontrolling interest in joint venture	48.6	27.6
Total stockholders' equity	11,459.5	9,759.1
Total liabilities and stockholders' equity	\$ 12,934.6	\$ 11,168.9

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements (Unaudited).

INTUITIVE SURGICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(UNAUDITED)

<i>in millions (except per share amounts)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product	\$ 1,170.6	\$ 898.4	\$ 3,481.1	\$ 2,521.0
Service	232.7	179.3	678.3	508.3
Total revenue	1,403.3	1,077.7	4,159.4	3,029.3
Cost of revenue:				
Product	355.8	287.7	1,049.1	868.2
Service	76.1	65.7	212.6	195.7
Total cost of revenue	431.9	353.4	1,261.7	1,063.9
Gross profit	971.4	724.3	2,897.7	1,965.4
Operating expenses:				
Selling, general and administrative	363.3	298.9	1,039.5	886.1
Research and development	165.5	155.0	487.6	445.3
Total operating expenses	528.8	453.9	1,527.1	1,331.4
Income from operations	442.6	270.4	1,370.6	634.0
Interest and other income, net	18.5	84.8	65.5	136.5
Income before taxes	461.1	355.2	1,436.1	770.5
Income tax expense	73.9	38.4	90.7	67.3
Net income	387.2	316.8	1,345.4	703.2
Less: net income attributable to noncontrolling interest in joint venture	6.7	2.9	21.4	7.8
Net income attributable to Intuitive Surgical, Inc.	\$ 380.5	\$ 313.9	\$ 1,324.0	\$ 695.4
Net income per share attributable to Intuitive Surgical, Inc.:				
Basic	\$ 1.07	\$ 0.89	\$ 3.72	\$ 1.98
Diluted	\$ 1.04	\$ 0.87	\$ 3.63	\$ 1.93
Shares used in computing net income per share attributable to Intuitive Surgical, Inc.:				
Basic	356.8	352.0	355.6	350.5
Diluted	366.8	361.9	365.1	360.1
Total comprehensive income	\$ 382.1	\$ 310.8	\$ 1,325.4	\$ 707.2
Less: comprehensive income attributable to noncontrolling interest	6.6	3.0	21.0	8.0
Total comprehensive income attributable to Intuitive Surgical, Inc.	\$ 375.5	\$ 307.8	\$ 1,304.4	\$ 699.2

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements (Unaudited).

INTUITIVE SURGICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

<i>in millions</i>	Nine Months Ended September 30,	
	2021	2020
Operating activities:		
Net income	\$ 1,345.4	\$ 703.2
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and loss on disposal of property, plant, and equipment	208.5	159.1
Amortization of intangible assets	20.8	37.3
Loss (gain) on investments, accretion, and amortization, net	(2.1)	(64.2)
Deferred income taxes	(40.6)	71.9
Share-based compensation expense	331.4	292.3
Amortization of contract acquisition assets	15.5	12.4
Changes in operating assets and liabilities, net of effects of acquisitions:		
Accounts receivable	(54.7)	57.2
Inventory	(189.2)	(177.0)
Prepays and other assets	(216.7)	(118.8)
Accounts payable	35.8	(3.9)
Accrued compensation and employee benefits	30.3	(76.4)
Deferred revenue	2.3	(9.2)
Other liabilities	35.0	(26.6)
Net cash provided by operating activities	1,521.7	857.3
Investing activities:		
Purchase of investments	(5,213.7)	(3,023.2)
Proceeds from sales of investments	72.4	800.7
Proceeds from maturities of investments	3,532.1	1,933.5
Purchase of property, plant, and equipment and intellectual property	(202.6)	(279.6)
Acquisition of businesses, net of cash	(8.7)	(37.7)
Net cash used in investing activities	(1,820.5)	(606.3)
Financing activities:		
Proceeds from issuance of common stock relating to employee stock plans	244.8	267.9
Taxes paid related to net share settlement of equity awards	(201.2)	(165.3)
Repurchase of common stock	—	(100.0)
Payment of deferred purchase consideration	(19.2)	(48.5)
Net cash provided by (used in) financing activities	24.4	(45.9)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(2.3)	(2.0)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(276.7)	203.1
Cash, cash equivalents, and restricted cash, beginning of period	1,638.5	1,182.6
Cash, cash equivalents, and restricted cash, end of period	\$ 1,361.8	\$ 1,385.7

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements (Unaudited).

INTUITIVE SURGICAL, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

In this report, “Intuitive Surgical,” “Intuitive,” the “Company,” “we,” “us,” and “our” refer to Intuitive Surgical, Inc. and its wholly and majority-owned subsidiaries.

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. (“Intuitive” or the “Company”) develops, manufactures, and markets the da Vinci[®] Surgical System and the Ion[™] endoluminal system. The Company’s products and related services enable physicians and healthcare providers to improve the quality of and access to minimally invasive care. The da Vinci Surgical System consists of a surgeon console or consoles, a patient-side cart, a high-performance vision system, and proprietary instruments and accessories. The Ion endoluminal system is a flexible, robotic-assisted, catheter-based platform that utilizes instruments and accessories for lung biopsies.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements (“Financial Statements”) of Intuitive Surgical, Inc. and its wholly and majority-owned subsidiaries have been prepared on a consistent basis with the audited Consolidated Financial Statements for the fiscal year ended December 31, 2020, and include all adjustments, consisting of only normal, recurring adjustments, necessary to fairly state the information set forth herein. The Financial Statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and, therefore, omit certain information and footnote disclosure necessary to present the Financial Statements in accordance with United States (“U.S.”) generally accepted accounting principles (“U.S. GAAP”). These Financial Statements should be read in conjunction with the audited Consolidated Financial Statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which was filed with the SEC on February 10, 2021. The results of operations for the first nine months of fiscal year 2021 are not necessarily indicative of the results to be expected for the entire fiscal year or any future periods.

The Financial Statements include the results and the balances of the Company’s majority-owned joint venture (referred to herein as the “Joint Venture”) with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“Fosun Pharma”). The Company holds a controlling financial interest in the Joint Venture, and the noncontrolling interest is reflected as a separate component of consolidated stockholders’ equity. The noncontrolling interest’s share of the earnings in the Joint Venture is presented separately in the condensed consolidated statements of comprehensive income.

Common Stock Split

Shares issued pursuant to the three-for-one stock split (the “Stock Split”) of the Company’s issued and outstanding common stock, par value \$0.001 per share, were distributed on October 4, 2021, to stockholders of record as of September 27, 2021. All share and per-share information presented in the Financial Statements have been retroactively adjusted to reflect the Stock Split.

Risks and Uncertainties

The Company is subject to additional risks and uncertainties due to the COVID-19 pandemic. The extent of the impact on the Company’s business is highly uncertain and difficult to predict. In certain regions, the Company’s customers continue to divert resources to treat COVID-19 patients and defer some elective surgical procedures, both of which may impact the Company’s customers’ ability to meet their obligations, including to the Company. Furthermore, economies worldwide have been negatively impacted by the COVID-19 pandemic, and it is possible that the impact could cause an extended local and/or global economic recession. Such economic disruption could have a material adverse effect on our business as hospitals curtail and reduce capital and overall spending. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and their economies. However, the magnitude and overall effectiveness of these actions remains uncertain.

The severity of the impact of the COVID-19 pandemic on the Company’s business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company’s customers, all of which are uncertain and cannot be predicted. The Company’s future results of operations and liquidity could be materially adversely affected by delays in payments of outstanding receivables, supply chain disruptions, including shortages and inflationary pressure, uncertain or reduced demand, and the impact of any initiatives or programs that the Company may undertake to address financial and operational challenges faced by its customers.

In particular, we have experienced increased difficulties in obtaining a sufficient amount of component materials used in our products, including those in the semiconductor market, as global supply has become significantly constrained due to increased demand in semiconductors and other materials. Additionally, prices of such materials have increased due to the increased demand and supply shortage. The Company is engaged in activities to seek to mitigate supply disruptions by, for example, increasing our communications with our suppliers and modifying our purchase order coverage and inventory levels.

However, the global semiconductor supply shortage is likely to remain a challenge for the foreseeable future. We have also experienced challenges in logistics, as certain shipping routes have been impacted by port closures. Such global shortages in important components and logistics challenges have resulted in, and will continue to cause, inflationary cost pressure in our supply chain. To date, these challenges have not materially impacted our ability to deliver product and services to our customers. However, if shortages in important supply chain materials in the semiconductor or other markets continue, we could fail to meet product demand, which would adversely impact our business, financial condition, results of operations, or cash flows.

Increased labor shortages globally, including staff burnout and attrition, could also impact our ability to hire and retain personnel critical to our manufacturing, logistics, and commercial operations. We are also highly dependent on the principal members of our management and scientific staff. Attracting and retaining qualified personnel is critical to our success, and competition for them has become more intense. The loss of critical members of our team, or our inability to attract and retain qualified personnel, could significantly harm our operations, business, and ability to compete. In addition, hospitals are also experiencing staffing shortages and supply chain issues that could impact their ability to provide patient care. As of the date of issuance of these Financial Statements, the extent to which the COVID-19 pandemic may materially adversely affect the Company's financial condition, liquidity, or results of operations is uncertain.

Recently Adopted Accounting Pronouncements

Certain Leases with Variable Lease Payments

In July 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-05, *Lessors - Certain Leases with Variable Lease Payments*, which amends the lessor lease classification guidance in ASC 842 for leases that include any amount of variable lease payments that are not based on an index or rate. The Company has early adopted this ASU as of July 1, 2021, on a prospective basis. The standard had no impact on the Company's consolidated financial statements and related disclosures.

Significant Accounting Policies

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

NOTE 3. FINANCIAL INSTRUMENTS

Cash, Cash Equivalents, and Investments

The following tables summarize the Company's cash and available-for-sale marketable securities' amortized cost, gross unrealized gains, gross unrealized losses, and fair value by significant investment category reported as cash and cash equivalents, short-term investments, or long-term investments as of September 30, 2021, and December 31, 2020 (in millions):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Loss	Fair Value	Reported as:		
						Cash and Cash Equivalents	Short-term Investments	Long-term Investments
September 30, 2021								
Cash	\$ 534.5	\$ —	\$ —	\$ —	\$ 534.5	\$ 534.5	\$ —	\$ —
Level 1:								
Money market funds	812.2	—	—	—	812.2	812.2	—	—
U.S. treasuries	3,250.7	10.6	(2.8)	—	3,258.5	—	1,104.6	2,153.9
Subtotal	4,062.9	10.6	(2.8)	—	4,070.7	812.2	1,104.6	2,153.9
Level 2:								
Commercial paper	632.7	—	—	—	632.7	—	632.7	—
Corporate debt securities	2,262.4	5.3	(2.0)	—	2,265.7	—	794.4	1,471.3
U.S. government agencies	538.3	0.5	(0.5)	—	538.3	—	150.8	387.5
Municipal securities	176.8	1.2	(0.2)	—	177.8	—	59.0	118.8
Subtotal	3,610.2	7.0	(2.7)	—	3,614.5	—	1,636.9	1,977.6
Total assets measured at fair value	\$ 8,207.6	\$ 17.6	\$ (5.5)	\$ —	\$ 8,219.7	\$ 1,346.7	\$ 2,741.5	\$ 4,131.5

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Loss	Fair Value	Reported as:		
						Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2020								
Cash	\$ 644.3	\$ —	\$ —	\$ —	\$ 644.3	\$ 644.3	\$ —	\$ —
Level 1:								
Money market funds	625.8	—	—	—	625.8	625.8	—	—
U.S. treasuries	2,626.8	23.0	—	—	2,649.8	212.5	1,567.9	869.4
Subtotal	3,252.6	23.0	—	—	3,275.6	838.3	1,567.9	869.4
Level 2:								
Commercial paper	671.3	—	—	—	671.3	64.1	607.2	—
Corporate debt securities	1,425.4	11.9	(0.2)	—	1,437.1	3.4	1,036.5	397.2
U.S. government agencies	716.5	2.5	—	—	719.0	72.5	233.6	412.9
Municipal securities	119.8	2.0	—	—	121.8	—	43.6	78.2
Subtotal	2,933.0	16.4	(0.2)	—	2,949.2	140.0	1,920.9	888.3
Total assets measured at fair value	\$ 6,829.9	\$ 39.4	\$ (0.2)	\$ —	\$ 6,869.1	\$ 1,622.6	\$ 3,488.8	\$ 1,757.7

The following table summarizes the contractual maturities of the Company's cash equivalents and available-for-sale investments (excluding cash and money market funds), as of September 30, 2021 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	\$ 2,735.3	\$ 2,741.5
Mature in one to five years	4,125.6	4,131.5
Total	\$ 6,860.9	\$ 6,873.0

Actual maturities may differ from contractual maturities, because certain borrowers have the right to call or prepay certain obligations. Gross realized gains recognized on the sale of investments were not material for the three and nine months ended September 30, 2021, and not significant and \$8.3 million for the three and nine months ended September 30, 2020, respectively. Gross realized losses recognized on the sale of investments were not material for any of the periods presented.

The Company's investment portfolio at any point in time contains available-for-sale debt securities including investments in U.S. treasury and U.S. government agency securities, taxable and tax-exempt municipal notes, corporate notes and bonds, commercial paper, non-U.S. government agency securities, cash deposits, and money market funds. The Company segments its portfolio based on the underlying risk profiles of the securities and have a zero-loss expectation for U.S. treasury and U.S. government agency securities. The Company regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. For the nine months ended September 30, 2021, the credit losses related to available-for-sales debt securities were not significant.

Equity Investments

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company generally recognizes equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments (in millions):

	December 31, 2020 Carrying Value	Changes in Fair Value	Sales/Purchases/Other	September 30, 2021 Carrying Value	Reported as:	
					Prepays and other current assets	Intangible and other assets, net
Equity investments with readily determinable value (Level 1)	\$ 60.1	\$ (0.9)	\$ (15.4)	\$ 43.8	\$ 43.8	\$ —
Equity investments without readily determinable value (Level 2)	\$ 30.2	\$ 34.5	\$ (52.2)	\$ 12.5	\$ —	\$ 12.5

⁽¹⁾ Recorded in Interest and other income, net.

⁽²⁾ Other includes conversion of certain equity investments without readily determinable value to equity investments with readily determinable value.

The Company recognized a \$34.5 million increase in fair value, which was reflected in Interest and other income, net, due to changes in observable prices for certain equity investments that had been held at cost, because they lacked readily determinable market values (Level 2). A total of \$34.2 million of this increase in fair value was related to an equity investment in preferred shares of Broncus Medical, Inc. ("Broncus"). There were no decreases in fair value reflected in net income due to impairments.

In September 2021, Broncus completed its initial public offering ("IPO"). Upon completion of its IPO, the Company's preferred shares were converted to common shares, which have a readily determinable value (Level 1). The Company is restricted from selling these shares for a period of six months. Subsequent to the IPO, the Company recognized a \$12.3 million decrease in fair value from this investment. As such, for the nine months ended September 30, 2021, the Company has recognized a net gain of \$21.9 million related to Broncus, comprised of the \$34.2 million gain reflected in changes in fair value for Level 2 equity investments, offset by the \$12.3 million loss reflected in changes in fair value for Level 1 equity investments, both of which were reflected in Interest and other income, net.

In January 2021, the Company sold all of its shares of Teladoc Health, Inc. ("Teladoc"), a publicly traded company, for \$71.5 million and recognized a gain of \$11.4 million, which was reflected in Interest and other income, net. This gain was offset by a \$7.5 million loss recognized upon the settlement of a corresponding derivative collar contract.

Foreign Currency Derivatives

The objective of the Company's hedging program is to mitigate the impact of changes in currency exchange rates on net cash flow from foreign currency-denominated sales, expenses, intercompany balances, and other monetary assets or liabilities denominated in currencies other than the U.S. dollar ("USD"). The terms of the Company's derivative contracts are generally twelve months or shorter. The derivative assets and liabilities are measured using Level 2 fair value inputs.

Cash Flow Hedges

The Company enters into currency forward contracts as cash flow hedges to hedge certain forecasted revenue transactions denominated in currencies other than the USD, primarily the Euro ("EUR"), the British Pound ("GBP"), the Japanese Yen ("JPY"), and the Korean Won ("KRW"). The Company also enters into currency forward contracts as cash flow hedges to hedge certain forecasted expense transactions denominated in EUR and the Swiss Franc ("CHF").

For these derivatives, the Company reports the unrealized after-tax gain or loss from the hedge as a component of accumulated other comprehensive income/(loss) in stockholders' equity and reclassifies the amount into earnings in the same period in which the hedged transaction affects earnings. The amounts reclassified to revenue and expenses related to the hedged transactions and the ineffective portions of cash flow hedges were not material for the periods presented.

Other Derivatives Not Designated as Hedging Instruments

Other derivatives not designated as hedging instruments consist primarily of forward contracts that the Company uses to hedge intercompany balances and other monetary assets or liabilities denominated in currencies other than the USD, primarily the EUR, GBP, JPY, KRW, CHF, Indian Rupee ("INR"), Mexican Peso ("MXN"), Chinese Yuan ("CNY"), and New Taiwan Dollar ("TWD").

These derivative instruments are used to hedge against balance sheet foreign currency exposures. The related gains and losses were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Recognized gains/(losses) in Interest and other income, net	\$ 4.4	\$ (5.0)	\$ 11.8	\$ (3.2)
Foreign exchange gains/(losses) related to balance sheet re-measurement	\$ (6.4)	\$ 5.9	\$ (12.4)	\$ (1.1)

Additionally, in January 2021, the Company settled a collar contract previously entered into to hedge its equity investment in Teladoc Health, Inc. For the nine months ended September 30, 2021, a loss of \$7.5 million was recognized in Interest and other income, net.

