

INTUITIVE SURGICAL INC
Form 10-Q
October 21, 2015
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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, 2015

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)
1020 Kifer Road
Sunnyvale, California 94086
(Address of principal executive offices) (Zip Code)
(408) 523-2100
(Registrant's telephone number, including area code)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller Reporting company

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 37,365,210 shares of Common Stock, \$0.001 par value per share, outstanding as of October 15, 2015.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INTUITIVE SURGICAL, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

in millions (except par values)	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$868.2	\$600.3
Short-term investments	871.5	632.2
Accounts receivable, net	334.7	315.1
Inventories	194.0	181.7
Prepays and other current assets	102.7	82.6
Deferred tax assets	27.7	35.1
Total current assets	2,398.8	1,847.0
Property, plant and equipment, net	427.3	387.4
Long-term investments	1,385.5	1,264.5
Long-term deferred tax assets	139.6	136.2
Intangible and other assets, net	130.0	126.3
Goodwill	201.1	198.0
Total assets	\$4,682.3	\$3,959.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$58.0	\$61.6
Accrued compensation and employee benefits	90.4	96.2
Deferred revenue	225.0	216.6
Other accrued liabilities	105.2	126.8
Total current liabilities	478.6	501.2
Other long-term liabilities	88.5	78.8
Total liabilities	567.1	580.0
Contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of September 30, 2015, and December 31, 2014	—	—
Common stock, 100.0 shares authorized, \$0.001 par value, 37.3 shares and 36.6 shares issued and outstanding as of September 30, 2015, and December 31, 2014, respectively	—	—
Additional paid-in capital	3,332.2	2,896.8
Retained earnings	785.7	487.7
Accumulated other comprehensive loss	(2.7) (5.1
Total stockholders' equity	4,115.2	3,379.4
Total liabilities and stockholders' equity	\$4,682.3	\$3,959.4
See accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).		

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

in millions (except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Product	\$472.3	\$441.6	\$1,363.3	\$1,208.0
Service	117.4	108.5	344.6	319.0
Total revenue	589.7	550.1	1,707.9	1,527.0
Cost of revenue:				
Product	155.3	150.3	468.9	397.6
Service	38.6	39.2	119.9	109.0
Total cost of revenue	193.9	189.5	588.8	506.6
Gross profit	395.8	360.6	1,119.1	1,020.4
Operating expenses:				
Selling, general and administrative	154.9	154.0	480.2	531.0
Research and development	51.0	47.5	144.8	130.7
Total operating expenses	205.9	201.5	625.0	661.7
Income from operations	189.9	159.1	494.1	358.7
Interest and other income, net	3.7	2.0	12.6	5.5
Income before taxes	193.6	161.1	506.7	364.2
Income tax expense	26.3	37.4	107.9	92.2
Net income	\$167.3	\$123.7	\$398.8	\$272.0
Net income per share:				
Basic	\$4.49	\$3.43	\$10.78	\$7.33
Diluted	\$4.40	\$3.35	\$10.55	\$7.18
Shares used in computing net income per share:				
Basic	37.3	36.1	37.0	37.1
Diluted	38.0	36.9	37.8	37.9
Total comprehensive income	\$171.0	\$124.5	\$401.2	\$271.3

See accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).

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

	Nine Months Ended September 30,	
in millions	2015	2014
Operating activities:		
Net income	\$398.8	\$272.0
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	46.3	38.2
Amortization of intangible assets	18.6	15.9
Loss on investments, accretion of discounts and amortization of premiums on investments, net	18.5	23.8
Deferred income taxes	2.8	(40.2)
Income tax benefits from employee stock plans	24.2	7.7
Excess tax benefit from employee stock plans	(33.2)	(15.2)
Share-based compensation expense	126.6	127.8
Changes in operating assets and liabilities, net of effects of acquisitions:		
Accounts receivable	(19.7)) 42.4
Inventories	(30.7)) (40.5)
Prepays and other assets	(41.1)) (69.4)
Accounts payable	(8.4)) 8.2
Accrued compensation and employee benefits	(5.1)) 2.8
Deferred revenue	7.6	17.6
Other liabilities	(16.7)) 79.8
Net cash provided by operating activities	488.5	470.9
Investing activities:		
Purchase of investments	(1,128.2)) (1,003.5)
Proceeds from sales of investments	177.6	623.2
Proceeds from maturities of investments	575.5	553.2
Purchase of property, plant and equipment, and acquired intellectual property	(61.3)) (40.4)
Acquisition of business, net of cash acquired	—	(82.9)
Net cash provided by (used in) investing activities	(436.4)) 49.6
Financing activities:		
Proceeds from issuance of common stock relating to employee stock plans	294.0	176.0
Excess tax benefit from employee stock plans	33.2	15.2
Taxes paid related to net share settlement of equity awards	(10.5)) —
Repurchase and retirement of common stock	(99.5)) (1,000.0)
Net cash provided by (used in) financing activities	217.2	(808.8)
Effect of exchange rate changes on cash and cash equivalents	(1.4)) (0.8)
Net increase (decrease) in cash and cash equivalents	267.9	(289.1)
Cash and cash equivalents, beginning of period	600.3	782.1
Cash and cash equivalents, end of period	\$868.2	\$493.0
See accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).		

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

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

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. designs, manufactures, and markets da Vinci® Surgical Systems and related instruments and accessories, which taken together, are advanced surgical systems that the Company believes enable a new generation of surgery. This advanced generation of surgery, which the Company calls da Vinci Surgery, combines the benefits of minimally invasive surgery (“MIS”) for patients with the ease of use, precision, and dexterity of open surgery. A da Vinci Surgical System consists of a surgeon’s console, a patient-side cart, and a high performance vision system. The da Vinci Surgical System translates a surgeon’s natural hand movements, which are performed on instrument controls at a console, into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. The da Vinci Surgical System is designed to provide its operating surgeons with intuitive control, range of motion, fine tissue manipulation capability, and Three Dimensional (“3-D”) High-Definition (“HD”) vision while simultaneously allowing surgeons to work through the small ports enabled by MIS procedures.

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-owned subsidiaries have been prepared on a consistent basis with the audited Consolidated Financial Statements for the fiscal year ended December 31, 2014, 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 accounting principles generally accepted in the United States (“U.S.”) (“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, 2014, which was filed with the SEC on February 5, 2015. The results of operations for the first nine months of fiscal year 2015 are not necessarily indicative of the results to be expected for the entire fiscal year or any future periods.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Updates No. 2014-09, Revenue from Contracts with Customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. In August 2015, the FASB issued an update to defer the effective date of this update by one year. The updated standard becomes effective for the Company in the first quarter of fiscal year 2018, but allows the Company to adopt the standard one year earlier if it so chooses. The Company has not yet selected a transition method and is currently evaluating the effect that the updated standard will have on its Consolidated Financial Statements and related disclosures, and is therefore unable to determine the impact on the Company's financial statements.

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, 2014 that are of significance, or potential significance to the Company.

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NOTE 3. FINANCIAL INSTRUMENTS

Cash, Cash Equivalents and Investments

The following tables summarize the Company's cash and available-for-sale securities' amortized cost, gross unrealized gains, gross unrealized losses, and fair value by significant investment category recorded as cash and cash equivalents, short-term, or long-term investments as of September 30, 2015, and December 31, 2014 (in millions):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short- term Investments	Long- term Investments
September 30, 2015							
Cash	\$188.5	\$—	\$—	\$188.5	\$188.5	\$—	\$—
Level 1:							
Money market funds	542.1	—	—	542.1	542.1	—	—
U.S. treasuries & corporate equity securities	127.1	0.2	(0.7)	126.6	—	60.5	66.1
Subtotal	669.2	0.2	(0.7)	668.7	542.1	60.5	66.1
Level 2:							
Commercial paper	223.0	—	—	223.0	64.9	158.1	—
Corporate securities	955.6	2.2	(0.6)	957.2	—	340.8	616.4
U.S. government agencies	509.6	0.9	—	510.5	62.7	192.5	255.3
Non-U.S. government securities	28.8	—	—	28.8	—	10.3	18.5
Municipal securities	546.9	1.6	—	548.5	10.0	109.3	429.2
Subtotal	2,263.9	4.7	(0.6)	2,268.0	137.6	811.0	1,319.4
Total assets measured at fair value	\$3,121.6	\$4.9	\$(1.3)	\$3,125.2	\$868.2	\$871.5	\$1,385.5
December 31, 2014							
Cash	\$227.7	\$—	\$—	\$227.7	\$227.7	\$—	\$—
Level 1:							
Money market funds	324.4	—	—	324.4	324.4	—	—
U.S. treasuries & corporate equity securities	46.1	—	(0.1)	46.0	—	19.3	26.7
Subtotal	370.5	—	(0.1)	370.4	324.4	19.3	26.7
Level 2:							
Commercial paper	120.5	—	—	120.5	48.2	72.3	—
Corporate securities	904.8	1.3	(1.6)	904.5	—	241.7	662.8
U.S. government agencies	446.0	0.3	(0.4)	445.9	—	105.6	340.3
Non-U.S. government securities	42.2	—	(0.1)	42.1	—	26.1	16.0
Municipal securities	385.4	0.7	(0.2)	385.9	—	167.2	218.7
Subtotal	1,898.9	2.3	(2.3)	1,898.9	48.2	612.9	1,237.8
Total assets measured at fair value	\$2,497.1	\$2.3	\$(2.4)	\$2,497.0	\$600.3	\$632.2	\$1,264.5

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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, 2015 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	\$1,006.9	\$1,007.6
Mature in one to five years	1,379.4	1,383.0
Mature in five to ten years	2.5	2.5
Total	\$2,388.8	\$2,393.1

Realized gains and losses, recognized on the sale of investments, were not material for any of the periods presented. There were no transfers between Level 1 and Level 2 measurements during the nine months ended September 30, 2015, and there were no changes in the valuation techniques used by the Company.

Foreign Currency Derivatives

The objective of the Company's hedging program is to mitigate the impact of changes in currency exchange rates on cash flow from foreign currency denominated sales, expenses, and 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 USD, primarily the European 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.

For these derivatives, the Company reports the after-tax gain or loss from the hedge as a component of accumulated other comprehensive loss in stockholders' equity and reclassifies it into earnings in the same period in which the hedged transaction affects earnings. The gains reclassified to revenue related to the hedged transactions were \$0.6 million and \$5.1 million for the three and nine months ended September 30, 2015, and \$1.7 million and \$2.2 million for the three and nine months ended September 30, 2014. The amounts reclassified to expenses related to the hedged transactions were not material for the three and nine months ended September 30, 2015, and 2014.

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, and the Swiss Franc ("CHF"). The net gains (losses) recognized in interest and other income, net in the condensed consolidated statements of comprehensive income for the three and nine months ended September 30, 2015, and 2014, were not material.

The notional amounts for derivative instruments provide one measure of the transaction volume. Total gross notional amounts (in USD) for outstanding derivatives and 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, 2015	December 31, 2014	September 30, 2015	December 31, 2014
Notional amounts:				
Forward contracts	\$114.1	\$7.9	\$100.7	\$102.1
Gross fair value recorded in:				
Prepaid and other current assets	\$1.6	\$1.1	\$1.2	\$7.9
Other accrued liabilities	\$0.4	\$—	\$0.4	\$0.1

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NOTE 4. BALANCE SHEET DETAILS AND OTHER FINANCIAL INFORMATION

Inventories

The following table provides further details of inventories (in millions):

	September 30, 2015	December 31, 2014
Raw materials	\$58.7	\$60.0
Work-in-process	8.0	8.7
Finished goods	127.3	113.0
Total inventories	\$194.0	\$181.7

Supplemental Cash Flow Information

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

	Nine Months Ended September 30,	
	2015	2014
Equipment transfers from inventories to property, plant and equipment	\$19.9	\$23.8

NOTE 5. LEASE RECEIVABLES

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

	As of	
	September 30, 2015	December 31, 2014
Gross lease receivable	\$64.7	\$40.4
Unearned income	(3.4) (2.2
Allowance for credit loss	(0.4) —
Net investment in sales-type leases	60.9	38.2
Reported as:		
Prepays and other current assets	14.3	5.8
Intangible and other assets, net	46.6	32.4
Total, net	\$60.9	\$38.2

Contractual maturities of gross lease receivables at September 30, 2015, are as follows (in millions):

	Amount
2015	\$3.2
2016	16.8
2017	16.9
2018	15.8
2019	8.1
Thereafter	3.9
Total	\$64.7

NOTE 6. CONTINGENCIES

The Company is involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, insurance, and contract disputes. 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. As of September 30, 2015, with the

exception of the tolled product liability claims described below, the Company has determined that a loss is not probable or that a range of probable losses related to material pending or threatened litigation matters cannot be reasonably estimated. It is possible that future legal costs (including settlements,

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judgments, legal fees, and other related legal costs) could have a material adverse effect on the Company's business, financial position, or future results of operations.