The notional amounts for derivative instruments provide one measure of the transaction volume. Total gross notional amounts (in USD) for outstanding derivatives and the aggregate gross fair value at the end of each period were as follows (in millions):

	Derivatives Designated as Hedging Instruments		Derivatives Not Designated as Hedging Instruments	
	September 30, 2021	December 31, 2020	September 30, 2021	December 31, 2020
Notional amounts:				
Forward contracts	\$ 203.7	\$ 154.3	\$ 285.8	\$ 309.8
Gross fair value recorded in:				
Prepays and other current assets	\$ 6.8	\$ 0.9	\$ 5.8	\$ 0.7
Other accrued liabilities	\$ 0.9	\$ 4.3	\$ 0.7	\$ 5.4

NOTE 4. BALANCE SHEET DETAILS AND OTHER FINANCIAL INFORMATION

Balance Sheet Details

The following tables provide details of selected balance sheet line items (in millions):

	As of	
	September 30, 2021	December 31, 2020
Inventory		
Raw materials	\$ 181.4	\$ 184.1
Work-in-process	85.7	75.6
Finished goods	317.8	341.8
Total inventory	\$ 584.9	\$ 601.5

	As of	
	September 30, 2021	December 31, 2020
Prepays and other current assets		
Prepaid taxes	\$ 78.2	\$ 28.9
Equity investments	43.8	60.1
Net investment in sales-type leases – short-term	98.6	81.1
Other prepaids and other current assets	139.3	97.4
Total prepaids and other current assets	\$ 359.9	\$ 267.5

	As of	
	September 30, 2021	December 31, 2020
Other accrued liabilities—short-term		
Taxes payable	\$ 65.9	\$ 47.2
Current portion of deferred purchase consideration payments	12.2	10.4
Current portion of contingent consideration	0.6	15.1
Other accrued liabilities	214.8	225.6
Total other accrued liabilities—short-term	\$ 293.5	\$ 298.3

	As of	
	September 30, 2021	December 31, 2020
Other long-term liabilities		
Income taxes—long-term	\$ 309.2	\$ 305.6
Deferred revenue—long-term	35.0	32.1
Other long-term liabilities	103.6	106.9
Total other long-term liabilities	\$ 447.8	\$ 444.6

Supplemental Cash Flow Information

The following table provides supplemental non-cash investing and financing activities (in millions):

	Nine Months Ended September 30,	
	2021	2020
Equipment transfers, including operating lease assets, from inventory to property, plant, and equipment	\$ 229.2	\$ 123.6
Acquisition of property, plant, and equipment in accounts payable and accrued liabilities	\$ 29.9	\$ 44.1
Deferred payments and contingent consideration related to business combinations and asset acquisitions	\$ 7.5	\$ 4.1

NOTE 5. REVENUE AND CONTRACT ACQUISITION COSTS

The following table presents revenue disaggregated by types and geography (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
U.S.				
Instruments and accessories	\$ 535.7	\$ 467.3	\$ 1,614.0	\$ 1,227.2
Systems	263.4	157.7	743.7	495.8
Services	153.1	118.8	447.8	337.8
Total U.S. revenue	\$ 952.2	\$ 743.8	\$ 2,805.5	\$ 2,060.8
Outside of U.S. (“OUS”)				
Instruments and accessories	\$ 219.7	\$ 163.2	\$ 643.7	\$ 481.6
Systems	151.8	110.1	479.7	316.3
Services	79.6	60.6	230.5	170.6
Total OUS revenue	\$ 451.1	\$ 333.9	\$ 1,353.9	\$ 968.5
Total				
Instruments and accessories	\$ 755.4	\$ 630.5	\$ 2,257.7	\$ 1,708.8
Systems	415.2	267.8	1,223.4	812.1
Services	232.7	179.4	678.3	508.4
Total revenue	\$ 1,403.3	\$ 1,077.7	\$ 4,159.4	\$ 3,029.3

Remaining Performance Obligations

The transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which revenue has not yet been recognized. A significant portion of these performance obligations relate to service obligations in the Company's system sale and lease arrangements that will be satisfied and recognized as revenue in future periods. The transaction price allocated to the remaining performance obligations was \$1,723 million as of September 30, 2021. The remaining performance obligations are expected to be satisfied over the term of the system sale and lease arrangements, which generally are up to 5 years. Service revenue associated with the lease arrangements will be recognized over the service period.

Contract Assets and Liabilities

The following information summarizes the Company's contract assets and liabilities (in millions):

	As of	
	September 30, 2021	December 31, 2020
Contract assets	\$ 44.8	\$ 34.6
Deferred revenue	\$ 383.5	\$ 382.3

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due 30 to 60 days from date of invoice. Contract assets for the periods presented primarily represent the difference between the revenue that was recognized based on the relative standalone selling price of the related performance obligations satisfied and the contractual billing terms in the arrangements. Deferred revenue for the periods presented primarily relates to service contracts where the service fees are billed up-front, generally quarterly or annually, prior to those services having been performed. The associated deferred revenue is generally recognized over the term of the service period. The Company did not have any significant impairment losses on its contract assets for the periods presented.

During the three and nine months ended September 30, 2021, the Company recognized \$66.1 million and \$319.3 million of revenue, respectively, that was included in the deferred revenue balance as of December 31, 2020. During the three and nine months ended September 30, 2020, the Company recognized \$58.1 million and \$249.7 million of revenue, respectively, net of the impact of the Customer Relief Program, that was included in the deferred revenue balance as of December 31, 2019.

Intuitive System Leasing

The following table presents revenue from Intuitive System Leasing arrangements (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Sales-type lease revenue	\$ 39.0	\$ 24.7	\$ 140.3	\$ 96.5
Operating lease revenue	\$ 72.5	\$ 45.7	\$ 198.8	\$ 127.0

For the three and nine months ended September 30, 2021, and 2020, variable lease revenue relating to usage-based arrangements was not material.

Trade Accounts Receivable

The allowance for doubtful accounts is based on the Company's assessment of the collectibility of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. For the three and nine months ended September 30, 2021, and 2020, bad debt expense was not material.

The Company's exposure to credit losses may increase if its customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, disruption associated with the current COVID-19 pandemic, or other customer-specific factors. Although the Company has historically not experienced significant credit losses, it is possible that there could be a material adverse impact from potential adjustments of the carrying amount of lease and trade receivables as hospital cash flows are impacted by their response to the COVID-19 pandemic and deferral of elective surgical procedures.

NOTE 6. LEASES
Lessor Information

Sales-type Leases. Lease receivables relating to sales-type lease arrangements are presented on the Condensed Consolidated Balance Sheets as follows (in millions):

	As of	
	September 30, 2021	December 31, 2020
Gross lease receivables	\$ 356.1	286.1
Unearned income	(11.7)	(11.1)
Subtotal	344.4	275.0
Allowance for credit loss	(3.7)	(4.4)
Net investment in sales-type leases	<u>\$ 340.7</u>	<u>\$ 270.6</u>
Reported as:		
Prepays and other current assets	\$ 98.6	81.1
Intangible and other assets, net	242.1	189.5
Total, net	<u>\$ 340.7</u>	<u>270.6</u>

Contractual maturities of gross lease receivables at September 30, 2021, are as follows (in millions):

Fiscal Year	Amount
Remainder of 2021	\$ 25.6
2022	101.4
2023	86.5
2024	74.2
2025	49.4
2026 and thereafter	19.0
Total	<u>\$ 356.1</u>

The Company enters into sales-type leases with certain qualified customers to purchase its systems. Sales-type leases have terms that generally range from 24 to 84 months and are usually collateralized by a security interest in the underlying assets. The allowance for loan loss is based on the Company's assessment of current expected lifetime loss on lease receivables. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, the age of the lease receivable balances, and current economic conditions that may affect a customer's ability to pay. Lease receivables are considered past due 90 days after invoice.

The Company manages the credit risk in net investment in sales-type leases using a number of factors, including, but not limited to the following: size of operations; profitability, liquidity, and debt ratios; payment history; and past due amounts. The Company also uses credit scores obtained from external providers as a key credit quality indicator for the purposes of determining credit quality. The following table presents credit quality by class of net investment in sales-type leases as of September 30, 2021. The following table summarizes the amortized cost basis by year of origination and credit quality indicator as of September 30, 2021 (in millions):

	2021	2020	2019	2018	2017	Prior	Net Investment
Credit Rating:							
High	\$ 76.0	\$ 56.0	\$ 25.8	\$ 5.5	\$ 3.6	\$ 0.9	\$ 167.8
Moderate	70.5	67.4	18.6	11.5	2.5	0.5	171.0
Low	0.7	4.7	0.2	—	—	—	5.6
Total	<u>\$ 147.2</u>	<u>\$ 128.1</u>	<u>\$ 44.6</u>	<u>\$ 17.0</u>	<u>\$ 6.1</u>	<u>\$ 1.4</u>	<u>\$ 344.4</u>

For the three and nine months ended September 30, 2021, and 2020, credit losses related to net investment in sales-type leases were not significant.

NOTE 7. GOODWILL AND INTANGIBLE ASSETS
Acquisitions in 2021

There were no material acquisitions for the three and nine months ended September 30, 2021.

Acquisitions in 2020
Orpheus Medical

In February 2020, the Company acquired Orpheus Medical Ltd. and its wholly owned subsidiaries (“Orpheus Medical”) to deepen and expand our integrated informatics platform (the “Orpheus Medical Acquisition”). Orpheus Medical provides hospitals with information technology connectivity, as well as expertise in capturing, processing, and archiving clinical videos across the hospital. The Orpheus Medical Acquisition did not have a material impact on the financial statements.

Goodwill

The following table summarizes the changes in the carrying amount of goodwill (in millions):

	Amount
Balance at December 31, 2020	\$ 336.7
Acquisition activity	8.0
Translation and other	(0.4)
Balance at September 30, 2021	<u>\$ 344.3</u>

Intangible Assets

The following table summarizes the components of gross intangible assets, accumulated amortization, and net intangible asset balances as of September 30, 2021, and December 31, 2020 (in millions):

	September 30, 2021			December 31, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and developed technology	\$ 219.3	\$ (169.3)	\$ 50.0	\$ 198.4	\$ (158.7)	\$ 39.7
Distribution rights and others	26.3	(17.8)	8.5	91.9	(77.4)	14.5
Customer relationships	31.8	(13.1)	18.7	59.0	(35.8)	23.2
Total intangible assets	<u>\$ 277.4</u>	<u>\$ (200.2)</u>	<u>\$ 77.2</u>	<u>\$ 349.3</u>	<u>\$ (271.9)</u>	<u>\$ 77.4</u>

Amortization expense related to intangible assets was \$6.3 million and \$12.6 million for the three months ended September 30, 2021, and 2020, respectively. Amortization expense related to intangible assets was \$20.8 million and \$37.3 million for the nine months ended September 30, 2021, and 2020, respectively.

The estimated future amortization expense related to intangible assets as of September 30, 2021, is as follows (in millions):

Fiscal Year	Amount
Remainder of 2021	\$ 6.1
2022	23.6
2023	19.0
2024	14.5
2025	9.7
2026 and thereafter	4.3
Total	<u>\$ 77.2</u>

The preceding expected amortization expense is an estimate. Actual amounts of amortization expense may differ from estimated amounts due to additional intangible asset acquisitions, measurement-period adjustments to intangible assets, changes in foreign currency exchange rates, impairments of intangible assets, accelerated amortization of intangible assets, and other events.

NOTE 8. CONTINGENCIES

From time to time, the Company is involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, intellectual property, insurance, contract disputes, employment, and other matters. Certain of these lawsuits and claims are described in further detail below. It is not possible to predict what the outcome of these matters will be, and the Company cannot guarantee that any resolution will be reached on commercially reasonable terms, if at all.

A liability and related charge to earnings are recorded in the Financial Statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. The assessment is re-evaluated each accounting period and is based on all available information, including the impact of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to each case. Nevertheless, it is possible that additional future legal costs (including settlements, judgments, legal fees, and other related defense costs) could have a material adverse effect on the Company's business, financial position, and future results of operations.

Product Liability Litigation

The Company is currently named as a defendant in a number of individual product liability lawsuits filed in various state and federal courts. The plaintiffs generally allege that they or a family member underwent surgical procedures that utilized the da Vinci Surgical System and sustained a variety of personal injuries and, in some cases, death as a result of such surgery. Several of the filed cases have trial dates in the next 12 months.

The cases raise a variety of allegations including, to varying degrees, that plaintiffs' injuries resulted from purported defects in the da Vinci Surgical System and/or failure on the Company's part to provide adequate training resources to the healthcare professionals who performed plaintiffs' surgeries. The cases further allege that the Company failed to adequately disclose and/or misrepresented the potential risks and/or benefits of the da Vinci Surgical System. Plaintiffs also assert a variety of causes of action, including, for example, strict liability based on purported design defects, negligence, fraud, breach of express and implied warranties, unjust enrichment, and loss of consortium. Plaintiffs seek recovery for alleged personal injuries and, in many cases, punitive damages. The Company disputes these allegations and is defending against these claims.

The Company's estimate of the anticipated cost of resolving the pending cases is based on negotiations with attorneys for the claimants. The final outcome of the pending lawsuits and claims, and others that might arise, is dependent on many variables that are difficult to predict, and the ultimate cost associated with these product liability lawsuits and claims may be materially different than the amount of the current estimate and accruals and could have a material adverse effect on the Company's business, financial position, and future results of operations. Although there is a reasonable possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

Patent Litigation

On June 30, 2017, Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US LLC (collectively, "Ethicon") filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware. The complaint, which was served on the Company on July 12, 2017, alleges that the Company's EndoWrist Stapler instruments infringe several of Ethicon's patents. Ethicon asserts infringement of U.S. Patent Nos. 9,585,658, 8,479,969, 9,113,874, 8,998,058, 8,991,677, 9,084,601, and 8,616,431. A claim construction hearing occurred on October 1, 2018, and the court issued a scheduling order on December 28, 2018. On March 20, 2019, the court granted the Company's Motion to Stay pending an Inter Partes Review to be held at the Patent Trademark and Appeals Board to review patentability of six of the seven patents noted above and vacated the trial date. On August 1, 2019, the court granted the parties' joint stipulation to modify the stay in light of Ethicon's U.S. International Trade Commission ("USITC") complaint against Intuitive involving U.S. Patent Nos. 8,479,969 and 9,113,874, discussed below.

On August 27, 2018, Ethicon filed a second complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware. The complaint alleges that the Company's SureForm 60 Staplers infringe five of Ethicon's patents. Ethicon asserts infringement of U.S. Patent Nos. 9,884,369, 7,490,749, 8,602,288, 8,602,287, and 9,326,770. The Company filed an answer denying all claims. On March 19, 2019, Ethicon filed a Motion for Leave to File a First Amended Complaint, removing allegations related to U.S. Patent No. 9,326,770 and adding allegations related to U.S. Patent Nos. 9,844,379 and 8,479,969. On July 17, 2019, the court entered an order denying the amendment, without prejudice, and granting the parties' joint stipulation to stay the case in its entirety in light of the USITC investigation involving U.S. Patent Nos. 9,844,369 and 7,490,749, discussed below.

Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from these matters.

On May 30, 2019, Ethicon filed a complaint with the USITC, asserting infringement of U.S. Patent Nos. 9,884,369 (“’369”), 7,490,749 (“’749”), 9,844,379 (“’379”), 9,113,874 (“’874”), and 8,479,969 (“’969”). On June 28, 2019, the USITC voted to institute an investigation (No. 337-TA-1167) with respect to the claims in this complaint. The accused products include the Company’s EndoWrist 30, EndoWrist 45, SureForm 45, and SureForm 60 Staplers, as well as the stapler reload cartridges. In March 2020, Ethicon dismissed its claims concerning the ’749 patent. The evidentiary hearing took place in February 2021. On June 8, 2021, the Chief Administrative Law Judge issued an Initial Determination concluding that (1) the accused products do not infringe the asserted claims in the ’874 or ’969 patents; (2) the asserted claims in the ’874 and ’969 patents are invalid; (3) the accused SureForm staplers and associated reload cartridges infringe two claims of the ’369 patent; (4) the accused SureForm staplers and associated reload cartridges infringe two claims of the ’379 patent; and (5) the Company was estopped from contending that the asserted claims in the ’379 patent are invalid. Ethicon has not challenged the Initial Determination with regard to the findings that absolve Intuitive of any liability regarding the accused EndoWrist staplers and associated reload cartridges. On October 14, 2021, the USITC issued its Opinion in which it made the following rulings: (1) the USITC absolved Intuitive from any liability regarding the ’874, ’969, and ’369 patents; and (2) the USITC found that, while the SureForm staplers and their associated reload cartridges infringe the asserted claims in the ’379 patent, it has suspended the imposition of any remedial order pending an opinion from the Federal Circuit Court of Appeal of whether the Patent and Trademark Office correctly found the asserted claims in this patent to be invalid. A lifting of the suspension of any remedial order by the USITC could result in a prohibition on importing the accused SureForm products into the U.S. or necessitating workarounds. Based on currently available information, the Company does not believe that any losses arising from this matter would be material.

Commercial Litigation

On February 27, 2019, Restore Robotics LLC and Restore Repair LLC (“Restore”) filed a complaint alleging anti-trust claims against the Company. On May 13, 2019, Restore filed an amended complaint alleging anti-trust claims relating to the da Vinci Surgical System and EndoWrist service, maintenance, and repair processes. On September 16, 2019, the Court partially granted and partially denied the Company’s Motion to Dismiss the amended complaint.

On September 30, 2019, the Company filed an answer denying the anti-trust allegations and filed a counterclaim against Restore. The Company filed amended counterclaims after the Court partially granted and partially denied Restore’s Motion to Dismiss the counterclaim. The amended counterclaims allege that Restore violated the Federal Lanham Act, the Federal Computer Fraud and Abuse Act, and Florida’s Deceptive and Unfair Trade Practices Act and that Restore is also liable to the Company for Unfair Competition and Tortious Interference with Contract. On January 7, 2020, the Court denied Restore’s Motion to Dismiss the amended counterclaims.

In its initial scheduling order, the Court stated that it anticipated trial in this case to occur in or before February 2022. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from these matters.

On September 28, 2020, Rebotix Repair Inc. (“Rebotix”) filed a complaint alleging anti-trust claims against the Company relating to EndoWrist service, maintenance, and repair processes. The complaint was formally served on the Company on October 6, 2020. On March 8, 2021, the Court partially granted and partially denied the Company’s Motion to Dismiss the complaint. The Company filed an answer denying the anti-trust allegations and filed counterclaims against Rebotix. The counterclaims allege that Rebotix violated the Federal Lanham Act and Florida’s Deceptive and Unfair Trade Practices Act and that Rebotix is also liable to the Company for Tortious Interference with Contract.

The Court stated that it anticipated trial in this case to occur in or around April 2022. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from this matter.

Similar to the claims asserted in the Restore case, on May 10, 2021, Surgical Instrument Service Company, Inc. (“SIS”) filed a complaint in the Northern District of California Court alleging anti-trust claims against the Company relating to EndoWrist service, maintenance, and repair processes. The Company filed a Motion to Dismiss on which a hearing was held on October 7, 2021. The Court has not yet issued an Order on this Motion to Dismiss. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from this matter.

Three class action complaints were filed against the Company in the Northern District of California Court alleging anti-trust allegations relating to the service and repair of certain instruments manufactured by the Company. A complaint by Larkin Community Hospital was filed on May 20, 2021, a complaint by Franciscan Alliance, Inc. and King County Public Hospital District No. 1 was filed on July 6, 2021, and a complaint by Kaleida Health was filed on July 8, 2021. The Court has consolidated the Franciscan Alliance, Inc. and King County Public Hospital District No. 1 and Kaleida Health cases with the Larkin Community Hospital case, which is now captioned on the Larkin docket as “In Re: da Vinci Surgical Robot Antitrust Litigation.” A Consolidated Amended Class Action Complaint has been filed on behalf of each plaintiff named in the earlier-filed cases. The Company filed a Motion to Dismiss this Consolidated Amended Class Action Complaint on October 11, 2021. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from these matters.

NOTE 9. STOCKHOLDERS' EQUITY
Stockholders' Equity

The following tables present the changes in stockholders' equity (in millions):

Three Months Ended September 30, 2021									
	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Intuitive Surgical, Inc. Stockholders' Equity	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity	
	Shares	Amount						Shares	Amount
Beginning balance	356.2	\$ 0.4	\$ 6,804.1	\$ 4,022.7	\$ 10.3	\$ 10,837.5	\$ 42.0	\$	10,879.5
Issuance of common stock through employee stock plans	1.1	—	91.1			91.1			91.1
Shares withheld related to net share settlement of equity awards	(0.1)	—	(0.2)	(13.1)		(13.3)			(13.3)
Share-based compensation expense related to employee stock plans			120.1			120.1			120.1
Net income attributable to Intuitive Surgical, Inc.				380.5		380.5			380.5
Other comprehensive income (loss)					(5.0)	(5.0)	(0.1)		(5.1)
Net income attributable to noncontrolling interest in joint venture						—	6.7		6.7
Ending balance	<u>357.2</u>	<u>\$ 0.4</u>	<u>\$ 7,015.1</u>	<u>\$ 4,390.1</u>	<u>\$ 5.3</u>	<u>\$ 11,410.9</u>	<u>\$ 48.6</u>	<u>\$</u>	<u>11,459.5</u>
Three Months Ended September 30, 2020									
	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Intuitive Surgical, Inc. Stockholders' Equity	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity	
	Shares	Amount						Shares	Amount
Beginning balance	351.0	\$ 0.4	\$ 6,084.8	\$ 2,633.0	\$ 22.3	\$ 8,740.5	\$ 25.9	\$	8,766.4
Issuance of common stock through employee stock plans	1.6	—	113.9			113.9			113.9
Shares withheld related to net share settlement of equity awards	—	—	(0.5)	(9.7)		(10.2)			(10.2)
Share-based compensation expense related to employee stock plans			105.8			105.8			105.8
Net income attributable to Intuitive Surgical, Inc.				313.9		313.9			313.9
Other comprehensive income (loss)					(6.1)	(6.1)	0.1		(6.0)
Net income attributable to noncontrolling interest in joint venture						—	2.9		2.9
Ending balance	<u>352.6</u>	<u>\$ 0.4</u>	<u>\$ 6,304.0</u>	<u>\$ 2,937.2</u>	<u>\$ 16.2</u>	<u>\$ 9,257.8</u>	<u>\$ 28.9</u>	<u>\$</u>	<u>9,286.7</u>

Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Intuitive Surgical, Inc. Stockholders' Equity	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity
	Shares	Amount						
Beginning balance	353.1	\$ 0.4	\$ 6,444.9	\$ 3,261.3	\$ 24.9	\$ 9,731.5	\$ 27.6	\$ 9,759.1
Issuance of common stock through employee stock plans	4.9	—	244.8			244.8		244.8
Shares withheld related to net share settlement of equity awards	(0.8)	—	(6.0)	(195.2)		(201.2)		(201.2)
Share-based compensation expense related to employee stock plans			331.4			331.4		331.4
Net income attributable to Intuitive Surgical, Inc.				1,324.0		1,324.0		1,324.0
Other comprehensive income (loss)					(19.6)	(19.6)	(0.4)	(20.0)
Net income attributable to noncontrolling interest in joint venture						—	21.4	21.4
Ending balance	<u>357.2</u>	<u>\$ 0.4</u>	<u>\$ 7,015.1</u>	<u>\$ 4,390.1</u>	<u>\$ 5.3</u>	<u>\$ 11,410.9</u>	<u>\$ 48.6</u>	<u>\$ 11,459.5</u>

Nine Months Ended September 30, 2020

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total Intuitive Surgical, Inc. Stockholders' Equity	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity
	Shares	Amount						
Beginning balance	347.9	\$ 0.4	\$ 5,756.5	\$ 2,494.5	\$ 12.4	\$ 8,263.8	\$ 20.9	\$ 8,284.7
Adoption of new accounting standard				(0.1)		(0.1)		(0.1)
Issuance of common stock through employee stock plans	6.1	—	267.9			267.9		267.9
Shares withheld related to net share settlement of equity awards	(0.8)	—	(7.5)	(157.8)		(165.3)		(165.3)
Share-based compensation expense related to employee stock plans			292.3			292.3		292.3
Repurchase and retirement of common stock	(0.6)	—	(5.2)	(94.8)		(100.0)		(100.0)
Net income attributable to Intuitive Surgical, Inc.				695.4		695.4		695.4
Other comprehensive income (loss)					3.8	3.8	0.2	4.0
Net income attributable to noncontrolling interest in joint venture						—	7.8	7.8
Ending balance	<u>352.6</u>	<u>\$ 0.4</u>	<u>\$ 6,304.0</u>	<u>\$ 2,937.2</u>	<u>\$ 16.2</u>	<u>\$ 9,257.8</u>	<u>\$ 28.9</u>	<u>\$ 9,286.7</u>

Stock Repurchase Program

The Company's Board of Directors (the "Board") has authorized an aggregate of \$7.5 billion of funding for the Company's common stock repurchase program (the "Repurchase Program") since its establishment in March 2009. The most recent authorization occurred in January 2019 when the Board increased the authorized amount available under the Repurchase Program to \$2.0 billion. As of September 30, 2021, the remaining amount of share repurchases authorized by the Board was \$1.6 billion.

The following table provides share repurchase activities (in millions, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Shares repurchased	—	—	—	0.6
Average price per share	—	—	\$ —	\$ 173.94
Value of shares repurchased	—	—	\$ —	\$ 100.0

Accumulated Other Comprehensive Income (Loss), Net of Tax, Attributable to Intuitive

The components of accumulated other comprehensive income (loss), net of tax, attributable to Intuitive are as follows (in millions):

	Three Months Ended September 30, 2021				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$ 3.1	\$ 13.5	\$ (0.1)	\$ (6.2)	\$ 10.3
Other comprehensive income (loss) before reclassifications	4.2	(3.4)	(2.7)	—	(1.9)
Amounts reclassified from accumulated other comprehensive income (loss)	(2.2)	(1.1)	—	0.2	(3.1)
Net current-period other comprehensive income (loss)	2.0	(4.5)	(2.7)	0.2	(5.0)
Ending balance	<u>\$ 5.1</u>	<u>\$ 9.0</u>	<u>\$ (2.8)</u>	<u>\$ (6.0)</u>	<u>\$ 5.3</u>

	Three Months Ended September 30, 2020				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$ 0.4	\$ 44.1	\$ (13.8)	\$ (8.4)	\$ 22.3
Other comprehensive income (loss) before reclassifications	(0.8)	(7.1)	2.2	—	(5.7)
Amounts reclassified from accumulated other comprehensive income (loss)	(0.6)	—	—	0.2	(0.4)
Net current-period other comprehensive income (loss)	(1.4)	(7.1)	2.2	0.2	(6.1)
Ending balance	<u>\$ (1.0)</u>	<u>\$ 37.0</u>	<u>\$ (11.6)</u>	<u>\$ (8.2)</u>	<u>\$ 16.2</u>

	Nine Months Ended September 30, 2021				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$ (2.9)	\$ 29.5	\$ 4.7	\$ (6.4)	\$ 24.9
Other comprehensive income (loss) before reclassifications	9.3	(19.4)	(7.5)	—	(17.6)
Amounts reclassified from accumulated other comprehensive income (loss)	(1.3)	(1.1)	—	0.4	(2.0)
Net current-period other comprehensive income (loss)	8.0	(20.5)	(7.5)	0.4	(19.6)
Ending balance	<u>\$ 5.1</u>	<u>\$ 9.0</u>	<u>\$ (2.8)</u>	<u>\$ (6.0)</u>	<u>\$ 5.3</u>

	Nine Months Ended September 30, 2020				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$ 0.7	\$ 20.4	\$ —	\$ (8.7)	\$ 12.4
Other comprehensive income (loss) before reclassifications	2.0	21.3	(11.6)	—	11.7
Amounts reclassified from accumulated other comprehensive income (loss)	(3.7)	(4.7)	—	0.5	(7.9)
Net current-period other comprehensive income (loss)	(1.7)	16.6	(11.6)	0.5	3.8
Ending balance	<u>\$ (1.0)</u>	<u>\$ 37.0</u>	<u>\$ (11.6)</u>	<u>\$ (8.2)</u>	<u>\$ 16.2</u>

NOTE 10. SHARE-BASED COMPENSATION

In April 2021, the Company's shareholders approved an amended and restated 2010 Incentive Award Plan to provide for an increase in the number of shares of common stock reserved for issuance thereunder from 32,450,000 to 34,450,000 (or, after giving effect to the Stock Split, 97,350,000 to 103,350,000). As of September 30, 2021, approximately 25.5 million shares were reserved for future issuance under the Company's stock plans. A maximum of approximately 11.1 million of these shares can be awarded as restricted stock units ("RSUs").

Stock Option Information

A summary of stock option activity under all stock plans for the nine months ended September 30, 2021, is presented as follows (in millions, except per share amounts):

	Stock Options Outstanding	
	Number Outstanding	Weighted Average Exercise Price Per Share
Balance at December 31, 2020	13.4	\$ 101.69
Options granted	1.1	\$ 294.53
Options exercised	(2.3)	\$ 74.06
Options forfeited/expired	(0.1)	\$ 194.12
Balance at September 30, 2021	<u>12.1</u>	<u>\$ 123.58</u>

As of September 30, 2021, options to purchase an aggregate of 9.5 million shares of common stock were exercisable at a weighted average price of \$94.76 per share.

Restricted Stock Units Information

A summary of RSUs activity under all stock plans for the nine months ended September 30, 2021, is presented as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2020	5.3	\$ 163.30
RSUs granted	1.9	\$ 252.42
RSUs vested	(2.1)	\$ 144.04
RSUs forfeited	(0.3)	\$ 191.29
Unvested balance at September 30, 2021	<u>4.8</u>	<u>\$ 204.31</u>

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan ("ESPP"), employees purchased approximately 0.5 million shares for \$75.9 million and approximately 0.5 million shares for \$71.2 million during the nine months ended September 30, 2021, and 2020, respectively.

Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2021, and 2020 (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of sales – products	\$ 19.0	\$ 16.2	\$ 50.9	\$ 43.0
Cost of sales – services	6.0	7.1	16.9	17.8
Total cost of sales	25.0	23.3	67.8	60.8
Selling, general, and administrative	62.5	54.2	171.3	149.5
Research and development	35.4	29.5	98.1	84.1
Share-based compensation expense before income taxes	122.9	107.0	337.2	294.4
Income tax benefit	24.8	22.3	67.9	61.2
Share-based compensation expense after income taxes	\$ 98.1	\$ 84.7	\$ 269.3	\$ 233.2

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company’s share-based compensation plans and rights to acquire stock granted under the ESPP. The weighted average estimated fair values of stock options and the rights to acquire stock under the ESPP, as well as the weighted average assumptions used in calculating the fair values of stock options and the rights to acquire stock under the ESPP that were granted during the three and nine months ended September 30, 2021, and 2020, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock Options				
Risk-free interest rate	0.8%	0.2%	0.8%	0.6%
Expected term (in years)	3.8	3.9	4.1	4.1
Expected volatility	31%	34%	32%	32%
Fair value at grant date	\$87.35	\$62.65	\$78.17	\$53.57
ESPP				
Risk-free interest rate	0.1%	0.1%	0.1%	0.9%
Expected term (in years)	1.2	1.3	1.2	1.2
Expected volatility	29%	34%	29%	30%
Fair value at grant date	\$91.07	\$67.85	\$89.98	\$57.29

NOTE 11. INCOME TAXES

Income tax expense for the three months ended September 30, 2021, was \$73.9 million, or 16.0% of income before taxes, compared to \$38.4 million, or 10.8% of income before taxes, for the three months ended September 30, 2020. Income tax expense for the nine months ended September 30, 2021, was \$90.7 million, or 6.3% of income before taxes, compared to \$67.3 million, or 8.7% of income before taxes, for the nine months ended September 30, 2020.

The effective tax rate for the three and nine months ended September 30, 2021, and 2020, differs from the U.S. federal statutory rate of 21% mainly due to excess tax benefits associated with employee equity plans, the effect of income earned by certain overseas entities being taxed at rates lower than the federal statutory rate, and the federal research and development (“R&D”) credit benefit, partially offset by U.S. tax on foreign earnings and state income taxes (net of federal benefit).

The effective tax rate for the nine months ended September 30, 2021, included a one-time benefit of \$66.4 million from re-measurement of the Company’s Swiss deferred tax assets resulting from the extension of the economic useful life of certain intangible assets. The effective tax rate for the nine months ended September 30, 2020, reflected a one-time increase of \$36.8 million in unrecognized tax benefits with a corresponding increase to income tax expense. This increase was related to intercompany charges for share-based compensation for relevant periods prior to 2020, triggered by the finalization of a Ninth Circuit Court of Appeals opinion (the “Ninth Circuit Opinion”) involving an independent third party. An additional charge of \$11.1 million related to this matter was recorded to income tax expense for the three and nine months ended September 30, 2021, as a result of additional IRS guidance issued in July 2021.

The provision for income taxes for the three and nine months ended September 30, 2021, included excess tax benefits associated with employee equity plans of \$41.9 million and \$158.9 million, which reduced our effective tax rate by 9.1 and 11.1 percentage points, respectively. The provision for income taxes for the three and nine months ended September 30, 2020, included excess tax benefits associated with employee equity plans of \$47.9 million and \$144.8 million, which reduced our effective tax rate by 13.5 and 18.8 percentage points, respectively.

The Company files federal, state, and foreign income tax returns in many U.S. and OUS jurisdictions. Years before 2016 are closed for the significant jurisdictions. Certain of the Company's unrecognized tax benefits could change due to activities of various tax authorities, including potential assessment of additional tax, possible settlement of audits, or through normal expiration of various statutes of limitations, which could affect the Company's effective tax rate in the period in which they change. Due to the uncertainty related to the timing and potential outcome of audits, the Company cannot estimate the range of reasonably possible change in unrecognized tax benefits that may occur in the next 12 months.

The Company is subject to the examination of its income tax returns by the Internal Revenue Service and other tax authorities. The outcome of these audits cannot be predicted with certainty. The Company's management regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of the Company's provision for income taxes. If any issues addressed in the Company's tax audits are resolved in a manner not consistent with management's expectations, the Company could be required to adjust its provision for income taxes in the period such resolution occurs.

NOTE 12. NET INCOME PER SHARE

The following table presents the computation of basic and diluted net income per share attributable to Intuitive Surgical, Inc. (in millions, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net income attributable to Intuitive Surgical, Inc.	\$ 380.5	\$ 313.9	\$ 1,324.0	\$ 695.4
Denominator:				
Weighted average shares outstanding used in basic calculation	356.8	352.0	355.6	350.5
Add: dilutive effect of potential common shares	10.0	9.9	9.5	9.6
Weighted average shares outstanding used in diluted calculation	366.8	361.9	365.1	360.1
Net income per share attributable to Intuitive Surgical, Inc.:				
Basic	\$ 1.07	\$ 0.89	\$ 3.72	\$ 1.98
Diluted	\$ 1.04	\$ 0.87	\$ 3.63	\$ 1.93

Share-based compensation awards of approximately 0.2 million and 0.6 million shares for the three months ended September 30, 2021, and 2020, respectively, and approximately 0.7 million and 2.6 million shares for the nine months ended September 30, 2021, and 2020, respectively, were outstanding but were not included in the computation of diluted net income per share attributable to Intuitive Surgical, Inc. common stockholders, because the effect of including such shares would have been anti-dilutive in the periods presented.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this report, "Intuitive Surgical," "Intuitive," the "Company," "we," "us," and "our" refer to Intuitive Surgical, Inc. and its wholly and majority-owned subsidiaries.

This management's discussion and analysis of financial condition as of September 30, 2021, and results of operations for the three and nine months ended September 30, 2021, and 2020, should be read in conjunction with management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2020.