The Company is also a party to various other legal actions that arise in the ordinary course of business and does not believe that any of these other legal actions will have a material adverse impact on the Company's business, financial position, or future results of operations.

In accordance with U.S. GAAP, the Company records a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impact of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to each case.

Purported Shareholder Class Action Lawsuits Filed April 26, 2013, and May 24, 2013

On April 26, 2013, a purported class action lawsuit entitled *Abrams v. Intuitive Surgical, et al.*, No. 5-13-cv-1920, was filed against a number of the Company's current and former officers and directors in the United States District Court for the Northern District of California. A substantially identical complaint, entitled *Adel v. Intuitive Surgical, et al.*, No. 5:13-cv-02365, was filed in the same court against the same defendants on May 24, 2013. The *Adel* case was voluntarily dismissed without prejudice on August 20, 2013.

On October 15, 2013, plaintiffs in the *Abrams* matter filed an amended complaint. The case has since been re-titled *In re Intuitive Surgical Securities Litigation*, No. 5:13-cv-1920. The plaintiffs seek unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired the Company's common stock between February 6, 2012, and July 18, 2013. The amended complaint alleges that the defendants violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in certain public statements and in the Company's filings with the SEC. On November 18, 2013, the court appointed the Employees' Retirement System of the State of Hawaii as lead plaintiff and appointed lead counsel. The Company filed a motion to dismiss the amended complaint on December 16, 2013, which was granted in part and denied in part on August 21, 2014. The plaintiffs elected not to further amend their complaint. On October 22, 2014, the court granted the Company's motion for leave to file a motion for reconsideration of the court's August 21, 2014, order. The Company filed its motion for reconsideration on November 5, 2014, the plaintiffs filed their opposition on November 19, 2014, and the Company filed its reply on November 26, 2014. The court denied the motion for reconsideration on December 15, 2014, and discovery is ongoing. The plaintiffs moved for class certification on September 1, 2015, and the Company filed its opposition to class certification on October 15, 2015. The case is moving forward on the claims that remain. No trial date has been set. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Purported Derivative Actions Filed on February 3, 2014, February 21, 2014, March 21, 2014, June 3, 2014, and March 5, 2015

On February 3, 2014, an alleged stockholder, Robert Berg, caused a purported stockholder's derivative lawsuit entitled *Berg v. Guthart et al.*, No. 4:14-CV-00515, to be filed in the United States District Court for the Northern District of California. The lawsuit names the Company as a nominal defendant and names a number of the Company's current and former officers and directors as defendants. The lawsuit seeks to recover, for the Company's benefit, unspecified damages purportedly sustained by the Company in connection with allegedly misleading statements and/or omissions made in connection with the Company's financial reporting for the period between 2012 and early 2014. It also seeks a series of changes to the Company's corporate governance policies and an award of attorneys' fees. On April 3, 2014, the case was related to *In re Intuitive Surgical Securities Litigation*. On July 30, 2014, the court granted Berg's motion to be appointed lead plaintiff, denied the City of Birmingham's motion seeking such appointment (see below for additional description), and re-titled the matter *In re Intuitive Surgical, Inc. Shareholder Derivative Litigation*, No. 4:14-CV-00515. On August 13, 2014, the plaintiffs filed a consolidated complaint, making allegations substantially similar to the allegations in the original complaint. On September 12, 2014, the Company filed a motion to dismiss the consolidated complaint. The plaintiff filed an opposition on October 9, 2014, and the Company filed its reply on October 30, 2014. The motion remains pending. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position

or future results of operations.

On February 21, 2014, a second alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled Public School Teachers' Pension and Retirement Fund of Chicago v. Guthart et al., No. CIV 526930, to be filed in the Superior Court of the State of California, County of San Mateo, against the same parties and seeking the same relief. On March 26, 2014, the case was removed to the United States District Court for the Northern District of California, where it was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart on April 30, 2014. The district court remanded the case back to San Mateo County Superior Court on June 30, 2014. On August 28, 2014, the Company filed a motion seeking to stay the case in favor of the federal action and asking that the plaintiff be required to post a bond because the action was duplicative and was not in the Company's best interests. On November 13, 2014, the superior court entered an order denying in part the Company's motion to stay and denying the Company's request for plaintiff's bond. On November 18, 2014, the Company petitioned the First

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Appellate District of the California, Court of Appeal for a writ of mandate directing the superior court to stay the case in its entirety. At the same time, the Company requested an immediate stay of proceedings pending resolution of the petition. On November 19, 2014, the court of appeal granted the Company's request for an immediate stay and set a briefing schedule for the petition. The plaintiff filed its opposition to the petition on December 8, 2014, and the Company filed its reply on December 22, 2014. The petition was denied on January 8, 2015. On January 20, 2015, the Company demurred (moved to dismiss) the complaint. The plaintiff filed its opposition to the demurrer on February 10, 2015, and the Company filed its reply on February 20, 2015. A hearing was held on February 27, 2015, and the court overruled the demurrer on March 27, 2015. The court's order was entered on April 2, 2015, and the case is moving forward. On June 19, 2015, the Company moved for summary judgment, and a hearing on the Company's motion was set for September 4, 2015. On July 6, 2015, the court amended the case schedule, and the Company withdrew its motion for summary judgment. The new deadline for the Company to move for summary judgment is October 22, 2015 and the Company plans to file a motion to move forward on the same day. Trial is currently set for February 2016. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations. On March 21, 2014, a third alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Birmingham Relief and Retirement System v. Guthart et al., No. 5-14-CV-01307, to be filed in the United States District Court for the Northern District of California against the same parties and seeking the same relief. On April 8, 2014, the lawsuit was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart. On July 30, 2014, the court consolidated the case with Berg v. Guthart and, as noted above, granted Berg's motion to be appointed lead plaintiff and denied the City of Birmingham's motion seeking such appointment. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

On June 3, 2014, a fourth alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Plantation Police Officers' Employees' Retirement System v. Guthart et al., C.A. No. 9726-CB, to be filed in the Court of Chancery of the State of Delaware. The Company filed a motion to stay proceedings in favor of the earlier-filed stockholder derivative lawsuits pending in federal and state courts in California. In light of the Company's motion, the plaintiff agreed to a stay of all proceedings in the case in favor of the earlier-filed actions. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

On March 5, 2015, a fifth alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled Back v. Guthart et al., No. 3:15-CV-01037, to be filed in the United States District Court for the Northern District of California. On April 7, 2015, the lawsuit was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart. The Company filed a motion to dismiss the complaint on July 10, 2015. On August 13, 2015, the parties stipulated to a complete stay of the matter and the Court entered an order reflecting the stay on August 17, 2015. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Product Liability Litigation

The Company is currently named as a defendant in approximately 90 individual product liability lawsuits filed in various state and federal courts by plaintiffs who 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. The Company has also received a large number of product liability claims from plaintiffs' attorneys, many of which are subject to certain tolling agreements further discussed below. The Company has also been named as a defendant in a multi-plaintiff lawsuit filed in Missouri state court. On May 1, 2015, plaintiffs amended their complaint to add 25 additional plaintiffs. In total, plaintiffs seek damages on behalf of 45 patients who had da Vinci Surgeries in 20 different states.

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 has reached confidential settlements in many of the filed cases. With certain exceptions, including the Taylor case described below, the remaining filed cases generally are in the early stages of pretrial activity.

Plaintiffs' attorneys have engaged in well-funded national advertising efforts seeking patients dissatisfied with da Vinci Surgery. Among the allegations, a substantial number of claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor ("MCS") instruments that included an MCS tip cover accessory that was the subject of a market withdrawal in 2012 and MCS instruments that were the subject of a recall in 2013. The Company has received a significant

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number of claims from plaintiffs' attorneys that it believes are a result of these advertising efforts. In an effort to avoid the expense and distraction of defending multiple lawsuits, the Company entered into tolling agreements to pause the applicable statutes of limitations for these claims and engaged in confidential mediation efforts.

After an extended confidential mediation process with legal counsel for many of the claimants covered by the tolling agreements, the Company determined during the first quarter of 2014 that, while it denies any and all liability, in light of the costs and risks of litigation, settlement of certain claims may be appropriate. During the year ended December 31, 2014, the Company recorded pre-tax charges of \$82.4 million, of which \$77.0 million was recorded in the nine months ended September 30, 2014, to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements. During the nine months ended September 30, 2015, the Company recorded pre-tax charges of \$13.8 million, of which \$7.2 million was recorded in the first quarter of 2015 and \$6.6 million in the second quarter of 2015, related to these product liability claims. No charges were recorded during the three months ended September 30, 2015, and 2014.

The Company's estimate of the anticipated cost of resolving these claims is based on negotiations with attorneys for claimants who have participated in the mediation process. Nonetheless, it is possible that more claims will be made by additional individuals and that the claimants whose claims were not resolved through the mediation program, as well as those claimants who have not participated in mediations, will choose to pursue greater amounts in a court of law. Consequently, the final outcome of these claims is dependent on many variables that are difficult to predict and the ultimate cost associated with these product liability 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. As of September 30, 2015, and December 31, 2014, a total of \$29.9 million and \$49.5 million, respectively, were included in other accrued liabilities in the accompanying Condensed Consolidated Balance Sheets related to the tolled product liability claims.

In February 2011, the Company was named as a defendant in a product liability action that had originally been filed in Washington State Superior Court for Kitsap County against the healthcare providers and hospital involved in plaintiff's decedent's surgery (Josette Taylor, as Personal Representative of the Estate of Fred E. Taylor, deceased; and on behalf of the Estate of Fred E. Taylor v. Intuitive Surgical, Inc., No. 09-2-03136-5). In Taylor, plaintiff asserted wrongful death and product liability claims against the Company, generally alleging that the decedent died four years after surgery as a result of injuries purportedly suffered during the surgery, which was conducted with the use of the da Vinci Surgical System. The plaintiff in Taylor asserted that such injuries were caused, in whole or in part, by the Company's purported failure to properly train, warn, and instruct the surgeon. The lawsuit sought unspecified damages for past medical expenses, pain and suffering, loss of consortium as well as punitive damages. A trial commenced in the action on April 15, 2013. On May 23, 2013, the jury returned a defense verdict, finding that the Company was not negligent. Judgment was entered in the Company's favor on June 7, 2013. Subsequent to the verdict, the plaintiff filed a notice of appeal. That appeal was denied on July 7, 2015. As of the date of this filing, no further appeal has been filed.

Insurance Litigation

In October 2013, the Company was named as a defendant in an insurance action entitled Illinois Union Insurance Co. v. Intuitive Surgical, Inc., No. 3:13-cv-04863-JST, filed in the United States District Court for the Northern District of California. Plaintiff Illinois Union Insurance Co. seeks to rescind the Life Sciences Products-Completed Operations Liability Policy issued by plaintiff to the Company, which provides coverage for products liability claims first made against the Company during the policy period March 1, 2013 to March 1, 2014. In December 2013, the Company was named as a defendant in another insurance action entitled Navigators Specialty Insurance Co. v. Intuitive Surgical, Inc., No. 5:13-cv-05801-HRL, also filed in the Northern District of California. Plaintiff Navigators Insurance Co. alleges that the Follow Form Excess Liability Insurance Policy issued by plaintiff to the Company for product liability claims first made against the Company during the policy period March 1, 2013 to March 1, 2014, should be rescinded. These cases have been consolidated under docket number 3:13-cf-04863. Both plaintiffs generally allege that the Company did not disclose the existence of tolling agreements or the number of claimants incorporated within those

agreements, and allege that those agreements were material to plaintiffs' underwriting processes. The Company intends to vigorously defend these actions. On March 3, 2015, the Company filed a cross-complaint for breach of contract and declaratory judgment against Ironshore Specialty Insurance Co. based on Ironshore's failure to indemnify the Company for insured losses incurred in the defense and settlement of certain products liability claims brought against the Company involving the da Vinci Surgical System. On April 14, 2015, Ironshore filed an answer and counterclaim denying the allegations of the Company's cross-complaint and asserting counterclaims against the Company for declaratory judgment and breach of contract. Based on currently available information, the Company does not believe the resolution of these matters will have a material adverse effect on the Company's business, financial position, or future results of operations.

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NOTE 7. STOCKHOLDERS' EQUITY

Stock Repurchase Program

On January 29, 2015, the Company's Board of Directors (the "Board") authorized the Company to repurchase up to \$1.0 billion of the Company's outstanding common stock. As of September 30, 2015, the remaining amount of share repurchases authorized by the Board was approximately \$900.5 million.

The following table provides the share repurchase activities during the three and nine months ended September 30, 2015, and 2014 (in millions, except per share amounts):

	Three Months Ended		Nine Months Ended September	
	September 30,	2014	30,	2014
	2015		2015	2014
Shares repurchased	0.1	—	0.2	2.5
Average price per share	\$509.36	\$—	\$499.81	\$397.52
Value of shares repurchased	\$35.5	\$—	\$99.5	\$1,000.0

Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss), net of tax, for the three and nine months ended September 30, 2015, and 2014, are as follows (in millions):

	Three Months Ended September 30, 2015				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$0.8	\$ 2.3	\$ (6.2)	\$(3.3)	\$(6.4)
Other comprehensive income before reclassifications	1.1	0.4	2.9	—	4.4
Amounts reclassified from accumulated other comprehensive income	(0.7)	(0.1)	—	0.1	(0.7)
Net current-period other comprehensive income (loss)	0.4	0.3	2.9	0.1	3.7
Ending balance	\$1.2	\$ 2.6	\$ (3.3)	\$(3.2)	\$(2.7)
	Three Months Ended September 30, 2014				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$(0.1)	\$ 2.5	\$ 0.7	\$(2.5)	\$0.6
Other comprehensive income before reclassifications	6.4	(2.9)	(1.0)	—	2.5
Amounts reclassified from accumulated other comprehensive income	(1.7)	(0.1)	—	0.1	(1.7)
Net current-period other comprehensive income (loss)	4.7	(3.0)	(1.0)	0.1	0.8
Ending balance	\$4.6	\$ (0.5)	\$ (0.3)	\$(2.4)	\$1.4

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	Nine Months Ended September 30, 2015				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$1.1	\$ (0.2)	\$ (2.1)	\$ (3.9)	\$ (5.1)
Other comprehensive income before reclassifications	5.6	3.5	(1.2)	0.4	8.3
Amounts reclassified from accumulated other comprehensive income	(5.5)	(0.7)	—	0.3	(5.9)
Net current-period other comprehensive income (loss)	0.1	2.8	(1.2)	0.7	2.4
Ending balance	\$1.2	\$ 2.6	\$ (3.3)	\$ (3.2)	\$ (2.7)

	Nine Months Ended September 30, 2014				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$—	\$ 1.7	\$ 0.4	\$—	\$2.1
Other comprehensive income before reclassifications	6.8	(1.5)	(0.7)	(2.6)	2.0
Amounts reclassified from accumulated other comprehensive income	(2.2)	(0.7)	—	0.2	(2.7)
Net current-period other comprehensive income (loss)	4.6	(2.2)	(0.7)	(2.4)	(0.7)
Ending balance	\$4.6	\$ (0.5)	\$ (0.3)	\$ (2.4)	\$1.4

NOTE 8. SHARE-BASED COMPENSATION

In April 2015, the Company's shareholders approved an amended and restated 2010 Incentive Award Plan ("2010 Plan") to provide for an increase in the number of shares of common stock reserved for issuance from 4,850,000 to 6,250,000. In April 2015, the Board amended and restated the 2009 Employment Commencement Incentive Plan ("2009 Plan") to provide for an increase in the number of shares of common stock authorized for issuance from 1,155,000 to 1,455,000.

As of September 30, 2015, approximately 2.0 million shares of common stock were reserved for future issuance under the Company's stock plans. A maximum of 0.9 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, 2015, 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, 2014	5.0	\$ 395.85
Options granted	0.4	\$ 520.10
Options exercised	(0.8)	\$ 321.19
Options forfeited/expired	(0.2)	\$ 496.02
Balance at September 30, 2015	4.4	\$ 417.89

As of September 30, 2015, options to purchase an aggregate of 3.1 million shares of common stock were exercisable at a weighted-average price of \$392.34 per share.

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Restricted Stock Units Information

A summary of RSU activity for the nine months ended September 30, 2015, is presented as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2014	0.2	\$ 441.07
Granted	0.3	\$ 512.62
Vested	(0.1) \$ 436.27
Canceled	0.0	\$ 480.78
Unvested balance at September 30, 2015	0.4	\$ 485.73

During the nine months ended September 30, 2015, approximately 27,000 RSUs were canceled.

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (“ESPP”), employees purchased approximately 0.1 million shares for \$31.2 million and 0.1 million shares for \$29.4 million during the nine months ended September 30, 2015, and 2014, respectively.

Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three and nine months ended September 30, 2015, and 2014 (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of sales - products	\$6.2	\$5.1	\$16.9	\$14.1
Cost of sales - services	3.2	3.7	9.8	10.1
Total cost of sales	9.4	8.8	26.7	24.2
Selling, general and administrative	25.0	26.3	71.7	75.6
Research and development	9.8	10.1	28.2	28.1
Share-based compensation expense before income taxes	44.2	45.2	126.6	127.9
Income tax benefit	14.9	14.9	41.5	41.1
Share-based compensation expense after income taxes	\$29.3	\$30.3	\$85.1	\$86.8

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 Company’s ESPP. The weighted average estimated fair values of stock options, the rights to acquire stock granted, and the weighted average assumptions used in calculating those fair values were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2015	2014	2015	2014	
Stock Option Plans					
Risk free interest rate	1.6	% 1.6	% 1.6	% 1.5	%
Expected term (in years)	4.0	4.1	4.3	4.3	
Expected volatility	27	% 30	% 28	% 31	%
Weighted average fair value at grant date	\$127.14	\$121.04	\$131.44	\$121.85	
Employee Stock Purchase Plan					
Risk free interest rate	0.4	% 0.2	% 0.4	% 0.2	%
Expected term (in years)	1.2	1.2	1.2	1.3	
Expected volatility	31	% 33	% 31	% 33	%
Weighted average fair value at grant date	\$146.87	\$131.70	\$146.72	\$130.37	

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NOTE 9. INCOME TAXES

Income tax expense for the three months ended September 30, 2015, was \$26.3 million, or 13.6% of income before taxes, compared with \$37.4 million, or 23.2% of income before taxes for the three months ended September 30, 2014. Income tax expense for the nine months ended September 30, 2015, was \$107.9 million, or 21.3% of income before taxes, compared with \$92.2 million, or 25.3% of income before taxes for the nine months ended September 30, 2014. The Company's effective tax rates for these periods differ from the U.S. federal statutory rate of 35% due primarily to the effect of income earned by certain of the Company's overseas entities being taxed at rates lower than the federal statutory rate, partially offset by state income taxes. The effective tax rate for the three and nine months ended September 30, 2015, also reflected a \$29.3 million tax benefit due to a recent U.S. Tax Court opinion involving an independent third party, filed July 27, 2015. Based on the findings of the U.S. Tax Court, the Company was required to, and did, refund to its foreign subsidiary the share-based compensation element of certain intercompany charges made in prior periods. On an ongoing basis, share-based compensation will be excluded from intercompany charges. The effective tax rate for the nine months ended September 30, 2015, further reflected discrete benefits of approximately \$7.8 million, recorded in the second quarter of 2015, mainly related to net releases of unrecognized tax benefits in connection with the conclusion of tax audits in various tax jurisdictions. The Company intends to indefinitely reinvest outside the U.S. all of its undistributed foreign earnings that were not previously subject to U.S. tax.

The Company's effective tax rate for the three and nine months ended September 30, 2015, did not include the tax benefit from the U.S. federal Research and Development ("R&D") credit because the credit expired at the end of 2014. If the credit is reinstated retroactively, the tax benefit will be recorded as a discrete item in the period of reinstatement. The income tax provision for the three and nine months ended September 30, 2014, also did not include any federal R&D credit, because the 2014 credit was not retroactively reinstated until December 2014, and the credit for the full year was reflected in the fourth quarter of 2014.

As of September 30, 2015, the Company had total gross unrecognized tax benefits of approximately \$83.5 million compared with approximately \$75.5 million as of December 31, 2014, representing a net increase of approximately \$8.0 million for the nine months ended September 30, 2015. If recognized, these gross unrecognized tax benefits would reduce the effective tax rate in the period of recognition.

The Company files federal, state, and foreign income tax returns in many jurisdictions in the U.S. and abroad. Years prior to 2012 are considered closed for most significant jurisdictions. Certain of the Company's unrecognized tax benefits could reverse based on the normal expiration of various statutes of limitations, which could affect the Company's effective tax rate in the period in which they reverse.

The Company is subject to the examination of its income tax returns by various 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 the Company's provision for income taxes. If any issues addressed in the 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 10. NET INCOME PER SHARE

The following table presents the computation of basic and diluted net income per share for the three and nine months ended September 30, 2015, and 2014 (in millions, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net income	\$ 167.3	\$ 123.7	\$ 398.8	\$ 272.0
Denominator:				
Weighted-average shares outstanding used in basic calculation	37.3	36.1	37.0	37.1
Add: dilutive effect of potential common shares	0.7	0.8	0.8	0.8
	38.0	36.9	37.8	37.9

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Weighted-average shares used in computing diluted

net income per share

Net income per share:

Basic	\$4.49	\$3.43	\$10.78	\$7.33
Diluted	\$4.40	\$3.35	\$10.55	\$7.18

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Share-based compensation awards of approximately 1.5 million and 2.5 million weighted-average shares for the three months ended September 30, 2015, and 2014, respectively, and approximately 1.7 million and 3.0 million weighted-average shares for the nine months ended September 30, 2015, and 2014, respectively, were outstanding, but were not included in the computation of diluted net income per share because the effect of including such shares would have been anti-dilutive.

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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-owned subsidiaries.

This management's discussion and analysis of financial condition as of September 30, 2015, and results of operations for the three and nine months ended September 30, 2015, and 2014, 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, 2014.

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 or expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, 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 and our ability to finance operations from cash flows and similar matters and include 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 the following: the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its impact on hospital spending, reimbursement, insurance deductibles, and fees which will be levied on certain medical device revenues; decreases in hospital admissions and actions by payers to limit or manage surgical procedures; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions, or any dispute that may occur with any regulatory body; guidelines and recommendations in the health care 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; unanticipated manufacturing disruptions; the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; product liability and other litigation claims; adverse publicity regarding our Company and safety of our products and the adequacy of training; our ability to expand in foreign markets; 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, 2014, 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 statements. 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® Si HD Surgical System™, da Vinci® S HD Surgical System®, da Vinci® Si™, da Vinci® Xi™, da Vinci® Si-e™, da Vinci® SP™, EndoWrist®, EndoWrist® One™, EndoWrist Stapler 45, Single-Site®, Firefly™, InSite® and da Vinci® Connect® are trademarks of Intuitive Surgical, Inc.

Overview

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 the patient, 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 two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures, but has not yet been widely adopted for reconstructive surgeries.

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 conventional MIS. Surgeons using a da Vinci Surgical System operate while seated comfortably at a console viewing a Three Dimensional (“3-D”) representation of a High Definition (“HD”) image of the surgical field. This immersive visualization 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 the open surgery technique. Our technology is designed to provide surgeons with a range of motion of MIS instruments 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.