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted," and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to the expected impacts of the COVID-19 pandemic on our business, financial condition, and results of operations, the potential impact on our procedure volume, our acquisitions, our expected business, our expected new product introductions, the impacts of Extended Use Instruments, procedures and procedure adoption, future results of operations, future financial position, our ability to increase our revenues, the anticipated mix of our revenues between product and service revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, and statements based on current expectations, estimates, forecasts, and projections about the economies and markets in which we operate and our beliefs and assumptions regarding these economies and markets. These forward-looking statements should be considered in light of various important factors, including, but not limited to, the following: our ability to obtain accurate procedure volume and mix in the midst of the COVID-19 pandemic; the risk that the COVID-19 pandemic could lead to further material delays and cancellations of, or reduced demand for, procedures; curtailed or delayed capital spending by hospitals; disruption to our supply chain, including increased difficulties in obtaining a sufficient amount of materials in the semiconductor and other markets; closures of our facilities; delays in surgeon training; delays in gathering clinical evidence; delays in obtaining new product approvals or clearances from the U.S. Food and Drug Administration due to the effects of the COVID-19 pandemic; the evaluation of the risks of robotic-assisted surgery in the presence of infectious diseases; diversion of management and other resources to respond to COVID-19 outbreaks; the impact of global and regional economic and credit market conditions on healthcare spending; the risk that the COVID-19 virus disrupts local economies and causes economies in our key markets to enter prolonged recessions; healthcare reform legislation in the U.S. and its impact on hospital spending, reimbursement, and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships, including the joint venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd.; our completion of and ability to successfully integrate acquisitions, including Schöolly Fiberoptic's robotic endoscope business and Orpheus Medical; procedure counts; regulatory approvals, clearances, and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; risks associated with our operations outside of the United States; unanticipated manufacturing disruptions or the inability to meet demand for products; our reliance on sole and single source suppliers; the results of legal proceedings to which we are or may become a party; product liability and other litigation claims; adverse publicity regarding us and the safety of our products and adequacy of training; our ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; changes in tariffs, trade barriers, and regulatory requirements; and other risk factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and in the Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and other periodic filings with the Securities and Exchange Commission. Our actual results may differ materially and adversely from those expressed in any forward-looking statement. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

Intuitive®, Intuitive Surgical®, da Vinci®, da Vinci S®, da Vinci S HD Surgical System®, da Vinci Si®, da Vinci Si HD Surgical System®, da Vinci Xi®, da Vinci SP®, EndoWrist®, Firefly®, InSite®, da Vinci Connect®, Intuitive Surgical EcoSystem®, da Vinci X®, SureForm™, Ion™, Iris™, and SynchroSeal™ are our trademarks or registered trademarks.

Overview

Intuitive is committed to advancing patient care in surgery and other acute medical interventions. We are focused on innovating to enable physicians and healthcare providers to improve the quality of and access to minimally invasive care. Our mission reflects that we believe that minimally invasive care is life-enhancing care. Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings. While surgery and acute interventions have improved significantly in the past decades, there remains a significant need for better outcomes and decreased variability of these outcomes across care teams. The current healthcare environment continues to stress critical resources, including the professionals who staff care teams: surgeons, anesthesiologists, nurses, and other staff. At the same time, governments strain to cover the healthcare needs of their populations and demand lower total cost per patient to treat disease. In the face of these challenges, we believe scientific, process, and technological advances in biology, computing, imaging, algorithms, and robotics offer new methods to solve continued and difficult problems.

We address these needs by focusing on the quadruple aim. First, we focus on products and services that can improve outcomes and decrease variability in the hands of care teams. Second, we seek to improve the patient experience by minimizing disruption to lives and creating greater predictability for the treatment experience. Third, we seek to improve care team satisfaction by creating products and services that are dependable, smart, and optimized for the care environment in which they are used. Finally, we seek to lower the total cost to treat per patient episode when compared with existing treatment alternatives, providing a return on investment for hospitals and healthcare systems and value for payers.

Open surgery remains the predominant form of surgery and is used in almost every area of the body. However, the large incisions required for open surgery create trauma to patients, typically resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering relative to minimally invasive surgery (“MIS”), where MIS is available. For over three decades, MIS has reduced trauma to patients by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures.

Da Vinci Surgical Systems enable surgeons to extend the benefits of MIS to many patients who would otherwise undergo a more invasive surgery by using computational, robotic, and imaging technologies to overcome many of the limitations of traditional open surgery or conventional MIS. Surgeons using a da Vinci Surgical System operate while seated comfortably at a console viewing a 3D, high-definition image of the surgical field. This immersive console connects surgeons to the surgical field and their instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, similar to open surgical technique. Our technology is designed to provide surgeons with a range of articulation of the surgical instruments used in the surgical field analogous to the motions of a human wrist, while filtering out the tremor inherent in a surgeon’s hand. In designing our products, we focus on making our technology easy and safe to use.

Our da Vinci products fall into five broad categories: da Vinci Surgical Systems, da Vinci instruments and accessories, da Vinci Stapling, da Vinci Energy, and da Vinci Vision, including Firefly Fluorescence imaging systems (“Firefly”) and da Vinci endoscopes. We also provide a comprehensive suite of services, training, and education programs. Within our integrated ecosystem, our hardware, software, and digital solutions are designed to decrease variability in surgery by offering dependable, consistent functionality and user experiences for surgeons seeking better outcomes. We take a holistic approach, offering intelligent technology and systems designed to work together to make MIS intervention more available and applicable.

We have commercialized the following da Vinci Surgical Systems: the da Vinci standard Surgical System in 1999, the da Vinci S Surgical System in 2006, the da Vinci Si Surgical System in 2009, and the fourth generation da Vinci Xi Surgical System in 2014. We have extended our fourth generation platform by adding the da Vinci X Surgical System, commercialized in the second quarter of 2017, and the da Vinci SP Surgical System, commercialized in the third quarter of 2018. The da Vinci SP Surgical System accesses the body through a single incision while the other da Vinci Surgical Systems access the body through multiple incisions. We are still in a measured launch of our da Vinci SP Surgical System, and we have an installed base of 89 da Vinci SP Surgical Systems as of September 30, 2021. Our plans for the rollout of the da Vinci SP Surgical System include putting systems in the hands of experienced da Vinci users first while we optimize training pathways and our supply chain. We received U.S. Food and Drug Administration (“FDA”) clearances for the da Vinci SP Surgical System for urological and certain transoral procedures. We also received clearance in South Korea where the da Vinci SP Surgical System may be used for a broad set of procedures. We plan to seek FDA clearances for additional indications for da Vinci SP over time. We also plan to seek clearances in other OUS markets over time. The success of the da Vinci SP Surgical System is dependent on positive experiences and improved clinical outcomes for the procedures for which it has been cleared as well as securing additional clinical clearances. All da Vinci systems include a surgeon’s console (or consoles), imaging electronics, a patient-side cart, and computational hardware and software.

We offer approximately 70 different multi-port da Vinci instruments to provide surgeons with flexibility in choosing the types of tools needed to perform a particular surgery. These multi-port instruments are generally robotically controlled and provide end effectors (tips) that are similar to those used in either open or laparoscopic surgery. We offer advanced instrumentation for the da Vinci Xi and da Vinci X platforms, including da Vinci Energy and da Vinci Stapler products, to

provide surgeons with sophisticated, computer-aided tools to precisely and efficiently interact with tissue. Da Vinci X and da Vinci Xi Surgical Systems share the same instruments whereas the da Vinci Si Surgical System uses instruments that are not compatible with da Vinci X or da Vinci Xi systems. We currently offer nine core instruments on our da Vinci SP Surgical System. We plan to expand the SP instrument offering over time.

Training technologies include our Intuitive Simulation products, our Intuitive Telepresence remote case observation and telementoring tools, and our dual console for use in surgeon proctoring and collaborative surgery.

During the first quarter of 2019, the FDA cleared our Ion endoluminal system to enable minimally invasive biopsies in the lung. Our Ion system extends our commercial offering beyond surgery into diagnostic procedures with this first application. Our rollout of the Ion system in the U.S. is progressing well, and we are continuing to gather additional clinical evidence. We have placed 98 Ion systems as of September 30, 2021. Ion systems are not included in our da Vinci Surgical System installed base. We plan to seek clearances for Ion in OUS markets over time.

The success of new product introductions depends on a number of factors including, but not limited to, pricing, competition, market and consumer acceptance, the effective forecasting and management of product demand, inventory levels, the management of manufacturing and supply costs, and the risk that new products may have quality or other defects in the early stages of introduction.

COVID-19 Pandemic

Procedures

In the first quarter of 2020, prior to the spread of COVID-19, we experienced procedure growth trends consistent with those experienced in the fourth quarter of 2019, including strength in general surgery, growth in mature procedures in the U.S., and growth in OUS urology. Beginning in January 2020, we saw a substantial reduction in da Vinci procedures in China and, by early February 2020, procedures per week in China had declined by approximately 90% compared to the weekly procedure rates experienced in early January 2020. As the COVID-19 pandemic subsided in China in March 2020, da Vinci procedure volume began to recover and, by the end of the first quarter of 2020, China procedures per week were approximately 70% of the early January 2020 weekly procedure rate. As the COVID-19 pandemic spread to Western Europe and the U.S., we experienced a significant decline in da Vinci procedures in the last half of March 2020 to approximately 65% of the weekly procedure rate experienced earlier in the first quarter of 2020.

In the second quarter of 2020, procedures per week in the U.S. continued to decline in April, reaching approximately 30% of pre-COVID-19 levels, followed by steady recovery in May and June, as COVID-19 cases dropped and elective procedures were permitted. However, with the resurgence of COVID-19 cases in the last two weeks of June, we experienced a corresponding decline in da Vinci procedures. The impact of COVID-19 in Europe during the second quarter of 2020 varied by country with procedures in Italy, France, and the UK declining more steeply, while Germany experienced a year-over-year increase in procedures. In China, procedures per week continued to increase to a level consistent with the early January 2020 weekly procedure rate. We experienced little impact on the procedure volume in Korea and Japan in the second quarter of 2020.

In the third quarter of 2020, in the U.S., procedures recovered slowly, leveling off to near pre-COVID-19 levels towards the end of the quarter. Outside of the U.S., da Vinci procedures varied depending on the spread and/or resurgence of COVID-19. For example, COVID-19 had a less significant impact in Germany where da Vinci procedures grew at mid-single digits relative to the third quarter of 2019, while it had a more significant impact in the U.K. where da Vinci procedures declined year over year. Procedures in China grew significantly year over year, while COVID-19 outbreaks resulted in year-over-year procedure growth rates in Japan slowing somewhat relative to the second quarter. The COVID-19 pandemic has also affected the volumes of certain procedure types differently. For example, patient concerns over exposure to COVID-19 and the fact that prostate cancer can be slow growing, combined with lower prostate diagnoses and treatments, have caused the number of da Vinci prostatectomy procedures to decline in the third quarter of 2020 relative to the third quarter of 2019. Notwithstanding the impacts of COVID-19, da Vinci bariatric procedures grew significantly year over year due to our optimized instrument set and focus by our sales organization and may also have benefited from certain patients prioritizing weight loss as obesity is a significant COVID-19 risk factor. However, the diagnoses and treatment pathways for bariatric patients are long, and many of the patients in the third quarter may have begun their treatment pathway prior to the spread of COVID-19.

In the first quarter of 2021, in the U.S., the COVID-19 resurgence that affected procedures later in the fourth quarter of 2020 continued well into January 2021. Then, as COVID-19 cases subsided beginning in February 2021, da Vinci procedures experienced a steady improvement throughout February and March. In Europe, the spread of COVID-19 varied regionally, and procedure growth rates were mixed with strength in France and a year-over-year decline in the U.K. While there have been COVID-19 hot spots within some of our Asia Pacific markets, they tended to be isolated and, in general, procedures performed well. China growth was significantly higher than other regions, reflecting the severity of the COVID-19 impact on China during the first quarter of the prior year and the additional system installations during 2020.

In the second quarter of 2021, as the U.S. continued its broad rollout of vaccinations, COVID-19 cases and hospitalizations decreased, and procedure volumes recovered, partially attributed to the performance of a number of procedures that were deferred during the pandemic. In Europe, the rollout of vaccinations and spread of COVID-19 varied regionally, and procedure growth rates were mixed with notable recovery in the U.K. We continued to see the impacts of regional resurgences of COVID-19 cases within the Asia Pacific markets with growth in India, Taiwan, and Japan lagging behind that of other markets. China growth continued to be strong year over year, primarily reflecting the growth in the system installed base.

In the third quarter of 2021, COVID-19 infections resurged as the quarter progressed, and we saw a corresponding impact to our da Vinci procedures. In the U.S., we saw decreasing procedure volumes in August and September compared to June as COVID-19 cases and hospitalizations increased. Late in the quarter, as COVID-19 cases began to slow, procedures began to recover. We continue to see certain regions of the U.S. particularly impacted. Outside of the U.S., in Europe, the impact of COVID-19 in the third quarter of 2021 varied regionally with slower growth in Italy and France. We continue to see the impacts of regional resurgences of COVID-19 cases within the Asia Pacific markets, particularly in Japan and Taiwan. China growth in the third quarter continued to be stronger than other Asia Pacific markets, primarily reflecting nearly 40% growth in the system installed base year over year.

The depth and extent to which the COVID-19 pandemic will impact individual markets will vary based on the availability of vaccinations, personal protective equipment, intensive care units and operating rooms, and medical staff, as well as government interventions. The impact of COVID-19 on our procedure volumes varies widely by country, region, and type. When COVID-19 infection rates spike in a particular region, procedure volumes have been negatively impacted and the diagnoses of new conditions and their related treatments have been deferred. 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 through surgery. Based on our experience during 2020, we do not expect all markets, regions, and procedure types to recover at the same time or at the same pace.

System Demand

In the first three quarters of 2020, customers in regions impacted by COVID-19 deferred decisions to purchase or lease systems into future quarters and, in some cases, indefinitely. However, in the first three quarters of 2021, we experienced strong system demand. In general, we believe that the COVID-19 pandemic had less of an impact on hospital spending capacity and that customers recognize that da Vinci surgery meets their quadruple aim objectives better than other surgical approaches. More specifically, during the first three quarters of 2021, system demand reflected procedure growth, hospitals purchasing systems in preparation for a post-COVID-19 pandemic environment, and hospitals upgrading their system portfolio to access and/or standardize on fourth generation capabilities.

General Increase in Risks

Worldwide economies have been significantly impacted by the COVID-19 pandemic, and it is possible that factors related to the COVID-19 pandemic could cause a prolonged recession in local and/or global economies. Such an economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. The COVID-19 pandemic and local actions, such as “shelter-in-place” orders and restrictions on our ability to travel and access our customers or temporary closures of our facilities, including our training and manufacturing operations, or the facilities of our suppliers and their contract manufacturers, could further significantly impact our sales and our ability to produce and ship our products and supply our customers.

In particular, we have experienced increased difficulties in obtaining a sufficient amount of component materials used in our products, including those in the semiconductor market, as global supply has become significantly constrained due to increased demand in semiconductors and other materials. Additionally, prices of such materials have increased due to the increased demand and supply shortage. The global semiconductor and other materials supply shortage is likely to remain a challenge for the foreseeable future. We have also experienced challenges in logistics, as certain shipping routes have been impacted by port closures. Such global shortages in important components and logistics challenges have resulted in, and will continue to cause, inflationary cost pressure in our supply chain. To date, these challenges have not materially impacted our ability to deliver product and services to our customers. However, if shortages in important supply chain materials in the semiconductor or other markets continue, we could fail to meet product demand, which would adversely impact our business, financial condition, results of operations, or cash flows.

Increased labor shortages globally, including staff burnout and attrition, could also impact our ability to hire and retain personnel critical to our manufacturing, logistics, and commercial operations. We are also highly dependent on the principal members of our management and scientific staff. Attracting and retaining qualified personnel is critical to our success, and competition for them has become more intense. The loss of critical members of our team, or our inability to attract and retain qualified personnel, could significantly harm our operations, business, and ability to compete. In addition, hospitals are also experiencing staffing shortages and supply chain issues that could impact their ability to provide patient care. Any of these

events could negatively impact the number of da Vinci procedures performed or the number of system placements and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Our Response

Our priorities and actions during the COVID-19 pandemic have been and remain as follows. First, we are focused on the health and safety of all those we serve – patients, customers, our communities, and our employees – implementing continuous updates to our health and safety policies and processes. Second, we are supporting our customers according to their priorities – clinical, operational, and economic – and ensuring continuity of supply by working with our suppliers and our distributors. Third, we are securing our workforce economically. We have built a valuable team over the years, and we believe they will be important in a recovery that follows the pandemic. Finally, we will continue to invest in our priority development programs while eliminating avoidable spend.

As COVID-19 vaccination rates increase and cases decline, we have enhanced our focus on evaluating and implementing our return-to-office strategy. We intend to remain flexible, allowing many of our employees to work remotely on at least a partial basis, while maintaining productivity and our culture. Our top priority in this process continues to be the health and safety of our employees.

Business Model

Overview

We generate revenue from the placements of da Vinci Surgical Systems, in sales or sales-type lease arrangements where revenue is recognized up-front or in operating lease transactions and usage-based models where revenue is recognized over time. We earn recurring revenue from the sales of instruments, accessories, and services, as well as the revenue from operating leases. The da Vinci Surgical System generally sells for between \$0.5 million and \$2.5 million, depending upon the model, configuration, and geography, and represents a significant capital equipment investment for our customers when purchased. Our instruments and accessories have limited lives and will either expire or wear out as they are used in surgery, at which point they need to be replaced. We generally earn between \$600 and \$3,500 of instruments and accessories revenue per surgical procedure performed, depending on the type and complexity of the specific procedures performed and the number and type of instruments used. Further, in late 2020, we launched our Extended Use Program (refer to further discussion immediately below) in the U.S. and Europe, with the intention to reduce the cost for customers to treat patients, which in turn will reduce the overall instruments and accessories revenue per procedure. We typically enter into service contracts at the time systems are sold or leased at an annual fee between \$80,000 and \$190,000, depending upon the configuration of the underlying system and composition of the services offered under the contract. These service contracts have generally been renewed at the end of the initial contractual service periods.