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Our products fall into four broad categories - the da Vinci Surgical Systems, InSite and Firefly Fluorescence imaging systems (“Firefly”), instruments and accessories (e.g., EndoWrist, EndoWrist One Vessel Sealer, da Vinci Single-Site and EndoWrist Stapler 45), and training technologies. We have commercialized four generations of da Vinci Surgical Systems: the first is our da Vinci standard Surgical System, commercialized in 1999, the second is our da Vinci S Surgical System, commercialized in 2006, the third is our da Vinci Si Surgical System, commercialized in 2009, and the fourth is our da Vinci Xi Surgical System, commercialized in the second quarter of 2014. Systems include a surgeon’s console (or consoles), imaging electronics, a patient-side cart, and computational hardware and software. da Vinci InSite imaging products provide surgeons with highly magnified, 3-D HD views of the patients’ anatomical structures during surgery. Our da Vinci Firefly products augment the white light images with real-time visualization and assessment of vessels, bile ducts, and tissue perfusion. Firefly products are available on the da Vinci Si and da Vinci Xi system platforms.

We offer over 65 different multiport da Vinci instruments enabling surgeons’ flexibility in choosing the types of tools needed in a particular surgery. These multiport instruments are generally robotically controlled versions of surgical tools that surgeons would use in either open or laparoscopic surgery. We offer our Single-Site instruments for use with the da Vinci Si Surgical System in cholecystectomy, benign hysterectomy, and salpingo-oophorectomy procedures. Single-Site instruments enable surgeons to also perform surgery through a single port via the patient’s belly button, resulting in the potential for virtually scarless results. We offer advanced energy instrumentation, including the EndoWrist One Vessel Sealer and EndoWrist Stapler 45 on the da Vinci Si and da Vinci Xi platforms to provide surgeons with sophisticated, computer-aided tools to precisely and efficiently interact with tissue.

Training technologies include our da Vinci Skills Simulator, da Vinci Connect remote case observation and mentoring tool, and our dual console for use in surgeon proctoring and collaborative surgery.

Procedure Overview and Historical Trends

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. da Vinci procedure adoption occurs procedure by procedure, 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.

Worldwide Procedures

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 but is not intended to promote for sale or use any Intuitive Surgical product outside of its licensed or cleared labeling and indications for use.

The adoption of da Vinci Surgery has the potential to grow for those procedures that offer greater patient value than non-da Vinci alternatives, while providing economic return to health care providers. da Vinci Surgical Systems are used primarily in gynecologic surgery, urologic surgery, general surgery, cardiothoracic surgery, and head and neck surgery. We focus our organization and investments on developing, marketing, and training for those products and procedures where da Vinci can bring patient value relative to alternative treatment options and/or economic benefit to health care providers. Principal target procedures in gynecology include da Vinci Hysterectomy (“dVH”) and sacrocolpopexy. Target procedures in urology include da Vinci Prostatectomy (“dVP”) and partial nephrectomy. Target procedures in general surgery include colorectal procedures, hernia repair, and Single-Site Cholecystectomy. In cardiothoracic surgery, target procedures include da Vinci Lobectomy and da Vinci Mitral Valve Repair. In head and neck surgery, target procedures include certain procedures resecting benign and malignant tumors classified as T1 and T2. Not all the indications, procedures, or products described may be available in a given country or region or on all generations of da Vinci Surgical Systems. Please consult the product labeling in a specific country and for each product in order to determine the actual authorized uses, as well as important limitations, restrictions, or contraindications.

In 2014, approximately 570,000 surgical procedures were performed with the da Vinci Surgical System, compared with approximately 523,000 and 450,000 procedures performed in 2013 and 2012, respectively. The growth in our overall procedure volume in 2014 was driven by growth in U.S. general surgery procedures and worldwide urologic procedures.

U.S. Procedures

Overall U.S. procedure volume grew to approximately 449,000 in 2014, compared with approximately 422,000 in 2013, and approximately 367,000 in 2012.

Gynecology is our largest U.S. surgical specialty. Overall U.S. gynecology procedure volume was approximately 235,000 in 2014, compared with 240,000 in 2013, and 222,000 in 2012. Our growth through 2013 was driven by adoption of dVH, our highest volume procedure, and other gynecologic procedures, including sacrocolpopexy and myomectomy largely resulting from capturing

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market share from open surgery techniques for these procedures. In 2014, our U.S. gynecology procedures declined 2% driven primarily by fewer benign dVH procedures. As of 2014, we estimate that approximately 80% of total benign hysterectomies were performed via minimally invasive approaches, including robotic, laparoscopic, and vaginal techniques. Given this high level of MIS penetration, we believe our benign hysterectomy volume largely declined with the overall market, which reflected payor trends encouraging more conservative non-surgical disease management approaches for certain uterine conditions. In addition, the number of myomectomies declined in 2014 after the Food and Drug Administration (“FDA”) discouraged the use of power morcellators in gynecologic procedures based upon their assessment of the risk of spreading an undiagnosed cancer. While we do not manufacture or sell these power morcellators, they were widely used in myomectomy procedures. Our benign dVH procedure volumes were approximately 148,000, 150,000, and 138,000 in 2014, 2013, and 2012, respectively. We believe robotic surgery is the most common method of performing hysterectomies for cancer. dVH for cancer procedure volumes were approximately 43,000, 41,000, and 38,000 in 2014, 2013, and 2012, respectively.

General surgery is our second largest and fastest growing specialty in the U.S. Overall, U.S. general surgery procedure volume grew to approximately 107,000 in 2014 compared with approximately 81,000 in 2013, and 42,000 in 2012. Growth through 2013 was driven by rapid adoption of da Vinci Cholecystectomies, the first procedure to be FDA-cleared for Single-Site Surgery, and earlier stage growth in low anterior resections, colon procedures, and several other general surgery procedures. In 2014, cholecystectomy growth moderated, and general surgery growth was driven by growth across a broad set of procedures, including ventral and inguinal hernia repair, colorectal, bariatric, foregut, and other procedures. The moderation in cholecystectomies reflected a shift in focus from Single-Site Cholecystectomy to hernia repair. While we continue to receive positive feedback from groups of the patient and surgeon populations that see value in the single incision approach to cholecystectomy and/or the real-time imaging of the biliary anatomy with our Firefly technology, we have experienced declines in 2015 cholecystectomy procedures.

U.S. urology procedure volume was approximately 91,000 in 2014, compared with approximately 85,000 in 2013, and 88,000 in 2012. We believe dVP to be the most common method of prostate cancer surgery in the U.S. About 60,000 dVPs were performed in 2014, compared with 58,000 in 2013, and 62,000 in 2012. We believe the U.S. Preventive Services Task Force recommendation against PSA screening, as well as changes in treatment patterns for low risk prostate cancer away from definitive treatment, contributed to an approximate 6% decline in our dVP business in 2013. After continuing to decline during the first half of 2014, U.S. dVP returned to growth during the second half of 2014 and the first three quarters of 2015. We believe the return to growth reflects broad prostate cancer patient care trends.

International Procedures

Overall international procedure volume grew to approximately 121,000 in 2014, compared with approximately 101,000 in 2013, and approximately 83,000 in 2012. International procedure growth was driven largely by dVP volume, which grew to approximately 65,000 in 2014, compared with approximately 56,000 in 2013, and approximately 47,000 in 2012. Partial nephrectomy, general surgery, and gynecologic oncology procedures also contributed to international procedure growth.

Business Model

We generate revenue from both the initial capital sales of da Vinci Surgical Systems as well as recurring revenue, derived from sales of instruments, accessories, and service. The da Vinci Surgical System generally sells for approximately between \$0.6 million and \$2.5 million, depending upon configuration and geography, and represents a significant capital equipment investment for our customers. We generate recurring revenue as our customers consume our EndoWrist and Single-Site instrument and accessory products used in performing procedures with the da Vinci Surgical System. Our instruments and accessories have a limited life and will either expire or wear out as they are used in surgery, at which point they are replaced. Also, we generate recurring revenue from ongoing system service. We typically enter into service contracts at the time systems are sold at an annual rate of approximately \$100,000 to \$170,000 per year, 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.

Recurring revenue has generally grown at a faster rate than system revenue in the last few fiscal years. Recurring revenue increased to \$1.5 billion or 70% of total revenue in 2014, compared with \$1.4 billion, or 63% of total revenue in 2013, and \$1.2 billion, or 57% of total revenue in 2012. The increasing proportion of recurring revenue largely reflects continued adoption of procedures on a growing base of installed da Vinci Surgical Systems. The installed base of da Vinci Surgical Systems has grown to approximately 3,266 at December 31, 2014, compared with approximately 2,966 at December 31, 2013, and approximately 2,585 at December 31, 2012. Recurring revenue for the nine months ended September 30, 2015, was \$1.2 billion, or 71% of revenue, compared with \$1.1 billion, or 73% of revenue for the nine months ended September 30, 2014. The decrease in the proportion of recurring revenue reflects higher systems revenue in the nine months ended September 30, 2015, relative to the nine months ended September 30, 2014. The installed base of da Vinci Surgical Systems was approximately 3,477 at September 30, 2015.

We provide our products through direct sales organizations in the U.S., Japan, Korea, and Europe, excluding Spain, Portugal, Italy, Greece and Eastern European countries. In the remainder of our international markets, we provide our products through

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distributors. In June 2014, we terminated our distribution relationship with Adachi Co., Ltd., a Japanese distributor and now market, sell, and service our products directly to end customers in Japan.

Regulatory Activities

Clearances and Approvals

We have obtained the clearances required to market our multiport products associated with the first three generations of our da Vinci Surgical Systems (Standard, S, and Si systems) for our targeted surgical specialties within the U.S. and most of Europe. In February 2013, we received FDA clearance to market our Single-Site instruments for benign hysterectomy and salpingo-oophorectomy procedures. In September 2014, we received FDA clearance to market the wristed version of our Single-Site needle driver product for use in benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures.

In March 2014, we received FDA clearance to market our da Vinci Xi Surgical System in the U.S., our fourth generation da Vinci Surgical System (see the complete description of the da Vinci Xi Surgical System in the New Product Introductions Section). In June 2014, we received CE mark clearance for our da Vinci Xi Surgical System in Europe. In October 2014, we received regulatory clearance for our da Vinci Xi Surgical System in Korea. In March 2015, we received regulatory clearance for the da Vinci Xi Surgical System in Japan. The regulatory status of the da Vinci Xi Surgical System in other international markets varies by country.

We also received FDA clearance on an initial set of instruments for the Xi Surgical system with the initial launch of the system. Since that time, we received FDA clearances for Xi versions of our EndoWrist One Vessel Sealer, Firefly, and EndoWrist Stapler 45. In the second quarter of 2015, we received FDA clearance for an additional set of da Vinci Xi instruments. In June 2015, we received CE mark clearance for our integrated table motion product in Europe.

Integrated table motion coordinates the movements of the da Vinci robot arms with a version of a Trumpf Medical™ TruSystem® 7000dV operating room table to enable shifting patient position while the da Vinci system remains docked. Initial cases were successfully completed using the integrated table motion technology in the third quarter of 2015 and we plan to begin a phased introduction in Europe during the fourth quarter of 2015. We filed for FDA 510(k) clearance for the integrated table motion technology in the U.S. in June 2015. We also filed for FDA 510(k) clearances in the U.S. for the Single-Site instruments and 30mm EndoWrist stapler products for the da Vinci Xi Surgical System in August 2015. In the future, we plan to apply for additional clearances to expand the da Vinci Xi platform product and feature set, including the da Vinci Single Port Surgical System, as described below.

In April 2014, we received FDA clearance to market our da Vinci Single Port Surgical System in the U.S. for single-port urologic surgeries. We are in the process of modifying the da Vinci Single Port Surgical System to be compatible with the da Vinci Xi Surgical system. We plan to seek additional FDA clearance(s) for the da Vinci Single Port Surgical System for procedure(s) in which a single small entry point to the body and parallel delivery of instruments is important. Such surgeries could include those performed through a natural orifice like the mouth for head and neck procedures or those performed through a single skin incision. We anticipate increased clinical evaluation of da Vinci Single Port Surgical System in 2016, particularly in transoral and transabdominal applications. We obtained approval from the Japanese Ministry of Health, Labor, and Welfare (“MHLW”) for our da Vinci Si Surgical System in October 2012 and for our da Vinci Xi Surgical System in March 2015. Effective April 2012, we obtained national reimbursement for dVP procedures in Japan, our only broadly reimbursed procedure to date. We are currently seeking reimbursement for additional procedures through the MHLW’s Senshin Iryo processes as well as alternative reimbursement processes. Our Senshin Iryo approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years. Japanese surgeons have submitted clinical data for consideration of partial nephrectomy reimbursement in the April 2016 cycle. There can be no assurance that we will gain additional Senshin Iryo reimbursements for the procedures or at the times we have targeted. We are continuing our discussions with stakeholders concerning the reimbursement for several other procedures; however inclusion of other procedures in reimbursement guidelines in 2016 are unlikely. If we are not successful in obtaining additional regulatory clearances, importation licenses, and adequate procedure reimbursements for future products and procedures, then the demand for our products in Japan could be limited.

FDA Inspections

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From October 7, 2015, to October 13, 2015, subsequent to the third fiscal quarter of 2015, the FDA conducted a routine inspection at our Sunnyvale facilities. The scope of the inspection included general surveillance in the form of a quality system inspection technique (“QSIT”) and follow-up on previous observations identified in the Form FDA 483 that was issued in 2014. No observations were communicated to us at the close of audit and we expect to receive a final establishment inspection report (“EIR”) from the FDA in the fourth quarter of 2015.

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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, re-labeling and issuance of new, added or reinforcement of 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 which a medical device manufacturer may take in the field without reporting, including routine servicing, the introduction of new products, and new indications for use 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. In general, upon submitting required notifications to regulators regarding a field action which 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. In addition, regulators can require the expansion, reclassification, or change in scope and language of the field action. Field actions can result in adverse effects on our business, including damage to reputation, delays by customers of purchase decisions, reduction or stoppage of use of installed systems, and reduced revenue as well as increased expenses to complete field actions.

In September 2014, we stopped shipping the EndoWrist Stapler 45 for the da Vinci Si Surgical System and advised our customers to suspend use. While the observed failure rate in the field was low at 0.023%, based on the total number of staple fires, we believe that immediately suspending use was the best course of action in the interest of patients. Our investigation of the three failed EndoWrist Staplers uncovered two separate failure modes in the clamp mechanism: 1) a component failure in two instruments and 2) an assembly error in one instrument. Based on these findings, in December 2014, we voluntarily initiated a field recall related to the EndoWrist Stapler 45 instrument for the da Vinci Si Surgical System. We have refined the relevant design elements and manufacturing processes to address these failure modes and began shipping replacement instruments in early 2015.

In March 2015, we issued a safety notice regarding certain equipment drapes that are used to cover a variety of surgical and non-surgical equipment in the clinical setting, advising our customers to inspect the drapes for cloudy or waxy appearances for potential tears prior to use, and to return affected drapes. We are currently working to establish sufficient supply of the replacement drapes. We do not believe that this matter will have a material impact on our

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

Year-to-Date 2015 Business Events and Trends

Procedures

Overall. During the nine months ended September 30, 2015, total da Vinci procedures grew approximately 14%, compared with growth of approximately 9% for the nine months ended September 30, 2014. U.S. procedure growth during the nine months ended September 30, 2015 was approximately 11%, compared with approximately 6% for the nine months ended September 30, 2014. The higher year-to-date 2015 U.S. procedure growth was largely attributable to growth in general surgery procedures, most notably hernia repair and colorectal procedures; growth in dVP; growth in gynecologic oncology procedures; and due to the unfavorable impact of transitional issues associated with the implementation of the Affordable Care Act had on our procedure growth in early 2014.

International procedure growth during the nine months ended September 30, 2015, was approximately 26%, compared with approximately 20% for the nine months ended September 30, 2014, driven by continued growth in dVP and earlier stage growth in kidney cancer, colorectal procedures, and gynecologic oncology.

The higher 2015 international procedure growth rate reflects increased da Vinci adoption in Asian markets, including China, Japan, and Korea. While we are encouraged by procedure adoption in China, future system placements are dependent on completion of the central purchasing tender under the current authorization, which is set to expire at the end of 2015. It is not certain whether the tender process will be completed, or when future governmental

authorizations and approvals may enable system placements in 2016 and beyond. In Japan, procedure growth rates are likely to be impacted by the timing of procedure reimbursement approval for procedures in addition to dVP. dVP. We believe the U.S. Preventive Services Task Force recommendation against PSA screening impacted our U.S. dVP procedure growth since 2013. U.S. dVP returned to growth during the second half of 2014 and the first three quarters of 2015. We believe the return to growth reflects broad prostate cancer patient care trends. Internationally, dVP adoption is at earlier stages, with lower market penetration, and has continued to grow over the past couple years despite shifting patient treatment trends that have negatively impacted the overall prostatectomy volumes in certain countries. We expect that the number of dVP procedures performed in the US will fluctuate with the overall prostatectomy market.

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U.S. Gynecology. For the year ended 2014, U.S. gynecology procedures declined by approximately 2% compared with 2013, with approximately 3% decline in benign procedures partly offset by an approximate 5% growth in oncology procedures. We believe that the pressure on U.S. benign gynecologic procedures reflected a macro trend of fewer benign gynecologic procedures caused by a number of factors including, but not limited to, larger patient deductibles and co-pays associated with the Affordable Care Act, a trend by payers toward encouraging conservative disease management, and FDA actions regarding the use of power morcellation in uterine surgeries, which mostly impacted da Vinci myomectomy procedures (see more detailed description of the FDA Actions Concerning Morcellation below). Minimally invasive surgery is presently approaching 80% penetration of the U.S. benign hysterectomy market, causing the rate of migration from open surgeries to minimally invasive surgeries to slow. Combined with the dispersion of the remaining open procedures among hospitals and surgeons, we believe the number of da Vinci hysterectomies performed for benign conditions has moved roughly in-line with the gradually decreasing surgical market in 2014. During the nine months ended September 30, 2015, our total U.S. gynecology procedure volume was approximately 1% higher compared with the first nine months of 2014. While benign hysterectomy procedures have continued to decline modestly in 2015, malignant hysterectomy procedures have grown at a higher rate than in 2014. In recent quarters, an increasing proportion of our total hysterectomy procedures have been performed by gynecologic oncologists. As a result, the classification of hysterectomy procedures as either cancerous or benign is potentially becoming less precise.

U.S. General Surgery. For the year ended 2014, U.S. general surgery procedures grew by approximately 32%, with growth shifting from cholecystectomy to hernia repair, colorectal resections, and other general surgery procedures. This trend has continued in 2015. The whole category of General Surgery has grown well with hernia repair procedures growing the most. We believe that growth in da Vinci hernia repair reflects improved clinical outcomes within certain patient populations, as well as potential cost benefits relative to certain alternative treatments. Given the differences in complexity among hernia patient populations, it is difficult to estimate the timing of and to what degree da Vinci hernia repair procedure volume will grow in the future. We expect a large portion of hernia repairs will continue to be performed in different modalities of surgery. Adoption of colorectal procedures, which include several underlying procedures including low anterior resections for rectal cancers and certain colon procedures for benign and cancer conditions, has been ongoing for several years, and is supported by recently launched technologies such as the da Vinci Xi Surgical System, EndoWrist Stapler, and EndoWrist Vessel Sealer.

In December 2011, we received FDA clearance for Single-Site Cholecystectomy, our first procedure cleared for Single-Site instruments. da Vinci cholecystectomies are performed with either Single-Site instruments or multiport instruments. While we believe da Vinci cholecystectomies provide meaningful value for a segment of the patient and surgeon population, it is a lower complexity procedure which can generally be executed in a minimally invasive manner via multiport laparoscopy and has lower reimbursement rates than more complex procedures. For these reasons, it is difficult to estimate to what degree or timing that we may capture these procedures. During 2014, total U.S. cholecystectomies grew at a lower rate than in previous years, and declined in the fourth quarter of 2014 and the first three quarters of 2015. However, broad growth across a number of general surgery procedures, most notably hernia repair and colorectal resections, offset the slowing adoption of cholecystectomy.

Intuitive Surgical da Vinci System Leasing. Starting in 2014, 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 da Vinci systems and expand da Vinci surgery availability while leveraging our balance sheet. The leases generally have commercially competitive terms as compared with other third party entities that offer equipment leasing. We include both operating and sales-type leases in our system shipment and installed base disclosures. We exclude operating leases from our system average selling prices computations. In the three and nine month periods ended September 30, 2015, we shipped 20 and 43 systems under lease arrangements, respectively, of which 13 and 27 were classified as operating leases, respectively. In the three and nine month periods ended September 30, 2014, we shipped 11 and 29 systems under leases, respectively, of which 6 and 9 were classified as operating leases, respectively. Generally, our operating leases provide our customers with the right to purchase the leased systems sometime during or at the end of the lease term. During the three and nine month periods ended September 30, 2015, customers purchased 2 and 4 systems, respectively, that were under operating lease arrangements resulting in \$2.6 million and \$4.9 million of

systems revenue being recognized during the three and nine month periods ended September 30, 2015, respectively. There were no lease buyouts in the first nine months of 2014.

In the three and nine month periods ended September 30, 2015, operating lease revenue was \$1.8 million and \$4.3 million, respectively, compared with \$0.4 million and \$0.6 million in the three and nine month periods ended September 30, 2014, respectively. As of September 30, 2015, 36 da Vinci systems were rented under operating lease arrangements.

Procedure Seasonality. More than half of da Vinci procedures performed are for benign conditions, most notably benign hysterectomies, hernia repairs, and cholecystectomies. The proportion of these benign procedures has grown over time in relation to the total number of procedures performed. Hysterectomies for benign conditions, cholecystectomies, hernia repairs, and other short-term elective procedures tend to be more seasonal than cancer operations and surgeries for other life threatening conditions. Seasonality for these benign procedures 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 for the first three quarters of 2015

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was similar to years prior to 2014 and less pronounced than in early 2014, when procedure volume was negatively impacted by transitional issues associated with the implementation of the Affordable Care Act.

Procedure Mix. Our procedure business is primarily comprised of: (1) cancer and other highly complex procedures and (2) less complex benign procedures. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex benign procedures. 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 in each of these procedure categories. More fully featured products, including 4-arm, dual console, Firefly enabled systems, and advanced instruments including vessel sealing and stapler are targeted towards more complex procedures. Lower priced products, including the three-arm da Vinci Si-e System and lower priced Single-Site instruments are targeted towards less complex procedures.

Recently, third party entities have begun to offer robotic surgery consulting services targeted at analyzing the cost-effectiveness of hospitals' robotic surgery programs, including procedures performed, placement of systems, and consumption of instruments and accessories. We currently provide similar services and analyses to our customers, but it is difficult to assess the impact that this may have on future procedure adoption and growth.

FDA Actions Concerning Morcellation. In April 2014, the FDA announced that it discourages the use of power morcellators in the surgical removal of assumed benign fibroids. This statement was followed in July 2014 by an FDA panel discussion on the topic. In November 2014, the FDA issued specific contraindications for the use of laparoscopic power morcellation and required specific patient warning prior to its use in surgery. We do not manufacture or sell power morcellation products and power morcellators do not attach to da Vinci Surgical Systems. Minimally invasive da Vinci gynecologic surgeries are routinely performed without the use of power morcellators. However, we believe that these FDA actions likely created some uncertainty for surgeons and patients when choosing among minimally invasive surgical methods for removing fibroids that may have adversely impacted the number of da Vinci procedures performed. Since the second quarter of 2014, we have experienced a decline in myomectomies that we believe likely reflected the impact of the FDA actions. Myomectomies are not a significant portion of our business. It is difficult to gauge what impact the FDA actions may have had on benign dVH procedures, although as indicated above, an increasing proportion of our hysterectomy procedures in recent quarters have been performed by gynecologic oncologists.