Consistent with the da Vinci Surgical System model described above, we generate revenue from the placements of the Ion endoluminal system at the time of sale in or sales-type lease arrangements or over time in operating lease transactions and usage-based models. We generate revenue from the placements of the Ion system, and we earn recurring revenue from the sales of instruments and accessories used in biopsies and ongoing system service. Ion systems are presented separately from our da Vinci Surgical Systems installed base. For the three and nine months ended September 30, 2021, Ion's contribution to revenue and gross margin was not significant.

Extended Use Program

In July 2020, we announced our "Extended Use Program," which consists of select da Vinci Xi and da Vinci X instruments possessing 12 to 18 uses ("Extended Use Instruments") compared to the current 10 use instruments. These Extended Use Instruments represent some of our higher volume instruments but exclude stapling, monopolar, and advanced energy instruments. Instruments included in the program are used across a number of da Vinci surgeries. Their increased uses are the result of continuous, significant investments in the design and production capabilities of our instruments, resulting in improved quality and durability. Extended Use Instruments have been introduced in the U.S. and Europe in the fourth quarter of 2020 and have launched in most other countries around the world in the first half of 2021, except China due to regulatory timelines. They will continue to be introduced at various times throughout the remainder of 2021 and 2022 in other geographies, depending on regulatory processes. In addition, simultaneous with the regional launches of Extended Use Instruments, we will lower the price of certain instruments that are most commonly used in lower acuity procedures and/or lower reimbursed procedures within the region. These actions will reduce the cost for customers to treat patients, which in turn will reduce our revenue per procedure. Based on 2019 volume and mix of procedures, our Extended Use Program and the reduced pricing on certain other instruments would have reduced 2019 annual instruments and accessories revenue by approximately \$150 to \$170 million. In the U.S. and Europe, during the first three quarters of 2021, we saw customers adjust their instrument buying patterns to reduce their inventory levels to reflect the additional uses per instrument. Additionally, we believe that, as of the end of Q3 2021, in the U.S. and Europe, full cutover to Extended Use Instruments has occurred, as customers have utilized substantially all of their

remaining 10 use instruments. The precise impact of these actions on future revenue will be dependent on the future volume and mix of procedures and whether cost elasticity will enable greater penetration into available markets.

Recurring Revenue

Recurring revenue consists of instruments and accessories revenue, service revenue, and operating lease revenue. Recurring revenue increased to \$3.4 billion, or 77% of total revenue in 2020, compared to \$3.2 billion, or 72% of total revenue in 2019, and \$2.6 billion, or 71% of total revenue in 2018.

Instruments and accessories revenue has grown at a faster rate than systems revenue over time. Instruments and accessories revenue increased to \$2.46 billion in 2020, compared to \$2.41 billion in 2019 and \$1.96 billion in 2018. The growth of instruments and accessories revenue largely reflects continued procedure adoption.

Service revenue was \$724 million in 2020, compared to \$724 million in 2019 and \$635 million in 2018. Service revenue remained unchanged, driven by growth of the installed base of da Vinci Surgical Systems, offset by an \$80 million decrease due to service fee credits provided to customers as part of the Customer Relief Program that was implemented as a result of the COVID-19 pandemic in the second quarter of 2020. The installed base of da Vinci Surgical Systems grew 7% to approximately 5,989 at December 31, 2020; 12% to approximately 5,582 at December 31, 2019; and 13% to approximately 4,986 at December 31, 2018.

We use the installed base, number of shipments, and utilization of da Vinci Surgical Systems as metrics for financial and operational decision-making and as a means to evaluate period-to-period comparisons. Management believes that the installed base, number of shipments, and utilization of da Vinci Surgical Systems provide meaningful supplemental information regarding our performance, as management believes that the installed base, number of shipments, and utilization of da Vinci Surgical Systems are an indicator of the rate of adoption of robotic-assisted surgery as well as an indicator of future recurring revenue (particularly service revenue). Management believes that both it and investors benefit from referring to the installed base, number of shipments, and utilization of da Vinci Surgical Systems in assessing our performance and when planning, forecasting, and analyzing future periods. The installed base, number of shipments, and utilization of da Vinci Surgical Systems also facilitate management's internal comparisons of our historical performance. We believe that the installed base, number of shipments, and utilization of da Vinci Surgical Systems are useful to investors as metrics, because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making, and (2) they are used by institutional investors and the analyst community to help them analyze the performance of our business. The vast majority of da Vinci Surgical Systems installed are connected via the internet. System logs can also be accessed by field engineers for systems that are not connected to the internet. We utilize this information as well as other information from agreements and discussions with our customers that involve estimates and judgments, which are, by their nature, subject to substantial uncertainties and assumptions. Estimates and judgments for determining the installed base, number of shipments, and utilization of da Vinci Surgical Systems may be impacted over time by various factors, including system internet connectivity, hospital and distributor reporting behavior, and inherent complexities in new agreements. Such estimates and judgments are also susceptible to technical errors. In addition, the relationship between the installed base, number of shipments, and utilization of da Vinci Surgical Systems and our revenues may fluctuate from period to period, and growth in the installed base, number of shipments, and utilization of da Vinci Surgical Systems may not correspond to an increase in revenue. The installed base, number of shipments, and utilization of da Vinci Surgical Systems are not intended to be considered in isolation or as a substitute for, or superior to, revenue or other financial information prepared and presented in accordance with GAAP.

Intuitive System Leasing

Since 2013, we have entered into sales-type and operating lease arrangements directly with certain qualified customers as a way to offer customers flexibility in how they acquire systems and expand their robotic-assisted surgery programs while leveraging our balance sheet. These leases generally have commercially competitive terms as compared to other third-party entities that offer equipment leasing. We have also entered into usage-based arrangements with qualified customers that have committed da Vinci programs where we charge for the system and service as the systems are utilized. We believe that these alternative financing structures have been effective and well-received, and we are willing to expand the proportion of these structures based on customer demand. We include operating and sales-type leases, and systems placed under usage-based arrangements, in our system shipment and installed base disclosures. We exclude operating lease-related revenue, usage-based revenue, and Ion system revenue from our da Vinci Surgical System average selling price ("ASP") computations.

In the years ended December 31, 2020, 2019, and 2018, we shipped 432, 425, and 272 da Vinci Surgical Systems, respectively, under lease and usage-based arrangements, of which 317, 384, and 229 systems, respectively, were operating lease and usage-based arrangements. Revenue from operating lease arrangements is generally recognized on a straight-line basis over the lease term or, in the case of usage-based arrangements, as the systems are used. We generally set operating lease and usage-based pricing at a modest premium relative to purchased systems reflecting the time value of money and, in the case of usage-based arrangements, the risk that system utilization may fall short of anticipated levels. The proportion of revenue recognized from usage-based arrangements has not been significant and has been included in our operating lease metrics herein. Operating

lease revenue has grown at a faster rate than overall systems revenue and was \$177 million, \$107 million, and \$51 million for the years ended December 31, 2020, 2019, and 2018, respectively. As revenue from operating lease and usage-based arrangements is recognized over time, total systems revenue growth is reduced in a period when the number of operating lease and usage-based placements increases as a proportion of total system placements. Generally, lease transactions generate similar gross margins as our sale transactions. As of December 31, 2020, a total of 901 da Vinci Surgical Systems were installed at customers under operating lease or usage-based arrangements.

Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, coverage, and reimbursement, economic pressures or uncertainty or other customer-specific factors. In addition, as customers continue to divert resources to the treatment of or the preparation to treat patients with COVID-19, we may be exposed to defaults under our lease financing arrangements. Moreover, usage-based arrangements generally contain no minimum payments; therefore, customers may exit such arrangements without paying a financial penalty to us. As a result of the COVID-19 pandemic, we anticipate that some customers will exit such arrangements or seek to amend the terms of our operating lease and usage-based arrangements with them.

For some operating lease arrangements, our customers are provided with the right to purchase the leased system at certain points during and/or at the end of the lease term. Revenue generated from customer purchases of systems under operating lease arrangements ("Lease Buyouts") was \$52.2 million, \$92.8 million, and \$48.8 million for the years ended December 31, 2020, 2019, and 2018, respectively. We expect that revenue recognized from customer exercises of the buyout options will fluctuate based on the timing of when, and if, customers choose to exercise their buyout options.

Systems Revenue

System placements are driven by procedure growth in most markets. In some markets, systems placements are constrained by regulation. In geographies where da Vinci procedure adoption is in an early stage, system sales will precede procedure growth. System placements also vary due to seasonality largely aligned with hospital budgeting cycles. We typically place a higher proportion of annual system placements in the fourth quarter and a lower proportion in the first quarter as customer budgets are reset. Systems revenue is also affected by the proportion of system placements under operating lease and usage-based arrangements, recurring operating lease and usage-based revenue, operating lease buyouts, product mix, ASPs, trade-in activities, and customer mix. Systems revenue declined 12% to \$1.18 billion in 2020. Systems revenue grew 19% to \$1.35 billion in 2019 and 21% to \$1.13 billion in 2018. Based on the factors outlined in the *COVID-19 Pandemic* section above, we believe that historical system shipment trends may not be a good indicator of future system shipments.

Procedure Mix / Products

Our da Vinci Surgical Systems are generally used for soft tissue surgery for areas of the body between the pelvis and the neck, primarily in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. Within these categories, procedures range in complexity from cancer and other highly complex procedures to less complex procedures for benign conditions. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex procedures for benign conditions. Thus, hospitals are more sensitive to the costs associated with treating less complex, benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions across the spectrum of procedure complexity. Our fully featured da Vinci Xi Surgical System with advanced instruments (including da Vinci Energy and EndoWrist and SureForm Stapler products) and our Integrated Table Motion product targets the more complex procedure segment. Our da Vinci X Surgical System is targeted towards price sensitive markets and procedures. Our da Vinci SP Surgical System complements the da Vinci Xi and X Surgical Systems by enabling surgeons to access narrow workspaces.

Procedure Seasonality

More than half of da Vinci procedures performed are for benign conditions, most notably hernia repairs, hysterectomies, and cholecystectomies. These benign procedures and other short-term elective procedures tend to be more seasonal than cancer operations and surgeries for other life-threatening conditions. Seasonality in the U.S. for procedures for benign conditions typically results in higher fourth quarter procedure volume when more patients have met annual deductibles and lower first quarter procedure volume when deductibles are reset. Seasonality outside the U.S. varies and is more pronounced around local holidays and vacation periods. As a result of the factors outlined in the *COVID-19 Pandemic* section above, including past and potentially future recommendations of authorities to defer elective procedures, historical procedure patterns may be disrupted.

Distribution Channels

We provide our products through direct sales organizations in the U.S., Europe (excluding Spain, Portugal, Italy, Greece, and most Eastern European countries), China, Japan, South Korea, India, and Taiwan. In 2018, we began direct operations in India and Taiwan. In January 2019, our Intuitive-Fosun joint venture began direct sales for da Vinci products and services in China. In the remainder of our OUS markets, we provide our products through distributors.

Regulatory Activities

Overview

Our products must meet the requirements of a large and growing body of international standards that govern the product safety, efficacy, advertising, labeling, safety reporting design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use, and disposal of our products. Examples of such standards include electrical safety standards, such as those of the International Electrotechnical Commission, and composition standards, such as the Reduction of Hazardous Substances and the Waste Electrical and Electronic Equipment Directives. Failure to meet these standards could limit our ability to market our products in those regions that require compliance to such standards.

Our products and operations are also subject to increasingly stringent medical device, privacy, and other regulations by regional, federal, state, and local authorities. We anticipate that timelines for the introduction of new products and/or indications may be extended relative to past experience as a result of these regulations. For example, we have seen elongated regulatory approval timelines in the U.S. and the EU.

Clearances and Approvals

We have generally obtained the clearances required to market our products associated with our da Vinci Surgical Multiport Systems (Standard, S, Si, Xi, and X systems) for our targeted surgical specialties within the U.S., South Korea, Japan, and the European markets in which we operate. Since 2019, we obtained regulatory clearances for the following products:

- In late 2020 and early 2021, we obtained FDA clearance, CE mark clearance, and regulatory clearances in most of our significant markets to market our Extended Use Instruments.
- In November 2019, we obtained FDA clearance for our SynchroSeal instrument and E-100 generator. Following the FDA clearance, in February 2020, we received CE mark clearance for both products. In March 2020, we received regulatory clearance in Japan to market both our SynchroSeal instrument and E-100 generator. We received regulatory clearance in South Korea to market our SynchroSeal instrument and E-100 generator in January 2020 and August 2020, respectively.
- In July 2019, we obtained FDA clearance for our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload, which round out our SureForm 45 portfolio. We have also received CE mark clearance for our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. In September 2019, we received regulatory clearance in Japan to market both our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. We received regulatory clearance in South Korea to market our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload in June 2021 and July 2021, respectively.
- In June 2019, we received CE mark clearance for our da Vinci Endoscope Plus for the da Vinci Xi and da Vinci X Surgical Systems in Europe. Following the CE mark, in July 2019, we obtained FDA clearance for our da Vinci Endoscope Plus. We have also received regulatory clearances in South Korea and Japan to market our da Vinci Endoscope Plus in December 2019 and May 2020, respectively.
- In June 2019, we obtained FDA clearance for our da Vinci Handheld Camera and, in February 2020, we received CE mark clearance.
- In February 2019, we obtained FDA clearance for our Ion endoluminal system, our new flexible, robotic-assisted, catheter-based platform, designed to navigate through very small lung airways to reach peripheral nodules for biopsies. Our rollout of the Ion system in the U.S. is progressing well, and we are continuing to gather additional clinical evidence. We have placed 98 Ion systems as of September 30, 2021.
- In February 2019, we obtained FDA clearance for our Iris augmented reality product. Iris is a service that delivers a 3D image of the patient anatomy (initially targeting kidneys) to aid surgeons in both pre- and intra-operative settings. We are currently conducting a pilot study of our Iris product and service in the field at a number of U.S. hospitals to gain initial product experience and insights.
- In December 2018, we received product registration for our da Vinci Xi Surgical System in China. The registration approval does not include advanced energy or stapling products that attach to the da Vinci Xi system. Separate product registrations are required for each of these products with the China National Medical Products Administration (“NMPA”).
- In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. After an adjustment notice was published in the third quarter of 2020, the government will now allow for the total sale of 225 new surgical robots into China, which could include da Vinci Surgical Systems as well as surgical systems introduced by others. As of September 30, 2021, we have sold 153 da Vinci Surgical Systems under this quota. Future sales of da Vinci Surgical Systems under the quota are uncertain, as they are dependent on hospitals completing a tender process and receiving associated approvals.

Refer to the descriptions of our products that received regulatory clearances in 2021, 2020, and 2019 in the New Product Introductions section below.

The Japanese Ministry of Health, Labor, and Welfare (“MHLW”) considers reimbursement for procedures in April of even-numbered years. The process for obtaining reimbursement requires Japanese university hospitals and surgical societies, with our support, to seek reimbursement. There are multiple pathways to obtain reimbursement for procedures, including those that require in-country clinical data/economic data. In April 2012 and April 2016, the MHLW granted reimbursement status for robotic-assisted prostatectomy and partial nephrectomy, respectively. Most prostatectomies and partial nephrectomies were open procedures prior to da Vinci reimbursement. Da Vinci procedure reimbursement for robotic-assisted prostatectomy and partial nephrectomy procedures are higher than open and conventional laparoscopic procedure reimbursements. An additional 12 da Vinci procedures were granted reimbursement effective April 1, 2018, including gastrectomy, low anterior resection, lobectomy, and hysterectomy, for both malignant and benign conditions. An additional 7 da Vinci procedures were granted reimbursement effective April 1, 2020. These additional 19 reimbursed procedures have varying levels of conventional laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these 19 procedures, there can be no assurance that the adoption pace for these procedures will be similar to robotic-assisted prostatectomy or partial nephrectomy, given their higher reimbursement, or any other da Vinci procedure.

Recalls and Corrections

Medical device companies have regulatory obligations to correct or remove medical devices in the field that could pose a risk to health. The definition of “recalls and corrections” is expansive and includes repair, replacement, inspections, relabeling, and issuance of new or additional instructions for use or reinforcement of existing instructions for use and training when such actions are taken for specific reasons of safety or compliance. These field actions require stringent documentation, reporting, and monitoring worldwide. There are other actions that a medical device manufacturer may take in the field without reporting including, but not limited to, routine servicing and stock rotations.

As we determine whether a field action is reportable in any regulatory jurisdiction, we prepare and submit notifications to the appropriate regulatory agency for the particular jurisdiction. Regulators can require the expansion, reclassification, or change in scope and language of the field action. In general, upon submitting required notifications to regulators regarding a field action that is a recall or correction, we will notify customers regarding the field action, provide any additional documentation required in their national language, and arrange, as required, return or replacement of the affected product or a field service visit to perform the correction.

Field actions as well as certain outcomes from regulatory activities can result in adverse effects on our business, including damage to our reputation, delays by customers of purchase decisions, reduction or stoppage of the use of installed systems, and reduced revenue as well as increased expenses.

Procedures

We model patient value as equal to *procedure efficacy / invasiveness*. In this equation, *procedure efficacy* is defined as a measure of the success of the surgery in resolving the underlying disease, and *invasiveness* is defined as a measure of patient pain and disruption of regular activities. When the patient value of a da Vinci procedure is greater than that of alternative treatment options, patients may benefit from seeking out surgeons and hospitals that offer da Vinci Surgery, which could potentially result in a local market share shift. Adoption of da Vinci procedures occurs procedure by procedure and market by market and is driven by the relative patient value and total treatment costs of da Vinci procedures as compared to alternative treatment options for the same disease state or condition.