System Demand

Future demand for da Vinci Surgical Systems will be impacted by factors including procedure growth rates, market response to our recently launched da Vinci Xi Surgical System, hospitals consolidation trends, evolving system utilization and point of care dynamics, additional reimbursements in various global markets including Japan, the timing around governmental tenders and authorizations, the timing of when we receive regulatory clearance in our other international markets for our Xi System and related instruments. Future demand may also be impacted by anticipated robotic surgery competition, including from companies that have made explicit statements about their efforts to enter the field, including Johnson & Johnson and Google Inc., MedRobotics Corp., meerecompany Inc., Medtronic PLC, Olympus Corp., SOFAR S.p.A., IMRIS Inc., TransEnterix, Inc., and Titan Medical, Inc., as well as other economic and geopolitical factors.

Recent Media and Lawsuits

In recent years, various print, television, and internet media have released pieces questioning the patient safety and efficacy associated with da Vinci Surgery, the cost of da Vinci Surgery relative to other disease management methods, and the adequacy of surgeon training and our sales and marketing practices. In addition, as further described in Note 6 to the Condensed Consolidated Financial Statements (Unaudited) included in Item 1, Part I, we are currently named as a defendant in approximately 90 individual product liability lawsuits and a multi-plaintiff product liability lawsuit filed on behalf of 45 patients who underwent da Vinci Surgery. Plaintiffs' attorneys have been engaged in well-funded national advertising campaigns soliciting clients who have undergone da Vinci Surgery and claim to have suffered an injury, and we have seen a substantial increase in these claims. In an effort to avoid the expense and distraction of defending multiple lawsuits, we entered into tolling agreements to pause the applicable statutes of limitations for the claims, and engaged in mediation efforts. We believe that da Vinci Surgery continues to be a safe and effective surgical method, as supported by a substantial and growing number of scientific studies and peer reviewed papers. We

also believe that we provide appropriate training on the use of the da Vinci Surgical System, consistent with our role as device manufacturer. However, the recent negative media publicity likely has and may continue to delay or adversely impact procedure adoption, system sales, and our revenue growth in future periods.

During the year ended December 31, 2014, we recorded pre-tax charges of \$82.4 million, of which \$77.0 million was recorded in the nine months ended September 30, 2014, to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements. During the nine months ended September 30, 2015, we recorded pre-tax charges of \$13.8 million, of which \$7.2 million was recorded in the first quarter of 2015 and \$6.6 million in the second quarter of 2015, related to these product liability claims. No charges were recorded during the three months ended September 30, 2015, and 2014. The claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor (MCS) instruments that included an MCS tip cover accessory that was the subject of a market withdrawal in 2012 and MCS instruments that were the subject of a recall in 2013.

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Our estimate of the anticipated cost of settling these claims is based on negotiations with attorneys for claimants who have participated in a mediation process. Nonetheless, it is possible that the claimants who participate in the mediations, as well as those claimants who have not participated in negotiations, will pursue greater amounts in mediation or in a court of law. Consequently, the final outcome of these claims is dependent on many variables that are difficult to predict and the ultimate cost associated with these product liability claims may be materially different than the amount of the current estimate and accruals and could have a material adverse effect on our business, financial condition, and results of operations or cash flows. Although there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. See Note 6 to the Condensed Consolidated Financial Statements (Unaudited) included in Item 1, Part I for further details.

New Product Introductions

da Vinci Xi Surgical System. During April 2014, we launched our newest da Vinci model, the da Vinci Xi, in the U.S. The da Vinci Xi can be used across a wide spectrum of minimally invasive surgical procedures, and has been optimized for multi-quadrant surgeries. The da Vinci Xi expands upon core da Vinci features including wristed instruments, 3-D HD visualization, intuitive motion, and ergonomic design, while improving ease, and delivering several new features, including:

- ▲ A new overhead instrument arm architecture designed to facilitate anatomical access from virtually any position.
- ▲ A new endoscope digital architecture that creates a simpler, more compact design with improved vision definition and clarity.
- ▲ An ability to attach the endoscope to any arm, providing flexibility for visualizing the surgical site.
- ◻ Smaller, thinner arms with newly designed joints that offer a greater range of motion than ever before.
- ◻ Longer instrument shafts designed to give surgeons greater operative reach.

With the da Vinci Xi, we now offer hospitals a broader line of da Vinci Surgical Systems to match their surgical profile and patient care requirements. These include the da Vinci Si-e, a lower price system suited for surgeries requiring two instrument arms; the da Vinci Si, which has the capability of controlling three instrument arms; and the da Vinci Xi, which has four universal instrument arms that attach to a rotating overhead platform. We separately applied for FDA clearance for the da Vinci Xi Firefly, Vessel Sealer, and Stapler products and received clearances for these products from June 2014 to August 2014. Our Single Site line of instruments is currently only available for our da Vinci Si and da Vinci Si-e systems.

We CE marked the da Vinci Xi system in June 2014 and have begun sales and marketing activities in certain countries recognizing the CE mark. In October 2014, we received regulatory clearance for the da Vinci Xi Surgical System in Korea. In March 2015, we received regulatory clearance for the da Vinci Xi Surgical System in Japan. The regulatory status of the da Vinci Xi Surgical System in other international markets varies by country.

da Vinci Single-Site Instruments. da Vinci Single-Site consists of a set of non-wristed instruments (except for wristed needle driver discussed below) and accessories that allow the da Vinci Si systems to work through a single incision, typically in the umbilicus, rather than multiple incisions. Single incision surgery is intended to minimize invasiveness to patients by reducing the number of ports required to enter the body and is typically utilized for less complex surgery than multi-port surgery. Non-robotic single incision surgery today is typically performed with modified laparoscopic instruments. Early clinical adoption of this manual technique has been mostly positive, although physicians have reported that manual single incision surgery is technically and ergonomically challenging. da Vinci Single-Site instruments and accessories were designed to address these issues. In February 2011, we received the CE mark for our da Vinci Single-Site instrument kit and began selling these new products in Europe. The majority of da Vinci Single-Site procedures performed in Europe to date have been cholecystectomies. In December 2011, we received FDA regulatory clearance to market our Single-Site instrumentation in the U.S. for laparoscopic cholecystectomy procedures. In February 2013, we received FDA clearance to market our Single-Site instruments for benign hysterectomy and salpingo-oophorectomy procedures. In September 2014, we received FDA clearance to market the wristed version of our Single-Site needle driver product for use on benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures. We believe this instrument may have particular utility in benign hysterectomy procedures. However, as these are our initial products targeted towards procedures already highly

penetrated by manual MIS techniques, we are not able to predict the extent or pace that da Vinci Single-Site may be adopted.

da Vinci Firefly Fluorescence Imaging. In the first quarter of 2011, we launched our Firefly product for use with the da Vinci Si Surgical System. Firefly is a standard feature of the da Vinci Xi Surgical System. This imaging capability combines a fluorescent dye with a specialized da Vinci camera head, endoscope, and laser-based illuminator to allow surgeons to identify vasculature in three dimensions beneath tissue surfaces to visualize critical anatomy. Adoption of Firefly is progressing with use across the categories of urology, gynecology, and general surgery. In September 2013, we received FDA 510(k) clearance to market our Firefly fluorescence imaging product for real-time imaging of bile ducts (cystic duct, common bile duct, and common hepatic

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duct). We believe that the use of Firefly during cholecystectomy procedures will enhance the ability of surgeons to identify key anatomical structures during the surgery.

EndoWrist One Vessel Sealer. In December 2011, we received FDA clearance for the EndoWrist One Vessel Sealer for use with the da Vinci Si Surgical system. The EndoWrist One Vessel Sealer is a wristed, single-use instrument intended for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. This instrument enables surgeons to fully control vessel sealing, while providing the benefits of da Vinci Surgery. This instrument is designed to enhance surgical efficiency and autonomy in a variety of general surgery and gynecologic procedures. Clinical response to the EndoWrist One Vessel Sealer has been encouraging, with positive commentary on precision, articulation, vessel sealing quality, and thermal spread. The adoption of the EndoWrist One Vessel Sealer has centered on general surgery and gynecology procedures. In June 2014, we received FDA clearance for the da Vinci Xi version of the EndoWrist One Vessel Sealer.

EndoWrist Stapler 45. In October 2012, we received FDA clearance for the EndoWrist Stapler 45 instrument with Blue and Green 45 mm reloads for use with the da Vinci Si Surgical System. The EndoWrist Stapler 45 is a wristed, stapling instrument intended for resection, transection and/or creation of anastomoses in general, gynecologic, and urologic surgery. This instrument enables operators to precisely position and fire the stapler. Its initial surgical use was directed towards colorectal procedures. During 2013, the EndoWrist Stapler was used by a limited and gradually increasing number of customers. In 2014, we expanded the availability of the EndoWrist Stapler to a broadening set of customers. In September 2014, we notified our customers to suspend the use of the EndoWrist Stapler 45 (see Recalls and Corrections section for additional discussion). In January 2015, we began to ship the replacement product for the da Vinci Si and began to ship initial da Vinci Xi versions of the EndoWrist Stapler 45, including Blue, Green, and White 45 mm reloads. The White reloads are only available on the da Vinci Xi platform. In April 2015, we received CE Mark status to sell the EndoWrist Stapler for the Si and Xi Surgical Systems in European markets. Although our early customer experiences have been positive, we are in the early stages of selling EndoWrist Stapler 45, and we are not able to predict the extent to which the instrument may be adopted.

Third Quarter 2015 Financial Highlights

Total revenue increased by 7% to \$589.7 million during the three months ended September 30, 2015, compared with \$550.1 million during the three months ended September 30, 2014.

Approximately 162,000 da Vinci procedures were performed during the three months ended September 30, 2015, an increase of approximately 15% compared with the three months ended September 30, 2014.

Instrument and accessory revenue increased by 9% to \$298.1 million during the three months ended September 30, 2015, compared with \$272.8 million during the three months ended September 30, 2014.

Recurring revenue increased by 9% to \$415.5 million during the three months ended September 30, 2015, representing 70% of total revenue, compared with \$381.3 million during the three months ended September 30, 2014, representing 69% of total revenue.

Systems revenue increased by 3% to \$174.2 million during the three months ended September 30, 2015, compared with \$168.8 million during the three months ended September 30, 2014. 117 da Vinci Surgical Systems were shipped during the three months ended September 30, 2015, compared with 111 during the three months ended September 30, 2014.

As of September 30, 2015, we had a da Vinci Surgical System installed base of approximately 3,477 systems, consisting of 2,344 in the U.S., 586 in Europe, 215 in Japan, and 332 in the rest of the world.

Operating income increased by 19% to \$189.9 million during the three months ended September 30, 2015, compared with \$159.1 million during the three months ended September 30, 2014. Operating income included \$44.2 million and \$45.2 million of share-based compensation expense related to employee stock plans during the three months ended September 30, 2015, and 2014, respectively.

As of September 30, 2015, we had \$3.1 billion in cash, cash equivalents and investments. Cash, cash equivalents and investments increased by \$628.2 million, compared with December 31, 2014, primarily driven by cash provided by operating activities and proceeds from employee stock option exercises.

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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,					
	2015	% of total revenue	2014	% of total revenue	2015	% of total revenue	2014	% of total revenue		
Revenue:										
Product	\$472.3	80	% \$441.6	80	% \$1,363.3	80	% \$1,208.0	79	%	
Service	117.4	20	% 108.5	20	% 344.6	20	% 319.0	21	%	
Total revenue	589.7	100	% 550.1	100	% 1,707.9	100	% 1,527.0	100	%	
Cost of revenue:										
Product	155.3	26	% 150.3	27	% 468.9	27	% 397.6	26	%	
Service	38.6	7	% 39.2	7	% 119.9	7	% 109.0	7	%	
Total cost of revenue	193.9	33	% 189.5	34	% 588.8	34	% 506.6	33	%	
Product gross profit	317.0	54	% 291.3	53	% 894.4	53	% 810.4	53	%	
Service gross profit	78.8	13	% 69.3	13	% 224.7	13	% 210.0	14	%	
Gross profit	395.8	67	% 360.6	66	% 1,119.1	66	% 1,020.4	67	%	
Operating expenses:										
Selling, general and administrative	154.9	26	% 154.0	28	% 480.2	28	% 531.0	35	%	
Research and development	51.0	9	% 47.5	9	% 144.8	9	% 130.7	9	%	
Total operating expenses	205.9	35	% 201.5	37	% 625.0	37	% 661.7	44	%	
Income from operations	189.9	32	% 159.1	29	% 494.1	29	% 358.7	23	%	
Interest and other income, net	3.7	1	% 2.0	—	% 12.6	1	% 5.5	—	%	
Income before taxes	193.6	33	% 161.1	29	% 506.7	30	% 364.2	23	%	
Income tax expense	26.3	5	% 37.4	7	% 107.9	7	% 92.2	5	%	
Net income	\$167.3	28	% \$123.7	22	% \$398.8	23	% \$272.0	18	%	

Total Revenue

Total revenue was \$589.7 million for the three months ended September 30, 2015, compared with \$550.1 million for the three months ended September 30, 2014, driven by 9% higher recurring revenue and 3% higher systems revenue. Total revenue was \$1.7 billion for the nine months ended September 30, 2015, compared with \$1.5 billion for the nine months ended September 30, 2014, driven by 10% higher recurring revenue and 17% higher systems revenue.

In 2014, we offered certain customers who purchased a 4-arm da Vinci Si Surgical System the opportunity to trade out their systems for a da Vinci Xi Surgical System subsequent to its launch in the second quarter of 2014. Under that program, customers were able to return their da Vinci Si Surgical System and receive a credit substantially equal to the price paid for the da Vinci Si Surgical System towards the purchase of a da Vinci Xi Surgical System. In accordance with guidance for accounting for arrangements in which return rights exist, system revenue and associated inventory costs were deferred based on our estimate of the number of systems that were expected to be returned by the participating customers. Subject to meeting all other criteria of our revenue recognition policy, the revenue deferred was recognized at the date the da Vinci Xi Surgical Systems and related instruments and accessories were shipped and accepted by the customers participating in the trade-in program. The program was substantially completed by the end of 2014. Total revenue for the nine months ended September 30, 2014, excluded \$3.9 million of net revenue which was deferred until the fourth quarter of 2014.

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We sell in local currency in most of the European markets where we sell direct, as well as in Japan and Korea. Revenue for the three and nine months ended September 30, 2015, as compared with same period in 2014, was negatively impacted by the strengthening of the U.S. dollar against other currencies. We hedge a portion of our foreign currency denominated revenue and those hedges partially offset the negative impact of the strengthened U.S. dollar on revenue for the three and nine months ended September 30, 2015. Revenue denominated in foreign currencies was approximately 19% of total revenue for both the three and nine months ended September 30, 2015, compared with approximately 17% and 16% of total revenue for the three and nine months ended September 30, 2014, respectively. If the U.S. dollar continues to be stronger than it was in 2014 against other currencies and we are not able to adjust our foreign currency denominated pricing, our revenue will likely be negatively impacted during the remainder of 2015.

Revenue generated in the U.S. accounted for 74% and 73% of total revenue for the three and nine months ended September 30, 2015, respectively, compared with 72% and 71% of total revenue for the three and nine months ended September 30, 2014, respectively. We believe that domestic revenue has accounted for the large majority of total revenue due to patients' ability to choose their provider and method of treatment in the U.S., reimbursement structures supportive of innovation and minimally invasive surgery, and initial investments focused on domestic infrastructure. We have been investing in our international business and our international procedures have grown faster in proportion to U.S. procedures. In future years, we expect our international procedures and revenue will grow at a faster rate than in the U.S. and will make up an increasing portion of our business.

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The following table summarizes our revenue and da Vinci Surgical System unit shipments for the three and nine months ended September 30, 2015, and 2014 (in millions, except percentages and unit shipments):

	Three Months Ended September		Nine Months Ended September		
	30, 2015	2014	30, 2015	2014	
Revenue					
Instruments and accessories	\$298.1	\$272.8	\$872.1	\$789.5	
Systems	174.2	168.8	491.2	418.5	
Total product revenue	472.3	441.6	1,363.3	1,208.0	
Services	117.4	108.5	344.6	319.0	
Total revenue	\$589.7	\$550.1	\$1,707.9	\$1,527.0	
Recurring revenue	\$415.5	\$381.3	\$1,216.7	\$1,108.5	
% of total revenue	70	% 69	% 71	% 73	%
Domestic	\$438.5	\$393.6	\$1,238.7	\$1,086.2	
International	151.2	156.5	469.2	440.8	
Total revenue	\$589.7	\$550.1	\$1,707.9	\$1,527.0	
% of Revenue - Domestic	74	% 72	% 73	% 71	%
% of Revenue - International	26	% 28	% 27	% 29	%
Unit Shipments by Region:					
Domestic unit shipments	80	61	215	167	
International unit shipments	37	50	119	127	
Total unit shipments*	117	111	334	294	
Unit Shipments by Model:					
da Vinci S unit shipments	—	7	1	10	
da Vinci Si-e - Single console unit shipments (3 arm)	—	7	6	25	
da Vinci Si - Single console unit shipments (4 arm)	22	35	68	116	
da Vinci Si - Dual console unit shipments	5	3	18	34	
da Vinci Xi - Single console unit shipments	61	46	167	85	
da Vinci Xi - Dual console unit shipments	29	13	74	24	
Total unit shipments*	117	111	334	294	
Unit Shipments involving System Trade-ins:					
Unit shipments involving trade-ins of da Vinci standard Surgical Systems	—	6	4	16	
Unit shipments involving trade-ins of da Vinci S Surgical Systems	22	22	72	53	
Unit shipments involving trade-ins of da Vinci Si Surgical Systems	15	10	39	15	
Total unit shipments involving trade-ins	37	38	115	84	
Unit shipments not involving trade-ins	80	73	219	210	
Total unit shipments*	117	111	334	294	
*Systems shipped on operating leases (included in total unit shipments)	13	6	27	9	

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Product Revenue

Product revenue was \$472.3 million for the three months ended September 30, 2015, compared with \$441.6 million for the three months ended September 30, 2014. Product revenue for the three months ended September 30, 2014, included \$14.9 million and \$1.1 million of system and instrument and accessory revenue recognized, respectively, associated with the trade-out offers provided in connection with our da Vinci Xi launch.

Instrument and accessory revenue increased 9% to \$298.1 million for the three months ended September 30, 2015, compared with \$272.8 million for the three months ended September 30, 2014. The increase in instrument and accessory revenue was driven by procedure growth of approximately 15%, partially offset by the unfavorable impact of foreign currency and timing of customer orders. Third quarter 2015 U.S. procedure growth was approximately 12% compared to 8% in the third quarter 2014 and was driven by a higher general surgery procedure volume, particularly in hernia repair and colorectal procedures, and dVP growth. Third quarter 2015 international procedure growth increased approximately 28% compared to 20% in the third quarter of 2014 driven by continued growth in dVP and earlier stage growth in kidney cancer, colorectal procedures, and gynecologic oncology.

Systems revenue increased to \$174.2 million during the three months ended September 30, 2015, from \$168.8 million during the three months ended September 30, 2014, driven by higher third quarter 2015 system shipments and higher third quarter 2015 average selling prices, partially offset by \$14.9 million of systems revenue recognized during the third quarter of 2014 associated with the da Vinci Xi Surgical System trade out offers. During the third quarter of 2015, 80 systems were shipped into the U.S., 19 into Europe, 9 into Japan, and 9 into other markets, of which none were into China, compared with 61 systems shipped into the U.S., 25 into Europe, 7 into Japan, and 18 into other markets, of which 10 were into China, during the third quarter of 2014. The increase in U.S. systems sales was driven by higher procedure growth in 2015 and a favorable market response to the da Vinci Xi System that was launched in the second quarter of 2014. Lower third quarter 2015 international systems sales were driven by fewer systems sold into China, reflecting the variability in the timing of capital sales and the central purchasing tender process in China. The da Vinci Surgical System average selling price (“ASP”), excluding the impact of systems shipped under operating leases, was approximately \$1.6 million and \$1.5 million for the three and nine months ended September 30, 2015, respectively, compared to \$1.5 million for both the three and nine months ended September 30, 2014, reflecting a higher proportion of da Vinci Xi and dual console systems in the third quarter 2015 product mix.

Product revenue was \$1.4 billion for the nine months ended September 30, 2015, compared with \$1.2 billion for the nine months ended September 30, 2014. Product revenue for the nine months ended September 30, 2014 excluded \$3.2 million and \$0.7 million of system and instrument and accessory revenue deferred, respectively, associated with the trade-out offers provided in connection with our da Vinci Xi launch.

Instrument and accessory revenue increased 10% to \$872.1 million for the nine months ended September 30, 2015, compared with \$789.5 million for the nine months ended September 30, 2014. The increase in revenue was driven by approximately 14% higher procedure volume, reflecting approximately 11% U.S. procedure growth and 26% international procedure growth, partially offset by the unfavorable impact of foreign currency.

Systems revenue increased to \$491.2 million during the nine months ended September 30, 2015, from \$418.5 million during the nine months ended September 30, 2014, driven by higher da Vinci Surgical System units shipped year-to-date 2015. We shipped 334 da Vinci Surgical Systems during the nine months ended September 30, 2015, compared with 294 in the same period last year. The increase in system unit shipments primarily reflected higher system sales into the U.S. partially offset by fewer systems sold into international markets. During the nine months ended September 30, 2015, 215 systems were shipped into the U.S., 59 into Europe, 23 into Japan, and 37 into other markets, compared with 167 systems shipped into the U.S., 58 into Europe, 31 into Japan, and 38 into other markets during the nine months ended September 30, 2014. The increase in U.S. systems sales was driven by higher procedure growth in 2015 and a favorable market response to the da Vinci Xi System that was launched in the second quarter of 2014.

Service Revenue

Service revenue increased by 8% to \$117.4 million for the three months ended September 30, 2015, compared with \$108.5 million for the three months ended September 30, 2014. Service revenue increased by 8% to \$344.6 million for the nine months ended September 30, 2015, compared with \$319.0 million for the nine months ended September 30,

2014. We typically enter into multi-year fixed annual rate service contracts at the time systems are sold. These service contracts have been generally renewed at the end of the service periods. Higher service revenue during the three and nine months ended September 30, 2015, was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue.

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Table of Contents**Gross Profit**

Product gross profit for the three months ended September 30, 2015, increased by 9% to \$317.0 million, representing 67.1% of product revenue, compared with \$291.3 million, representing 66.0% of product revenue, for the three months ended September 30, 2014. Product gross profit for the nine months ended September 30, 2015, increased 10% to \$894.4 million, representing 65.6% of product revenue, compared with \$810.4 million, representing 67.1% of product revenue, for the nine months ended September 30, 2014. The higher third quarter and year to date 2015 product gross profit was driven by higher product revenue.

The higher product gross profit margin for the three months ended September 30, 2015, as compared with the same period in 2014, was primarily driven by higher recall costs in the third quarter of 2014 as well as improved manufacturing efficiency in 2015, partially offset by unfavorable foreign currency impact related to international sales.

The lower product profit margin for the nine months ended September 30, 2015, was driven by a higher sales mix of recently introduced products that yield lower gross profit margins, including the da Vinci Xi Surgical System and EndoWrist One Vessel Sealer and Stapler; and an unfavorable foreign currency impact related to international sales. Margins on newly launched products will typically be lower than our mature products reflecting vendor pricing on lower volumes, temporary tooling costs and other start-up costs. Over time, as volumes increase and we refine our manufacturing processes and products, we expect to see improvement in the margins of these newly launched products. However, gross margins may ultimately differ for these newly launched products relative to previously launched products based on market conditions, volume, and complexity of the product.

Product gross profit for the three months ended September 30, 2015, and 2014, reflected share-based compensation expense of \$6.2 million and \$5.1 million, respectively. Product gross profit for the three months ended September 30, 2015, and 2014, included amortization expense of purchased intellectual property of \$3.2 million and \$3.4 million, respectively.