We use the number and type of da Vinci procedures as metrics for financial and operational decision-making and as a means to evaluate period-to-period comparisons. Management believes that the number and type of da Vinci procedures provide meaningful supplemental information regarding our performance, as management believes procedure volume is an indicator of the rate of adoption of robotic-assisted surgery as well as an indicator of future revenue (including revenue from usage-based arrangements). Management believes that both it and investors benefit from referring to the number and type of da Vinci procedures in assessing our performance and when planning, forecasting, and analyzing future periods. The number and type of da Vinci procedures also facilitate management’s internal comparisons of our historical performance. We believe that the number and type of da Vinci procedures are useful to investors as metrics, because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making, and (2) they are used by institutional investors and the analyst community to help them analyze the performance of our business. The vast majority of da Vinci Surgical Systems installed are connected via the internet. System logs can also be accessed by field engineers for systems that are not connected to the internet. We utilize certain methods that rely on information collected from the systems installed for determining the number and type of da Vinci procedures performed that involve estimates and judgments, which are, by their nature, subject to substantial uncertainties and assumptions. Estimates and judgments for determining the number and type

of da Vinci procedures may be impacted over time by various factors, including changes in treatment modalities, hospital and distributor reporting behavior, and system internet connectivity. Such estimates and judgments are also susceptible to algorithmic or other technical errors. In addition, the relationship between the number and type of da Vinci procedures and our revenues may fluctuate from period to period, and da Vinci procedure volume growth may not correspond to an increase in revenue. The number and type of da Vinci procedures are not intended to be considered in isolation or as a substitute for, or superior to, revenue or other financial information prepared and presented in accordance with GAAP.

Worldwide Procedures

Our da Vinci systems and instruments are regulated independently in various countries and regions of the world. The discussion of indications for use and representative or target procedures is intended solely to provide an understanding of the market for da Vinci products and is not intended to promote for sale or use of any Intuitive product outside of its licensed or cleared labeling and indications for use.

The adoption of robotic-assisted surgery using the da Vinci Surgical System has the potential to grow for those procedures that offer greater patient value than to non-da Vinci alternatives and competitive total economics for healthcare providers. Our da Vinci Surgical Systems are used primarily in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. We focus our organization and investments on developing, marketing, and training products and services for procedures in which da Vinci can bring patient value relative to alternative treatment options and/or economic benefit to healthcare providers. Target procedures in general surgery include hernia repair (both ventral and inguinal), colorectal procedures, bariatrics, and cholecystostomies. Target procedures in gynecology include hysterectomy for both cancer and benign conditions. Target procedures in urology include prostatectomy and partial nephrectomy. In cardiothoracic surgery, target procedures include lobectomy. In head and neck surgery, target procedures include certain procedures resecting benign and malignant tumors classified as T1 and T2. Not all of the indications, procedures, or products described may be available in a given country or region or on all generations of da Vinci surgical systems. Surgeons and their patients need to consult the product labeling in their specific country and for each product in order to determine the cleared uses, as well as important limitations, restrictions, or contraindications.

In 2020, approximately 1,243,000 surgical procedures were performed with da Vinci Surgical Systems, compared to approximately 1,229,000 and 1,038,000 surgical procedures performed with da Vinci Surgical Systems in 2019 and 2018, respectively. The reduced growth in our overall procedure volume in 2020 reflects significant disruption caused by the COVID-19 pandemic, as noted in the *COVID-19 Pandemic* section above, and was driven by growth in U.S. general surgery procedures and worldwide urology procedures.

U.S. Procedures

Overall U.S. procedure volume with da Vinci Surgical Systems declined to approximately 876,000 in 2020, compared to approximately 883,000 in 2019 and approximately 753,000 in 2018. General surgery was our largest and fastest growing U.S. specialty in 2020 with procedure volume that grew to approximately 434,000 in 2020, compared to approximately 421,000 in 2019 and approximately 325,000 in 2018. Gynecology was our second largest U.S. surgical specialty in 2020 with procedure volume that declined to approximately 267,000 in 2020, compared to approximately 282,000 in 2019 and approximately 265,000 in 2018. Urology was our third largest U.S. surgical specialty in 2020 with procedure volume that declined to approximately 134,000 in 2020, compared to approximately 138,000 in 2019 and approximately 128,000 in 2018.

Procedures Outside of the U.S.

Overall OUS procedure volume with da Vinci Surgical Systems grew to approximately 367,000 in 2020, compared to approximately 346,000 in 2019 and approximately 285,000 in 2018. Procedure growth in most OUS markets was driven largely by urology procedure volume, which grew to approximately 214,000 in 2020, compared to approximately 206,000 in 2019 and approximately 175,000 in 2018. General surgery and thoracic procedures also contributed to OUS procedure growth with higher growth rates than urology procedures.

Recent Business Events and Trends

Procedures

Overall. Total da Vinci procedures performed by our customers grew approximately 20% for the three months ended September 30, 2021, compared to approximately 7% for the three months ended September 30, 2020. Total da Vinci procedures performed by our customers grew approximately 32% for the nine months ended September 30, 2021, as compared with the same period in the prior year. Total da Vinci procedures declined approximately 1% for the nine months ended September 30, 2020. The third quarter and year-to-date procedure results for both periods reflect impacts from the COVID-19 pandemic, as noted in the *COVID-19 Pandemic* section above. Growth in the third quarter of 2021 was impacted by a resurgence of COVID-19. We saw growth in most of the major procedure categories in the third quarter of 2021, most notably in general surgery procedures (particularly bariatrics, cholecystectomies, and hernia repair) and, to a lesser extent, urology and gynecology procedures. The rates of recovery in urology procedures continue to be impacted by the COVID-19 pandemic due to delays in both the diagnosis of and procedures in patient populations that are considered to be at higher risk from COVID-19 infections as well as for conditions that may progress more slowly.

U.S. Procedures. U.S. da Vinci procedures grew approximately 16% for the three months ended September 30, 2021, compared to approximately 7% for the three months ended September 30, 2020. U.S. da Vinci procedures grew approximately 31% for the nine months ended September 30, 2021, as compared with the same period in the prior year. U.S. da Vinci procedures declined approximately 3% for the nine months ended September 30, 2020. As noted in the *COVID-19 Pandemic* section above, the U.S. procedure results for the three and nine months ended September 30, 2020, reflected significant disruption caused by the COVID-19 pandemic. Growth in the third quarter of 2021 was impacted by a resurgence of COVID-19 as cases and hospitalizations once again increased. During the third quarter of 2021, U.S. procedure growth was largely attributable to general surgery procedures, most notably bariatric, cholecystectomy, and hernia repair procedures and, to a lesser extent, urology and gynecology procedures.

OUS Procedures. OUS da Vinci procedures grew approximately 30% for the three months ended September 30, 2021, compared to approximately 9% for the three months ended September 30, 2020. OUS da Vinci procedures grew approximately 34% for the nine months ended September 30, 2021, compared to approximately 5% for the nine months ended September 30, 2020. As noted in the *COVID-19 Pandemic* section above, the OUS procedure results for the three and nine months ended September 30, 2020, reflected significant disruption caused by the COVID-19 pandemic. Similar to U.S. procedures above, during the third quarter of 2021, OUS da Vinci procedure volumes were impacted as COVID-19 cases and hospitalizations increased in a number of countries. By procedure category, OUS procedure growth was driven by continued growth in urology procedures, most notably prostatectomy and partial nephrectomy procedures, as well as earlier stage growth in general surgery (particularly colorectal), gynecology, and thoracic procedures. The OUS procedure growth rate also reflects continued da Vinci adoption in European and Asian markets. We saw strong procedure growth in China, the UK, South Korea, Germany, and Japan during the third quarter of 2021.

System Demand

We placed 336 da Vinci Surgical Systems in the third quarter of 2021, compared to 195 systems in the third quarter of 2020. The increase in systems placed reflects the significant disruption experienced as a result of the COVID-19 pandemic in the third quarter of 2020, as well as procedure growth, more customers trading in da Vinci Si Surgical Systems for fourth generation da Vinci systems in order to access fourth generation instruments and capabilities as well as to standardize their system portfolio, and further customer validation that da Vinci surgery addresses their quadruple aim objectives.

While third quarter 2021 placements grew 72% compared with 2020, future placements of da Vinci Surgical Systems will be impacted by a number of factors: supply chain risks; economic and geopolitical factors; the impact of the current COVID-19 pandemic, as noted in the *COVID-19 Pandemic* section above; hospital response to the evolving healthcare environment; procedure growth rates; hospital consolidation trends; evolving system utilization and point of care dynamics; capital replacement trends; additional reimbursements in various global markets, including Japan: the timing around governmental tenders and authorizations, including China; the timing of when we receive regulatory clearance in our other OUS markets for our da Vinci Xi Surgical System, da Vinci X Surgical System, and da Vinci SP Surgical System, and related instruments; and market response. Market acceptance of our recently launched da Vinci SP Surgical System and the nature and timing of additional da Vinci SP regulatory indications may also impact future system placements.

Demand may also be impacted by robotic-assisted surgery competition, including from companies that have introduced products in the field of robotic-assisted surgery or have made explicit statements about their efforts to enter the field. A few of these companies include, but are not limited to, Asensus Surgical, Inc.; avateramedical GmbH; CMR Surgical Ltd.; Johnson & Johnson (including their wholly owned subsidiaries Auris Health, Inc. and Verb Surgical Inc.); Medcaroid Corporation; Medrobotics Corporation; Medtronic plc; meerecompany Inc.; MicroPort Scientific Corporation; Olympus Corporation; Samsung Group; Shandong Weigao Group Medical Polymer Company Ltd.; and Titan Medical Inc.

Many of the above factors will also impact future demand for our Ion system, as we extend our commercial offering into diagnostics, along with additional factors associated with a new product introduction, including, but not limited to, our ability to optimize manufacturing and our supply chain, competition, clinical data to demonstrate value, and market acceptance.

New Product Introductions

SynchroSeal and E-100 Generator. In November 2019, we obtained FDA clearance for our SynchroSeal instrument and E-100 generator. Following the FDA clearance, in February 2020, we received CE mark clearance for both products. In March 2020, we received regulatory clearance in Japan to market both our SynchroSeal instrument and E-100 generator. We received regulatory clearance in South Korea to market our SynchroSeal instrument and E-100 generator in January 2020 and August 2020, respectively. SynchroSeal is a single-use, bipolar, electrosurgical instrument intended for grasping, dissection, sealing, and transection of tissue. With its wristed articulation, rapid sealing cycle, and refined curved jaw, SynchroSeal offers enhanced versatility to the da Vinci Energy portfolio. The E-100 generator is an electrosurgical generator developed to power two key instruments – Vessel Sealer Extend and SynchroSeal – on the da Vinci X and da Vinci Xi Surgical Systems. The generator delivers high frequency energy for cutting, coagulation, and vessel sealing of tissues.

SureForm 45 Curved-Tip and Gray Reload. In July 2019, we obtained FDA clearance for the SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. We have also received CE mark clearance for our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. SureForm 45 Curved-Tip is a single-use, fully wristed stapling instrument with a curved tip intended for resection, transection, and/or creation of anastomoses. SureForm 45 Gray reload is a new, single-use cartridge that contains multiple staggered rows of implantable staples and a stainless steel knife. The SureForm 45 Curved-Tip stapler and Gray reload have particular utility in thoracic procedures and round out our SureForm 45 portfolio. In September 2019, we received regulatory clearance in Japan to market both our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. We received regulatory clearance in South Korea to market our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload in June 2021 and July 2021, respectively. Not all reloads or staplers are available for use on all systems or in all countries.

Da Vinci Endoscope Plus. In June 2019, we received CE mark clearance for our da Vinci Endoscope Plus, an enhanced 3D endoscope for use with our da Vinci X and Xi Surgical Systems. Following the CE mark, in July 2019, we obtained FDA clearance for our da Vinci Endoscope Plus. We have also received regulatory clearances in South Korea and Japan to market our da Vinci Endoscope Plus in December 2019 and May 2020, respectively. The da Vinci Endoscope Plus leverages new sensor technology to allow for increased sharpness and color accuracy.

Da Vinci Handheld Camera. In June 2019, we obtained FDA clearance for our da Vinci Handheld Camera, a lightweight, 2D camera head, which can be connected to third-party laparoscopes. This allows the laparoscopic image to be displayed on the da Vinci X/Xi vision cart to address aspects of da Vinci procedures that may require use of a laparoscope, thus eliminating the need for redundant equipment in the operating room and increasing procedure efficiency. In February 2020, we received CE mark clearance for our da Vinci Handheld Camera. We broadly launched the da Vinci Handheld Camera in our European direct markets as well as in the U.S. in May 2020 and June 2020, respectively.

Ion endoluminal system. In February 2019, we obtained FDA clearance for the Ion endoluminal system, our new flexible, robotic-assisted, catheter-based platform designed to navigate through very small lung airways to reach peripheral nodules for biopsies. The Ion system uses an ultra-thin articulating robotic catheter that can articulate 180 degrees in all directions. The outer diameter of the catheter is 3.5mm, which allows physicians to navigate through small and tortuous airways to reach nodules in most airway segments within the lung. The Ion system's flexible biopsy needle can also pass through very tight bends via Ion's catheter to collect tissue in the peripheral lung. The catheter's 2mm working channel can also accommodate other biopsy tools, such as biopsy forceps or cytology brushes, if necessary. Our rollout of the Ion system in the U.S. is progressing well, and we are continuing to gather additional clinical evidence. We have placed 98 Ion systems as of September 30, 2021.

Iris. In February 2019, we obtained FDA clearance for our Iris augmented reality product. Iris is a service that delivers a 3D image of the patient anatomy (initially targeting kidneys) to aid surgeons in both the pre- and intra-operative settings. We are now in the early stages of an Iris pilot study in the field at a number of U.S. hospitals to gain initial product experience and insights.

Third Quarter 2021 Operational and Financial Highlights

- Total revenue increased by 30% to \$1.40 billion for the three months ended September 30, 2021, compared to \$1.08 billion for the three months ended September 30, 2020. The compound annual growth rate between the third quarter of 2019 and the third quarter of 2021 was 12%.
- Approximately 395,000 da Vinci procedures were performed during the three months ended September 30, 2021, an increase of 20% compared to approximately 329,000 for the three months ended September 30, 2020. The compound annual growth rate between the third quarter of 2019 and the third quarter of 2021 was 13%.
- Instruments and accessories revenue increased by 20% to \$755 million for the three months ended September 30, 2021, compared to \$631 million for the three months ended September 30, 2020.
- Systems revenue increased by 55% to \$415 million for the three months ended September 30, 2021, compared to \$268 million during the three months ended September 30, 2020.
- A total of 336 da Vinci Surgical Systems were shipped during the three months ended September 30, 2021, an increase of 72% compared to 195 systems during the three months ended September 30, 2020.
- As of September 30, 2021, we had a da Vinci Surgical System installed base of approximately 6,525 systems, an increase of approximately 11% compared to the installed base of approximately 5,865 systems as of September 30, 2020.
- Utilization of da Vinci systems, measured in terms of procedures per system per year, increased 9% relative to the third quarter of 2020. The compound annual growth rate between the third quarter of 2019 and the third quarter of 2021 was 3%.
- During the three months ended September 30, 2021, we placed 28 Ion systems, compared to 11 systems during the three months ended September 30, 2020.
- Gross profit as a percentage of revenue was 69.2% for the three months ended September 30, 2021, compared to 67.2% for the three months ended September 30, 2020.
- Operating income increased by 64% to \$443 million for the three months ended September 30, 2021, compared to \$270 million during the three months ended September 30, 2020. Operating income included charges for share-based compensation of \$123 million and \$107 million related to employee stock plans and \$6.4 million and \$21.7 million of intangible asset-related charges for the three months ended September 30, 2021, and 2020, respectively.
- As of September 30, 2021, we had \$8.22 billion in cash, cash equivalents, and investments. Cash, cash equivalents, and investments increased by \$1.35 billion, compared to December 31, 2020, primarily as a result of cash provided by our operations and proceeds from stock option exercises and employee stock purchases, partially offset by capital expenditures and taxes paid related to net share settlements of equity awards.

Results of Operations

The following table sets forth, for the periods indicated, certain unaudited Condensed Consolidated Statements of Income information (in millions, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	% of total revenue	2020	% of total revenue	2021	% of total revenue	2020	% of total revenue
Revenue:								
Product	\$ 1,170.6	83 %	\$ 898.4	83 %	\$ 3,481.1	84 %	\$ 2,521.0	83 %
Service	232.7	17 %	179.3	17 %	678.3	16 %	508.3	17 %
Total revenue	1,403.3	100 %	1,077.7	100 %	4,159.4	100 %	3,029.3	100 %
Cost of revenue:								
Product	355.8	25 %	287.7	27 %	1,049.1	25 %	868.2	29 %
Service	76.1	6 %	65.7	6 %	212.6	5 %	195.7	6 %
Total cost of revenue	431.9	31 %	353.4	33 %	1,261.7	30 %	1,063.9	35 %
Product gross profit	814.8	58 %	610.7	56 %	2,432.0	59 %	1,652.8	54 %
Service gross profit	156.6	11 %	113.6	11 %	465.7	11 %	312.6	11 %
Gross profit	971.4	69 %	724.3	67 %	2,897.7	70 %	1,965.4	65 %
Operating expenses:								
Selling, general and administrative	363.3	26 %	298.9	28 %	1,039.5	25 %	886.1	29 %
Research and development	165.5	11 %	155.0	14 %	487.6	12 %	445.3	15 %
Total operating expenses	528.8	37 %	453.9	42 %	1,527.1	37 %	1,331.4	44 %
Income from operations	442.6	32 %	270.4	25 %	1,370.6	33 %	634.0	21 %
Interest and other income, net	18.5	1 %	84.8	8 %	65.5	2 %	136.5	5 %
Income before taxes	461.1	33 %	355.2	33 %	1,436.1	35 %	770.5	26 %
Income tax expense (benefit)	73.9	5 %	38.4	4 %	90.7	3 %	67.3	2 %
Net income	387.2	28 %	316.8	29 %	1,345.4	32 %	703.2	24 %
Less: net income attributable to noncontrolling interest in joint venture	6.7	1 %	2.9	— %	21.4	— %	7.8	— %
Net income attributable to Intuitive Surgical, Inc.	\$ 380.5	27 %	\$ 313.9	29 %	\$ 1,324.0	32 %	\$ 695.4	24 %

Total Revenue

Total revenue increased by 30% to \$1.4 billion for the three months ended September 30, 2021, compared to \$1.1 billion for the three months ended September 30, 2020, resulting from 55% higher systems revenue, driven by 72% higher system placements, 20% higher instruments and accessories revenue, driven by approximately 20% higher procedure volume, and 30% higher service revenue. Total revenue increased by 37% to \$4.2 billion for the nine months ended September 30, 2021, compared to \$3.0 billion for the nine months ended September 30, 2020, resulting from 51% higher systems revenue, driven by 58% higher system placements, 32% higher instruments and accessories revenue, driven by approximately 32% higher procedure volume, and 33% higher service revenue. In conjunction with our 2020 COVID-19 Customer Relief Program implemented in the second quarter of 2020, service revenue was reduced by \$23 million and \$82 million for the three and nine months ended September 30, 2020, respectively, for service fee credits provided to customers.

Revenue denominated in foreign currencies as a percentage of total revenue was approximately 23% and 22% for the three and nine months ended September 30, 2021, respectively, and 22% and 23% for the three and nine months ended September 30, 2020, respectively. We generally sell our products and services in local currencies where we have direct distribution channels. Foreign currency rate fluctuations did not have a material impact on total revenue for the three and nine months ended September 30, 2021, nor for the three and nine months ended and September 30, 2020.

Revenue generated in the U.S. accounted for 68% and 67% of total revenue for the three and nine months ended September 30, 2021, and 69% and 68% for the three and nine months ended September 30, 2020, respectively. We believe that

U.S. revenue has accounted for the large majority of total revenue due to U.S. patients' ability to choose their provider and method of treatment, reimbursement structures supportive of innovation and MIS, and our initial investments focused on U.S. infrastructure. We have been investing in our business in the OUS markets, and our OUS procedures have grown faster in proportion to U.S. procedures. We expect that our OUS procedures and revenue will make up a greater portion of our business in the long term.

As the COVID-19 pandemic is expected to continue to cause a strain on hospital resources, as outlined in the *COVID-19 Pandemic* section above, we cannot reliably estimate the extent total revenue will be impacted in the fourth quarter of 2021 and beyond.

The following table summarizes our revenue and system unit shipments for the three and nine months ended September 30, 2021, and 2020, respectively (in millions, except percentages and unit shipments):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Instruments and accessories	\$ 755.4	\$ 630.5	\$ 2,257.7	\$ 1,708.9
Systems	415.2	267.8	1,223.4	812.1
Total product revenue	1,170.6	898.3	3,481.1	2,521.0
Services	232.7	179.4	678.3	508.3
Total revenue	\$ 1,403.3	\$ 1,077.7	\$ 4,159.4	\$ 3,029.3
United States	\$ 952.2	\$ 743.8	\$ 2,805.5	\$ 2,060.8
OUS	451.1	333.9	1,353.9	968.5
Total revenue	\$ 1,403.3	\$ 1,077.7	\$ 4,159.4	\$ 3,029.3
% of Revenue – U.S.	68 %	69 %	67 %	68 %
% of Revenue – OUS	32 %	31 %	33 %	32 %
Instruments and accessories	\$ 755.4	\$ 630.5	\$ 2,257.7	\$ 1,708.9
Services	232.7	179.4	678.3	508.3
Operating lease revenue	72.5	45.7	198.8	127.0
Total recurring revenue	\$ 1,060.6	\$ 855.6	\$ 3,134.8	\$ 2,344.2
% of Total revenue	76 %	79 %	75 %	77 %

Da Vinci Surgical Systems Shipments by Region:

U.S. unit shipments	227	116	630	404
OUS unit shipments	109	79	332	206
Total unit shipments*	336	195	962	610
*Systems shipped under operating leases (included in total unit shipments)	139	68	374	197

Da Vinci Surgical Systems Shipments involving System Trade-ins:

Unit shipments involving trade-ins	136	78	393	286
Unit shipments not involving trade-ins	200	117	569	324

Ion Systems Shipments	28	11	62	22
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Product Revenue

Three Months Ended September 30, 2021

Product revenue increased by 30% to \$1.17 billion for the three months ended September 30, 2021, compared to \$0.90 billion for the three months ended September 30, 2020.

Instruments and accessories revenue increased by 20% to \$755 million for the three months ended September 30, 2021, compared to \$631 million for the three months ended September 30, 2020. The increase in instruments and accessories revenue was driven primarily by procedure growth of approximately 20%. The third quarter 2021 U.S. procedure growth was approximately 16%, driven by growth in general surgery procedures, most notably bariatric, cholecystectomy, and hernia repair procedures and, to a lesser extent, urology and gynecology procedures. The third quarter 2021 OUS procedure growth was approximately 30%, driven by continued growth in urology procedures, most notably prostatectomy and partial nephrectomy procedures, as well as earlier stage growth in general surgery (particularly colorectal), gynecology, and thoracic procedures. Both growth rates were impacted by the disruption caused by the COVID-19 pandemic, as noted in the *COVID-19 Pandemic* section above. Geographically, the third quarter 2021 OUS procedure growth was driven by procedure expansion in China, the UK, South Korea, Germany, and Japan.

Systems revenue increased by 55% to \$415 million for the three months ended September 30, 2021, compared to \$268 million for the three months ended September 30, 2020. The higher third quarter 2021 systems revenue was primarily driven by higher system shipments, higher operating lease revenue, higher lease buyouts, and higher third quarter 2021 ASPs, partially offset by a higher proportion of system shipments under operating leases.

During the third quarter of 2021, a total of 336 da Vinci Surgical Systems were shipped compared to 195 systems during the third quarter of 2020. By geography, 227 systems were shipped into the U.S., 47 into Europe, 47 into Asia, and 15 into other markets during the third quarter of 2021, compared to 116 systems shipped into the U.S., 39 into Europe, 34 into Asia, and 6 into other markets during the third quarter of 2020. The increase in systems shipments was primarily driven by decisions in the third quarter of 2020 by customers to defer purchases or leases of systems into future quarters as a result of the COVID-19 pandemic, as well as procedure growth, more customers trading in da Vinci Si Surgical Systems for fourth generation da Vinci Xi and da Vinci X systems in order to access fourth generation instruments and capabilities as well as to standardize their system portfolio, and further customer validation that da Vinci surgery addresses their quadruple aim objectives.

We shipped 166 and 83 da Vinci Surgical Systems under lease arrangements, of which 139 and 68 systems were classified as operating leases, for the three months ended September 30, 2021, and 2020, respectively. Operating lease revenue was \$72.5 million for the three months ended September 30, 2021, compared to \$45.7 million for the three months ended September 30, 2020. Systems placed as operating leases represented 41% of total shipments during the third quarter of 2021, compared to 35% during the third quarter of 2020. A total of 1,179 da Vinci Surgical Systems were installed at customers under operating lease or usage-based arrangements as of September 30, 2021, compared to 806 as of September 30, 2020. Revenue from Lease Buyouts was \$24.7 million for the three months ended September 30, 2021, compared to \$16.9 million for the three months ended September 30, 2020. We expect revenue from Lease Buyouts to fluctuate period to period depending on the timing of when, and if, customers choose to exercise the buyout options embedded in their leases.

The da Vinci Surgical System ASP, excluding the impact of systems shipped under operating lease or usage-based arrangements and Ion systems, was approximately \$1.57 million for the three months ended September 30, 2021, compared to approximately \$1.55 million for the three months ended September 30, 2020. ASP fluctuates from period to period based on geographic and product mix, product pricing, systems shipped involving trade-ins, and changes in foreign exchange rates.

Nine Months Ended September 30, 2021

Product revenue increased by 38% to \$3.5 billion for the nine months ended September 30, 2021, compared to \$2.5 billion for the nine months ended September 30, 2020.

Instruments and accessories revenue increased by 32% to \$2.26 billion for the nine months ended September 30, 2021, compared to \$1.71 billion for the nine months ended September 30, 2020. The increase in instruments and accessories revenue was driven primarily by procedure growth of approximately 32%. The year-to-date 2021 U.S. procedure growth was approximately 31%, driven by growth in general surgery procedures, most notably bariatric, cholecystectomy, and hernia repair procedures, as well as moderate growth in the more mature gynecologic and urologic procedures categories. The year-to-date 2021 OUS procedure growth was approximately 34%, driven by continued growth in urology procedures, most notably prostatectomy and partial nephrectomy procedures, as well as earlier stage growth in general surgery (particularly colorectal), gynecology, and thoracic procedures. Both growth rates were positively impacted by the disruption caused by the COVID-19 pandemic in 2020, as noted in the *COVID-19 Pandemic* section above. Geographically, the year-to-date 2021 OUS procedure growth was driven by procedure expansion in China, Germany, Japan, the UK, and South Korea.

Systems revenue increased by 51% to \$1,223 million for the nine months ended September 30, 2021, compared to \$812 million for the nine months ended September 30, 2020. The higher year-to-date 2021 systems revenue was primarily driven by higher system shipments, higher operating lease revenue, higher year-to-date 2021 ASPs, and higher lease buyouts, partially offset by a higher proportion of system shipments under operating leases.

During the nine months ended September 30, 2021, a total of 962 da Vinci Surgical Systems were shipped compared to 610 systems during the nine months ended September 30, 2020. By geography, 630 systems were shipped into the U.S., 169 into Europe, 132 into Asia, and 31 into other markets during the nine months ended September 30, 2021, compared to 404 systems shipped into the U.S., 82 into Europe, 109 into Asia, and 15 into other markets during the nine months ended September 30, 2020. The increase in systems shipments was primarily driven by decisions in the second and third quarters of 2020 by customers to defer purchases or leases of systems into future quarters as a result of the COVID-19 pandemic, as well as procedure growth, more customers trading in da Vinci Si Surgical Systems for fourth generation da Vinci Xi and da Vinci X systems in order to access fourth generation instruments and capabilities as well as to standardize their system portfolio, and further customer validation that da Vinci surgery addresses their quadruple aim objectives.

We shipped 471 and 265 da Vinci Surgical Systems under lease arrangements, of which 374 and 197 systems were classified as operating leases, for the nine months ended September 30, 2021, and 2020, respectively. Operating lease revenue was \$198.8 million for the nine months ended September 30, 2021, compared to \$127.0 million for the nine months ended September 30, 2020. Systems placed as operating leases represented 39% of total shipments during the nine months ended September 30, 2021, compared to 32% during the nine months ended September 30, 2020. Revenue from Lease Buyouts was \$69.9 million for the nine months ended September 30, 2021, compared to \$38.5 million for the nine months ended September 30, 2020. We expect revenue from Lease Buyouts to fluctuate period to period depending on the timing of when, and if, customers choose to exercise the buyout options embedded in their leases.

The da Vinci Surgical System ASP, excluding the impact of systems shipped under operating lease or usage-based arrangements and Ion systems, was approximately \$1.59 million for the nine months ended September 30, 2021, compared to approximately \$1.54 million for the nine months ended September 30, 2020. ASP fluctuates from period to period based on geographic and product mix, product pricing, systems shipped involving trade-ins, and changes in foreign exchange rates.

Service Revenue

Service revenue increased by 30% to \$233 million for the three months ended September 30, 2021, compared to \$179 million for the three months ended September 30, 2020. The increase in service revenue was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue, as well as the effects of the Customer Relief Program in the prior year, which resulted in a \$23 million decrease in service revenue in the three months ended September 30, 2020.

Service revenue increased by 33% to \$678 million for the nine months ended September 30, 2021, compared to \$508 million for the nine months ended September 30, 2020. The increase in service revenue was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue, as well as the effects of the Customer Relief Program in the prior year, which resulted in an \$82 million decrease in service revenue in the nine months ended September 30, 2020.

Gross Profit

Product gross profit for the three months ended September 30, 2021, increased 33% to \$815 million, representing 69.6% of product revenue, compared to \$611 million, representing 68.0% of product revenue, for the three months ended September 30, 2020. The higher product gross profit for the three months ended September 30, 2021, was primarily driven by higher product revenue and higher product gross profit margin. The higher product gross profit margin for the three months ended September 30, 2021, was primarily driven by higher third quarter 2021 ASPs and lower year-over-year excess and obsolete inventory costs, partially offset by higher freight costs. In addition, we incurred period costs associated with abnormally low production in the third quarter of 2020, which did not recur in the third quarter of 2021 as a result of increased production volumes.

Product gross profit for the nine months ended September 30, 2021, increased 47% to \$2.4 billion, representing 69.9% of product revenue, compared to \$1.7 billion, representing 65.6% of product revenue, for the nine months ended September 30, 2020. The higher product gross profit for the nine months ended September 30, 2021, was primarily driven by higher product revenue and higher product gross profit margin. The higher product gross profit margin for the nine months ended September 30, 2021, was primarily driven by higher year-to-date 2021 ASPs, lower year-over-year excess and obsolete inventory costs, lower year-over-year intangible assets amortization expense, and lower year-over-year costs associated with da Vinci Si product transitions, partially offset by higher share-based compensation expense. In addition, we incurred period costs in the second and third quarters of 2020 associated with abnormally low production, which did not recur in the second and third quarters of 2021 as a result of increased production volumes.

Product gross profit for the three and nine months ended September 30, 2021, included share-based compensation expense of \$19.0 million and \$50.9 million, respectively, compared with \$16.2 million and \$43.0 million, for the three and nine months ended September 30, 2020, respectively. Product gross profit for the three and nine months ended September 30, 2021, included intangible assets amortization expense of \$3.8 million and \$12.7 million, respectively, compared with \$9.0 million and \$26.7 million, for the three and nine months ended September 30, 2020, respectively.

Service gross profit for the three months ended September 30, 2021, increased 38% to \$157 million, representing 67.3% of service revenue, compared to \$114 million, representing 63.4% of service revenue, for the three months ended September 30, 2020. The higher service gross profit for the three months ended September 30, 2021, was primarily driven by higher service revenue, reflecting a larger installed base of da Vinci Surgical Systems, and higher service gross profit margin. The lower service gross profit margin for the three months ended September 30, 2020, was primarily driven by the decrease in service revenue as a result of the Customer Relief Program.

Service gross profit for the nine months ended September 30, 2021, increased 49% to \$466 million, representing 68.7% of service revenue, compared to \$313 million, representing 61.5% of service revenue, for the nine months ended September 30, 2020. The higher service gross profit for the nine months ended September 30, 2021, was primarily driven by higher service revenue, reflecting a larger installed base of da Vinci Surgical Systems, and higher service gross profit margin. The lower service gross profit margin for the nine months ended September 30, 2020, was primarily driven by the decrease in service revenue as a result of the Customer Relief Program.

Service gross profit for the three and nine months ended September 30, 2021, included share-based compensation expense of \$6.0 million and \$16.9 million, respectively, compared with \$7.1 million and \$17.8 million, for the three and nine months ended September 30, 2020, respectively. Service gross profit for the three and nine months ended September 30, 2021, included intangible asset charges of \$0.2 million and \$1.9 million, respectively, compared with \$0.9 million and \$2.7 million, for the three and nine months ended September 30, 2020, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses include costs for sales, marketing, and administrative personnel, sales and marketing activities, tradeshow expenses, legal expenses, regulatory fees, and general corporate expenses.

Selling, general and administrative expenses for the three months ended September 30, 2021, increased by 22% to \$363 million, compared to \$299 million for the three months ended September 30, 2020. Selling, general and administrative expenses for the nine months ended September 30, 2021, increased by 17% to \$1,040 million, compared to \$886 million for the nine months ended September 30, 2020. The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2021, was primarily driven by higher headcount, resulting in increased fixed and share-based compensation expense, higher variable compensation, and increased infrastructure to support our growth. In addition, there were higher marketing, travel, and training expenses for the three and nine months ended September 30, 2021, as compared with the prior year.

Selling, general and administrative expenses for the three and nine months ended September 30, 2021, included share-based compensation expense of \$62.5 million and \$171.3 million, respectively, compared with \$54.2 million and \$149.5 million, for the three and nine months ended September 30, 2020, respectively. Selling, general and administrative expenses for the three and nine months ended September 30, 2021, included intangible assets amortization expense of \$1.8 million and \$5.4 million, respectively, compared with \$1.8 million and \$5.2 million, for the three and nine months ended September 30, 2020, respectively.

Selling, general and administrative expenses were 26% and 25% for the three and nine months ended September 30, 2021, as a percentage of revenue, compared to 28% and 29% for the three and nine months ended September 30, 2020, and 25% and 26% for the three and nine months ended September 30, 2019. Our spending in the third quarter of 2021 reflected a continued but less pronounced curtailment of certain costs as a result of the COVID-19 pandemic, including travel, marketing events, clinical trials, and other related expenses. We expect that these costs will continue to increase to the extent that the impact of COVID-19 decreases and decline to the extent that the impact of COVID-19 increases. In addition, we expect spending to increase overall and as a percentage of sales as we continue to support our customers, invest in innovation focused on the quadruple aim, and invest in manufacturing and our supply chain to ensure supply for our customers.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include costs associated with the design, development, testing, and significant enhancement of our products.

Research and development expenses for the three months ended September 30, 2021, increased by 7% to \$166 million, compared to \$155 million for the three months ended September 30, 2020. Research and development expenses for the nine months ended September 30, 2021, increased by 9% to \$488 million, compared to \$445 million for the nine months ended

September 30, 2020. The increases in research and development expenses for the three and nine months ended September 30, 2021, were primarily driven by higher personnel-related expenses and other project costs incurred to support a broader set of product development initiatives, including Ion and SP platform investments, informatics, advanced instrumentation, advanced imaging, and future generations of robotics.

Research and development expenses for the three and nine months ended September 30, 2021, included share-based compensation expense of \$35.4 million and \$98.1 million, respectively, compared with \$29.5 million and \$84.1 million for the three and nine months ended September 30, 2020, respectively. Research and development expenses for the three and nine months ended September 30, 2021, included intangible asset-related charges of \$0.6 million and \$5.3 million, respectively, compared with \$10.0 million and \$15.0 million for the three and nine months ended September 30, 2020, respectively.

Research and development expenses fluctuate with project timing. Based upon our broader set of product development initiatives and the stage of the underlying projects, we expect to continue to make substantial investments in research and development and anticipate that research and development expenses will continue to increase in the future.