Product gross profit for the nine months ended September 30, 2015, and 2014, reflected share-based compensation expense of \$16.9 million and \$14.1 million, respectively. Product gross profit for the nine months ended September 30, 2015, and 2014, included amortization expense of purchased intellectual property of \$9.8 million and \$6.8 million, respectively.

Service gross profit during the three months ended September 30, 2015 was \$78.8 million, or 67.1% of service revenue, compared with \$69.3 million, or 63.9% of service revenue during the three months ended September 30, 2014. Service gross profit during the nine months ended September 30, 2015, was \$224.7 million, or 65.2% of service revenue, compared with \$210.0 million, or 65.9% of service revenue during the nine months ended September 30, 2014. The higher 2015 service gross profit was driven by higher service revenue reflecting a larger installed base of da Vinci Surgical Systems.

Third quarter 2015 service gross profit margin was higher than the third quarter of 2014, primarily driven by service cost charges incurred during the third quarter of 2014 associated with the launch of the da Vinci Xi Surgical System. The decrease in service profit margin for the nine months ended September 30, 2015, was primarily due to initial costs to service the da Vinci Xi Surgical System, such as spare parts, tooling, and field service engineer training. In addition, the new digital technology associated with the da Vinci Xi vision products is significantly more costly to service at this stage than the more mature technology associated with previous generation vision systems. We have programs in place to reduce the cost of repairing da Vinci Xi endoscopes.

Service gross profit for the three months ended September 30, 2015, and 2014, reflected share-based compensation expense of \$3.2 million and \$3.7 million, respectively. Service gross profit for the nine months ended September 30, 2015, and 2014, reflected share-based compensation expense of \$9.8 million and \$10.1 million, 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, 2015, increased by 1% to \$154.9 million, compared with \$154.0 million for the three months ended September 30, 2014. The higher third quarter selling, general, and administrative expenses were driven by higher international expenses associated with our

direct Japanese organization, expansion of our European team, and higher variable compensation, partially offset by the impact of the stronger U.S. dollar on expenses denominated in foreign currencies. Share-based compensation expense for the three months ended September 30, 2015, and 2014, was approximately \$25.0 million and \$26.3 million, respectively.

Selling, general and administrative expenses for the nine months ended September 30, 2015, decreased 10% to \$480.2 million, compared with \$531.0 million for the nine months ended September 30, 2014. The decrease was primarily due to lower pre-tax charge of \$13.8 million recorded in the nine months ended September 30, 2015, compared with \$77.0 million pre-tax charge recorded in the nine months ended September 30, 2014, to reflect the estimated cost of settling a number of product liability claims covered by the tolling agreements, and to a lesser extent, the impact of the stronger U.S. dollar on expenses denominated in foreign

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currencies. The favorable impact was partially offset by expansion of our Japanese and other international organizations and higher regulatory compliance costs. Share-based compensation expense for the nine months ended September 30, 2015, and 2014, was \$71.7 million and \$75.6 million, respectively.

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. These enhancements represent significant improvements to our products.

Research and development expenses for the three months ended September 30, 2015, increased by 7% to \$51.0 million, compared with \$47.5 million for the three months ended September 30, 2014. Research and development expenses for the nine months ended September 30, 2015, increased 11% to \$144.8 million, compared with \$130.7 million for the nine months ended September 30, 2014. The increase in research and development expenses for the three and nine months ended September 30, 2015 as compared with the same periods in 2014, was primarily due to growth in our product development organization and higher development project costs.

Share-based compensation expense charged to research and development expense was \$9.8 million and \$10.1 million for the three months ended September 30, 2015, and 2014, respectively, and was \$28.2 million and \$28.1 million, for the nine months ended September 30, 2015, and 2014, respectively.

Amortization expense related to purchased intellectual property for the three months ended September 30, 2015, and 2014, was \$3.0 million and \$2.9 million, respectively. Amortization expense related to purchased intellectual property during the nine months ended September 30, 2015, and 2014 was \$8.8 million and \$9.1 million, respectively.

Research and development expenses fluctuate with project timing. 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 months ended September 30, 2015, and 2014, was \$3.7 million and \$2.0 million, respectively, primarily reflecting higher interest earned during the third quarter of 2015 on higher cash and investment balances. Interest and other income, net, for the nine months ended September 30, 2015, and 2014, was \$12.6 million and \$5.5 million, respectively. The increase in interest and other income, net for the nine months ended September 30, 2015, was primarily driven by a charge of \$4.2 million recorded in the second quarter of 2014 related to an impairment of a cost method investment and higher 2015 interest income.

Income Tax Expense

Income tax expense for the three months ended September 30, 2015, was \$26.3 million, or 13.6% of income before taxes, compared with \$37.4 million, or 23.2% of income before taxes for the three months ended September 30, 2014. Income tax expense for the nine months ended September 30, 2015, was \$107.9 million, or 21.3% of income before taxes, compared with \$92.2 million, or 25.3% of income before taxes for the nine months ended September 30, 2014. The effective tax rates for these periods differ from the U.S. federal statutory rate of 35% due primarily to the effect of income earned by certain of our overseas entities being taxed at rates lower than the federal statutory rate, partially offset by state income taxes. The effective tax rate for the three and nine months ended September 30, 2015, also reflected a \$29.3 million tax benefit due to a recent U.S. Tax Court opinion involving an independent third party, filed July 27, 2015. Based on the findings of the U.S. Tax Court, we were required to, and did, refund to our foreign subsidiary the share-based compensation element of certain intercompany charges made in prior periods. On an ongoing basis, share-based compensation will be excluded from intercompany charges, however the impact of this change is not expected to have a material effect on our effective tax rate. The effective tax rate for the nine months ended September 30, 2015, further reflected discrete benefits of approximately \$7.8 million, recorded in the second quarter of 2015, mainly related to net releases of unrecognized tax benefits in connection with the conclusion of tax audits in various tax jurisdictions. We intend to indefinitely reinvest outside the U.S. all of our undistributed foreign earnings that were not previously subject to U.S. tax.

The lower effective tax rate for the three and nine months ended September 30, 2015 as compared to the same periods of 2014 is mainly attributable to the above-mentioned discrete benefits in the three and nine months ended September 30, 2015.

We file federal, state, and foreign income tax returns in many jurisdictions in the U.S. and abroad. Years prior to 2012 are considered closed for most significant jurisdictions. Certain of our unrecognized tax benefits could reverse based on the normal expiration of various statutes of limitations, which could affect our effective tax rate in the period in which they reverse.

We are subject to the examination of our income tax returns by various tax authorities and 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.

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Liquidity and Capital Resources

Sources and Uses of Cash

Our principal source of liquidity is cash provided by operations and proceeds from employee exercises of stock options. Cash and cash equivalents plus short and long-term investments increased from \$2.5 billion at December 31, 2014, to \$3.1 billion at September 30, 2015. Cash generation is one of our fundamental strengths and provides us with substantial financial flexibility in meeting our operating, investing, and financing needs.

As of September 30, 2015, \$882.6 million of our cash, cash equivalents and investments were held by foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. We currently have no plans to repatriate any foreign earnings back to the U.S. as we believe our cash flows provided by our U.S. operations will meet our U.S. liquidity needs.

Condensed Consolidated Cash Flow Data (unaudited)

The following table summarizes our cash flows for the nine months ended September 30, 2015, and 2014 (in millions):

	Nine Months Ended September 30,	
	2015	2014
Net cash provided by (used in)		
Operating activities	\$488.5	\$470.9
Investing activities	(436.4) 49.6
Financing activities	217.2	(808.8
Effect of exchange rates on cash and cash equivalents	(1.4) (0.8
Net increase (decrease) in cash and cash equivalents	\$267.9	\$(289.1

Operating Activities

For the nine months ended September 30, 2015, cash flow provided by operating activities of \$488.5 million exceeded our net income of \$398.8 million primarily for the following reasons:

Our net income included non-cash charges in the form of share-based compensation of \$126.6 million, amortization of intangible assets of \$18.6 million, depreciation of \$46.3 million, and accretion of discounts and amortization of premiums on investments of \$18.5 million.

The non-cash charges outlined above were partly offset by unfavorable changes in operating assets and liabilities.

These changes primarily consisted of an increase in prepaids and other assets of \$41.1 million driven by the increase in lease receivables and prepaid taxes, an increase in inventory of \$30.7 million, an increase in accounts receivable of \$19.7 million, and a decrease in other accrued liabilities of \$16.7 million mainly due to settlement payments made in relation to product liability litigation.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2015, included purchases of investments (net of proceeds from sales and maturities of investments) of \$375.1 million and acquisition of property and equipment of \$61.3 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/or tax exempt municipal notes, corporate notes and bonds, commercial paper, cash deposits, and money market funds.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2015, consisted primarily of the proceeds from stock option exercises and employee stock purchase of \$294.0 million and excess tax benefits from employee stock plans of \$33.2 million. The cash provided by financing activities was partly offset by cash used in the repurchase of approximately 199,000 shares of our common stock in the open market for \$99.5 million and taxes paid on behalf of employees related to net share settlement of vested employee equity awards of \$10.5 million. Net cash used in financing activities during the nine months ended September 30, 2014, consisted primarily of the repurchase of 2.5 million shares of our common stock through an accelerated share repurchase program for \$1.0 billion, partly offset by proceeds from stock option exercises and employee stock purchases of \$176.0 million and excess tax benefits from employee stock plans of \$15.2 million.

Capital Expenditures

Our business is not capital intensive and we had no material commitments for capital expenditures as of the end of the third quarter of 2015.

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Our cash requirements depend on numerous factors, including the market acceptance of our products, the resources we devote to developing and supporting our products and other factors. In 2015, we made substantial investments in our commercial operations, product development activities, facilities, and intellectual property. We expect to continue to devote substantial resources to expand our commercial operations, product development and manufacturing activities, facilities, as well as procedure adoption and acceptance of our products. 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.

Critical Accounting Policies and 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. generally accepted accounting principles (“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 policies and 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 policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, that are of significance, or potential significance to the Company.

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, 2015, compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014.

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 Securities and Exchange Commission’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 controls over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial statements.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information included in Note 6 to the Condensed Consolidated Financial Statements (Unaudited) included in Part I, Item 1 of this quarterly report is incorporated herein by reference.

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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, 2014, 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, 2014, 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.

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, 2015:

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, 2015	—	\$—	—	\$936.0 million
August 1 to August 31, 2015	24,415	\$503.63	24,415	\$923.7 million
September 1 to September 30, 2015	45,304	\$512.44	45,304	\$900.5 million
Total during quarter ended September 30, 2015	69,719	\$509.36	69,719	

(1) Since March 2009, we have had an active stock repurchase program. As of September 30, 2015, the Board of Directors has authorized an aggregated amount of up to \$4.0 billion for stock repurchases, of which the most recent authorization occurred in January 2015 when the Board of Directors increased the authorization for stock repurchases by \$1.0 billion. The remaining \$900.5 million represents the amount available to repurchase shares under the authorized repurchase program as of September 30, 2015.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Exhibit

Number Description

3.1	Amended and Restated Certificate of Incorporation of Intuitive Surgical, Inc. (incorporated by reference to Exhibit 3.1 on Form 10-K filed with the Securities and Exchange Commission on February 6, 2009).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Intuitive Surgical, Inc. (incorporated by reference to Exhibit 3.2 on Form 10-K filed with the Securities and Exchange Commission on February 6, 2009).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Intuitive Surgical, Inc. (incorporated by reference to Exhibit A to Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on March 1, 2012).
3.4	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 April 24, 2012).
10.1	Intuitive Surgical, Inc. Form of Indemnity Agreement (incorporated by reference to Exhibit 10.1 on Form 8-K filed with the Securities and Exchange Commission on August 3, 2015).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Intuitive Surgical, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in 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.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INTUITIVE SURGICAL, INC.

By: */s/ MARSHALL L. MOHR*
Marshall L. Mohr
Senior Vice President and Chief Financial Officer
(Principal Financial Officer and duly authorized signatory)
Date: October 21, 2015