Interest and Other Income, Net

Interest and other income, net, for the three and nine months ended September 30, 2021, was \$18.5 million, and \$65.5 million, respectively, compared with \$84.8 million, and \$136.5 million, for the three and nine months ended September 30, 2020, respectively. The decrease in interest and other income, net, for the three and nine months ended September 30, 2021, was primarily driven by lower unrealized gains on investments resulting from strategic arrangements, lower interest income earned, despite higher cash and investment balances, due to the decline in average interest rates, and gains on the sale of certain securities in the second quarter of 2020, partially offset by higher foreign exchange losses realized in the second quarter of 2020.

We held an equity investment in preferred shares of Broncus, which was reflected in our financial statements on a cost basis. In September 2021, Broncus completed an IPO. Upon completion of the IPO, the preferred shares were converted to common shares in Broncus, and we recognized a net gain on this investment in the third quarter of 2021 of approximately \$8 million. We are restricted from selling these shares for a period of six months. Additionally, during the first quarter of 2021, we recorded an unrealized gain on our investment in Broncus of approximately \$14 million.

We held an equity investment in preferred shares of InTouch, which was reflected in our financial statements on a cost basis. On July 1, 2020, Teladoc completed its acquisition of InTouch. Based on the terms of the agreement, we received Teladoc shares on the date of closing and recognized a gain on its investment in the third quarter of 2020 of approximately \$45 million.

Income Tax Expense

Income tax expense for the three months ended September 30, 2021, was \$73.9 million, or 16.0% of income before taxes, compared to \$38.4 million, or 10.8% of income before taxes, for the three months ended September 30, 2020. Income tax expense for the nine months ended September 30, 2021, was \$90.7 million, or 6.3% of income before taxes, compared to \$67.3 million, or 8.7% of income before taxes, for the nine months ended September 30, 2020.

Our effective tax rate for the three and nine months ended September 30, 2021, and 2020, differs from the U.S. federal statutory rate of 21% primarily due to excess tax benefits associated with employee equity plans, the effect of income earned by certain overseas entities being taxed at rates lower than the federal statutory rate, and federal R&D credit benefit, partially offset by U.S. tax on foreign earnings and state income taxes (net of federal benefit).

Our effective tax rate for the nine months ended September 30, 2021, included a one-time benefit of \$66.4 million from re-measurement of our Swiss deferred tax assets resulting from the extension of the economic useful life of certain intangible assets. Our effective tax rate for the nine months ended September 30, 2020, reflected a one-time increase of \$36.8 million in unrecognized tax benefits with a corresponding increase to income tax expense. This increase was related to intercompany charges for share-based compensation for relevant periods prior to 2020, triggered by the finalization of a Ninth Circuit Court of Appeals opinion involving an independent third party. An additional charge of \$11.1 million related to this matter was recorded to income tax expense for the three and nine months ended September 30, 2021, as a result of additional IRS guidance issued in July 2021.

Our provision for income taxes for the three and nine months ended September 30, 2021, included excess tax benefits associated with employee equity plans of \$41.9 million and \$158.9 million, which reduced our effective tax rate by 9.1 and 11.1 percentage points, respectively. Our provision for income taxes for the three and nine months ended September 30, 2020, included excess tax benefits associated with employee equity plans of \$47.9 million and \$144.8 million, which reduced our effective tax rate by 13.5 and 18.8 percentage points, respectively. The amount of excess tax benefits or deficiencies will fluctuate from period to period based on the price of our stock, the volume of share-based instruments settled or vested, and the value assigned to employee equity awards under U.S. GAAP, which results in increased income tax expense volatility.

We file federal, state, and foreign income tax returns in many U.S. and OUS jurisdictions. Years before 2016 are closed for the significant jurisdictions. Certain of our unrecognized tax benefits could change due to activities of various tax authorities, including evolving interpretations of existing tax laws in the jurisdictions we operate, potential assessment of additional tax, possible settlement of audits, or through normal expiration of various statutes of limitations, which could affect our effective tax rate in the period in which they change. Due to the uncertainty related to the timing and potential outcome of audits, we cannot estimate the range of reasonably possible change in unrecognized tax benefits that may occur in the next 12 months.

We are subject to the examination of our income tax returns by the IRS and other tax authorities. The outcome of these audits cannot be predicted with certainty. Management regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes. If any issues addressed in our tax audits are resolved in a manner not consistent with management's expectations, we could be required to adjust our provision for income taxes in the period such resolution occurs.

Net Income Attributable to Noncontrolling Interest in Joint Venture

Net income attributable to noncontrolling interest in Joint Venture for the three and nine months ended September 30, 2021, was \$6.7 million and \$21.4 million, respectively. Net income attributable to noncontrolling interest in Joint Venture for the three and nine months ended September 30, 2020, was \$2.9 million and \$7.8 million, respectively. The increase in net income attributable to noncontrolling interest in Joint Venture was primarily due to increased sales in China during the three and nine months ended September 30, 2021, as well as re-measurement losses related to contingent consideration during the three and nine months ended September 30, 2020, which did not recur in the same periods of 2021 as the contingent consideration has been finalized and paid.

Liquidity and Capital Resources

Sources and Uses of Cash

Our principal source of liquidity is cash provided by operations and by the issuance of common stock through the exercise of stock options and our employee stock purchase program. Cash and cash equivalents plus short- and long-term investments increased by \$1.35 billion to \$8.22 billion as of September 30, 2021, from \$6.87 billion as of December 31, 2020, primarily from cash provided by our operations and proceeds from stock option exercises and employee stock purchases, partially offset by capital expenditures and taxes paid related to net share settlements of equity awards.

Our cash requirements depend on numerous factors, including market acceptance of our products, the resources we devote to developing and supporting our products, and other factors. We expect to continue to devote substantial resources to expand procedure adoption and acceptance of our products. We have made substantial investments in our commercial operations, product development activities, facilities, and intellectual property. Based upon our business model, we anticipate that we will continue to be able to fund future growth through cash provided by our operations. We believe that our current cash, cash equivalents, and investment balances, together with income to be derived from the sale of our products, will be sufficient to meet our liquidity requirements for the foreseeable future.

See "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in our Form 10-K for the fiscal year ended December 31, 2020, for discussion on the impact of interest rate risk and market risk on our investment portfolio.

Condensed Consolidated Cash Flow Data

The following table summarizes our cash flows for the nine months ended September 30, 2021, and 2020 (in millions):

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by (used in)		
Operating activities	\$ 1,521.7	\$ 857.3
Investing activities	(1,820.5)	(606.3)
Financing activities	24.4	(45.9)
Effect of exchange rates on cash, cash equivalents, and restricted cash	(2.3)	(2.0)
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (276.7)</u>	<u>\$ 203.1</u>

Operating Activities

For the nine months ended September 30, 2021, net cash provided by operating activities of \$1,522 million exceeded our net income of \$1,345 million, primarily due to the following reasons:

1. Our net income included non-cash charges of \$534 million, consisting primarily of the following significant items: share-based compensation of \$331 million; depreciation expense and losses on the disposal of property, plant, and equipment of \$209 million; changes in deferred income taxes of \$(41) million; and amortization of intangible assets of \$21 million.
2. The non-cash charges outlined above were partially offset by changes in operating assets and liabilities that resulted in \$357 million of cash used by operating activities during the nine months ended September 30, 2021. Prepaid expenses and other assets increased by \$217 million, primarily due to an increase in prepaid taxes, driven by the timing of tax payments, and an increase in leasing. Inventory, including the effect of systems inventory built and transferred to property, plant, and equipment as a result of systems placed under operating lease and usage-based arrangements, increased by \$189 million, primarily to address the growth in the business as well as to mitigate risks of disruption that could arise from trade, supply, or other matters. Refer to further details in the supplemental cash flow information in Note 4 to the Condensed Consolidated Financial Statements (Unaudited) included in Item 1, Part I. Accounts receivable increased by \$55 million, primarily due to the timing of collections. The unfavorable impact of these items on cash provided by operating activities was partially offset by a \$36 million increase in accounts payable, primarily due to the timing of payments and vendor billings, a \$35 million increase in other liabilities, primarily due to the timing of payments, and a \$30 million increase in accrued compensation and employee benefits, primarily due to higher headcount and variable compensation.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2021, consisted primarily of purchases of investments (net of proceeds from sales and maturities of investments) of \$1,609 million, the acquisition of property and equipment of \$203 million, and the acquisition of a business, net of cash acquired, of \$9 million. We invest predominantly in high quality, fixed income securities. Our investment portfolio may, at any time, contain investments in U.S. treasury and U.S. government agency securities, taxable and tax-exempt municipal notes, corporate notes and bonds, commercial paper, non-U.S. government agency securities, cash deposits, and money market funds.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2021, consisted primarily of proceeds from stock options and exercises and employee stock purchases of \$245 million, partially offset by taxes paid on behalf of employees related to net share settlements of vested employee stock purchases of \$201 million and the payment of deferred purchase consideration from prior acquisitions of \$19 million.

Capital Expenditures

Our business is not capital equipment intensive. However, with the growth of our business and our investments in property and facilities and in manufacturing automation, capital investments in these areas have increased. We expect these capital investments to exceed \$300 million in 2021 and increase further in 2022. We intend to fund these needs with cash generated from operations.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations are based upon our Financial Statements, which have been prepared in accordance with U.S. GAAP. The preparation of these Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses. On an ongoing basis, we evaluate our critical accounting estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no new or material changes to the critical accounting estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, that are of significance, or potential significance, to us.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the nine months ended September 30, 2021, compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information included in Note 8 to the Condensed Consolidated Financial Statements (Unaudited) included in Part I, Item 1 of this quarterly report is incorporated herein by reference.

ITEM 1A. RISK FACTORS

You should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which could materially affect our business, financial position, or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial position, or future results of operations. The risk factors set forth below update, and should be read together with, the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

RISKS RELATING TO OUR BUSINESS

OUR RELIANCE ON SOLE AND SINGLE SOURCE SUPPLIERS AND OUR ABILITY TO PURCHASE AT ACCEPTABLE PRICES A SUFFICIENT AMOUNT OF MATERIALS, PARTS, AND COMPONENTS COULD HARM OUR ABILITY TO MEET DEMAND FOR OUR PRODUCTS IN A TIMELY MANNER OR WITHIN BUDGET.

Some of the components necessary for the assembly of our products are currently provided to us by sole-sourced suppliers or single-sourced suppliers. We generally purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and could be identified for single-sourced components, the disruption or termination of the supply of components, or inflationary pressure in our supply chain, could cause a significant increase in the costs of these components, which could affect our operating results. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction, and damage our reputation and our brand. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The time and processes associated with the verification of a new manufacturer could delay our ability to manufacture our products on schedule or within budget, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

In addition, our ability to meet customers’ demands depends, in part, on our ability to timely obtain an adequate delivery of quality materials, parts, and components from our suppliers. An information technology systems interruption, including cybersecurity attacks, could adversely affect the ordering, distribution, and manufacturing processes of our suppliers. Difficulties in obtaining a sufficient amount of semiconductor and other component materials continue to increase, and we expect such difficulties to persist in the foreseeable future. Prices of such materials have also increased, and global supply has become significantly constrained due to the increased demand for materials, including semiconductors, to support expansion of server and cloud networks as a greater proportion of the global population worked remotely, the introduction of 5G, and the continued electrification of vehicles. We engage in activities to seek to mitigate such supply disruptions by, for example, increasing our communications with our suppliers and modifying our purchase order coverage and inventory levels. However, notwithstanding these activities, the global semiconductor and materials supply shortage is likely to remain a challenge for the foreseeable future. Such global shortages in important components have resulted in, and will continue to cause, inflationary pressure in our supply chain, which would impact our profits and profit margin. If shortages and price increases in important supply-chain materials in the semiconductor or other markets continue, we could also fail to meet product demand, which would adversely impact our business, financial condition, results of operations, or cash flows.

DISRUPTION OF CRITICAL INFORMATION SYSTEMS OR MATERIAL BREACHES IN THE SECURITY OF OUR SYSTEMS COULD HARM OUR BUSINESS, CUSTOMER RELATIONS, AND FINANCIAL CONDITION.

Information technology helps us serve and interface with customers, maintain our supply chain and manufacturing operations, operate effectively and efficiently, maintain financial accuracy and efficiency, and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions or the unauthorized access to, loss of, or damage to intellectual property, confidential information, or personally identifiable information (“PII”). If our data management systems do not effectively collect, store, process, and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, security incidents, or human error, our ability to effectively plan, forecast, and execute our business plan and comply with applicable laws and

regulations would be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows, and the timeliness with which we report our internal and external operating results.

Our business requires us to use and store customer, employee, and business partner PII. This may include names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers, and payment account information. We require user names and passwords in order to access our information technology systems. We also use encryption and authentication technologies to secure the transmission and storage of data. These security measures may be compromised as a result of security breaches by unauthorized persons, employee error, malfeasance, faulty password management, or other irregularity and result in persons obtaining unauthorized access to our data or accounts. Third parties may attempt to fraudulently induce employees or customers into disclosing user names, passwords, or other sensitive information, which may in turn be used to access our information technology systems. For example, our employees have received “phishing” emails and phone calls attempting to induce them to divulge passwords and other sensitive information.

In addition, unauthorized persons may attempt to hack into our products or systems to obtain personal data relating to patients or employees, our confidential or proprietary information, or confidential information we hold on behalf of third parties. If the unauthorized persons successfully hack into or interfere with our connected products or services, they may create issues with product functionality that could pose a risk of loss of data, a risk to patient safety, and a risk of product recall or field activity, which could adversely impact our business and reputation. We have programs in place to detect, contain, and respond to data security incidents, and we make ongoing improvements to our information-sharing products in order to minimize vulnerabilities, in accordance with industry and regulatory standards. However, because the techniques used to obtain unauthorized access to or steal PII or intellectual property, or sabotage systems containing PII or intellectual property, change frequently and may be difficult to detect, we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur.

We also rely on external vendors to supply and/or support certain aspects of our information technology systems. The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise information security of our own systems, and we are dependent on these third parties to deploy appropriate security programs to protect their systems. In addition to potential exposure to data breaches, security incidents, or other actions that may compromise the security of or interfere with the function of our systems, defects or vulnerabilities in the software or systems of our external vendors may expose failures in our internal controls and risk management processes, which may adversely impact our business, financial condition, results of operations, or cash flows and may also harm our reputation, brand, and customer relationships.

While we devote significant resources to network security, data encryption, and other security measures to protect our systems and data, these security measures cannot provide absolute security. We may experience a breach of our systems and may be unable to protect PII, confidential, or sensitive data. It is possible for such vulnerabilities to remain undetected for an extended period, including several years or longer. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, ransomware and other malicious software programs, and security vulnerabilities could be significant. Our efforts to address these problems may not be successful and could result in unexpected interruptions, delays, cessation of service, and harm to our business operations. Moreover, if a computer security breach affects our systems or results in the unauthorized release of PII, our reputation and brand could be materially damaged, and use of our products and services could decrease. We would also be exposed to a risk of loss, litigation and potential liability, and regulatory scrutiny, which could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

There were no unregistered sales of equity securities during the period covered by this report.

(c) Issuer Purchases of Equity Securities

The table below summarizes our stock repurchase activity for the quarter ended September 30, 2021.

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Purchased As Part of a Publicly Announced Program	Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program (1)
July 1 to July 31, 2021	—	\$ —	—	\$ 1.6 billion
August 1 to August 31, 2021	—	\$ —	—	\$ 1.6 billion
September 1 to September 30, 2021	—	\$ —	—	\$ 1.6 billion
Total during quarter ended September 30, 2021	—	\$ —	—	—

(1) Since March 2009, we have had a stock repurchase program in place. As of September 30, 2021, our Board of Directors (the “Board”) had authorized an aggregate amount of up to \$7.5 billion for stock repurchases, of which the most recent authorization occurred in January 2019, when the Board increased the authorized amount available under our share repurchase program to \$2.0 billion. The remaining \$1.6 billion represents the amount available to repurchase shares under the authorized repurchase program as of September 30, 2021. The authorized stock repurchase program does not have an expiration date.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
	Amended and Restated Certificate of Incorporation of Intuitive Surgical, Inc., as amended.
	Amended and Restated Bylaws of Intuitive Surgical, Inc. (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2021).
	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	The following materials from Intuitive Surgical, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Inline XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Comprehensive Income, (iii) the unaudited Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements (unaudited), tagged at Level I through IV.
	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Inline XBRL and contained in Exhibit 101.

**CERTIFICATE OF AMENDMENT TO
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
INTUITIVE SURGICAL, INC.**

Intuitive Surgical, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify that:

FIRST: Paragraph (A) of Article IV of the Amended and Restated Certificate of Incorporation is hereby amended to read in its entirety as follows:

"A. Classes of Stock. This corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the corporation is authorized to issue is six hundred two million five hundred thousand (602,500,000) shares, of which six hundred million (600,000,000) shares shall be Common Stock, par value \$0.001 per share, and two million five hundred thousand (2,500,000) shares shall be Preferred stock, par value \$0.001 per share. At the effective time of this Certificate of Amendment, each issued and outstanding share of the corporation's Common Stock shall be divided into three (3) validly issued, fully paid and non-assessable shares of Common Stock reflecting a three (3) for one (1) stock split (the "Stock Split"). The Stock Split shall occur without any further action on the part of the corporation or the holders of shares of Common Stock and whether or not certificates representing such holders' shares prior to the Stock Split are surrendered for cancellation."

SECOND: The said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed and made effective as of this 27th day of September 2021.

By:

Siang Chin

Vice President, Assistant General Counsel, and Corporate Secretary

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gary S. Guthart, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Intuitive Surgical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By:

/s/ GARY S. GUTHART

Gary S. Guthart, Ph.D.
President and Chief Executive Officer

Date: October 20, 2021

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Marshall L. Mohr, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Intuitive Surgical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By:

/s/ MARSHALL L. MOHR

Marshall L. Mohr

Executive Vice President and Chief Financial Officer

Date: October 20, 2021

Certification of Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 20, 2021

By:

/s/ GARY S. GUTHART

Gary S. Guthart, Ph.D.
President and Chief Executive Officer

Certification of Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 20, 2021

By:

/s/ MARSHALL L. MOHR

Marshall L. Mohr
Executive Vice President and Chief Financial Officer