

INTUITIVE SURGICAL INC

Form 10-Q

April 19, 2016

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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 March 31, 2016

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 77-0416458

(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification No.)

1020 Kifer Road

Sunnyvale, California 94086

(Address of principal executive offices) (Zip Code)

(408) 523-2100

(Registrant's telephone number, including area code)

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 38,060,364 shares of Common Stock, \$0.001 par value per share, outstanding as of April 15, 2016.

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INTUITIVE SURGICAL, INC.

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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) | March 31, 2016 | December 31, 2015 |
|--|-------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 980.5 | \$ 714.6 |
| Short-term investments | 827.9 | 845.2 |
| Accounts receivable, net | 325.9 | 394.3 |
| Inventory | 163.0 | 167.9 |
| Prepays and other current assets | 109.1 | 73.5 |
| Total current assets | 2,406.4 | 2,195.5 |
| Property, plant and equipment, net | 439.0 | 432.1 |
| Long-term investments | 1,992.7 | 1,788.0 |
| Long-term deferred tax assets | 135.6 | 167.8 |
| Intangible and other assets, net | 131.5 | 122.8 |
| Goodwill | 201.1 | 201.1 |
| Total assets | \$ 5,306.3 | \$ 4,907.3 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 57.9 | \$ 52.6 |
| Accrued compensation and employee benefits | 77.5 | 117.3 |
| Deferred revenue | 225.3 | 225.6 |
| Other accrued liabilities | 92.2 | 96.4 |
| Total current liabilities | 452.9 | 491.9 |
| Other long-term liabilities | 103.0 | 95.9 |
| Total liabilities | 555.9 | 587.8 |
| 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 March 31, 2016, and December 31, 2015 | — | — |
| Common stock, 100.0 shares authorized, \$0.001 par value, 38.1 shares and 37.4 shares issued and outstanding as of March 31, 2016, and December 31, 2015, respectively | — | — |
| Additional paid-in capital | 3,739.5 | 3,429.8 |
| Retained earnings | 1,009.6 | 899.2 |
| Accumulated other comprehensive gain (loss) | 1.3 | (9.5) |
| Total stockholders' equity | 4,750.4 | 4,319.5 |
| Total liabilities and stockholders' equity | \$ 5,306.3 | \$ 4,907.3 |
| 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 March 31, | |
|--|------------------------------------|---------|
| | 2016 | 2015 |
| Revenue: | | |
| Product | \$470.0 | \$418.2 |
| Service | 124.5 | 113.9 |
| Total revenue | 594.5 | 532.1 |
| Cost of revenue: | | |
| Product | 151.6 | 153.5 |
| Service | 37.9 | 41.8 |
| Total cost of revenue | 189.5 | 195.3 |
| Gross profit | 405.0 | 336.8 |
| Operating expenses: | | |
| Selling, general and administrative | 172.8 | 162.0 |
| Research and development | 53.2 | 44.4 |
| Total operating expenses | 226.0 | 206.4 |
| Income from operations | 179.0 | 130.4 |
| Interest and other income, net | 5.5 | 4.3 |
| Income before taxes | 184.5 | 134.7 |
| Income tax expense | 48.1 | 37.7 |
| Net income | \$136.4 | \$97.0 |
| Net income per share: | | |
| Basic | \$3.62 | \$2.64 |
| Diluted | \$3.54 | \$2.57 |
| Shares used in computing net income per share: | | |
| Basic | 37.7 | 36.7 |
| Diluted | 38.5 | 37.7 |
| Total comprehensive income | \$147.2 | \$100.9 |

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

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

| | Three Months Ended March 31, | |
|--|------------------------------------|----------|
| in millions | 2016 | 2015 |
| Operating activities: | | |
| Net income | \$136.4 | \$97.0 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and loss on disposal of property, plant, and equipment, net | 18.3 | 14.0 |
| Amortization of intangible assets | 5.1 | 6.2 |
| Loss on investments, accretion of discounts and amortization of premiums on investments, net | 8.3 | 5.4 |
| Deferred income taxes | 28.9 | 2.1 |
| Income tax benefits from employee stock plans | 10.8 | 8.2 |
| Excess tax benefit from employee stock plans | (18.3) | (10.2) |
| Share-based compensation expense | 42.7 | 41.1 |
| Changes in operating assets and liabilities | | |
| Accounts receivable | 68.4 | 22.7 |
| Inventory | (7.8) | (27.9) |
| Prepays and other assets | (49.9) | 9.2 |
| Accounts payable | 5.3 | 2.7 |
| Accrued compensation and employee benefits | (39.7) | (26.6) |
| Deferred revenue | 0.3 | (4.5) |
| Other liabilities | (0.3) | (15.7) |
| Net cash provided by operating activities | 208.5 | 123.7 |
| Investing activities: | | |
| Purchase of investments | (487.7) | (282.5) |
| Proceeds from sales of investments | 64.5 | 74.5 |
| Proceeds from maturities of investments | 240.9 | 139.5 |
| Purchase of property, plant and equipment | (9.6) | (19.2) |
| Net cash used in investing activities | (191.9) | (87.7) |
| Financing activities: | | |
| Proceeds from issuance of common stock relating to employee stock plans | 258.8 | 80.2 |
| Excess tax benefit from employee stock plans | 18.3 | 10.2 |
| Taxes paid related to net share settlement of equity awards | (20.6) | (9.7) |
| Repurchase and retirement of common stock | (8.1) | (14.7) |
| Net cash provided by financing activities | 248.4 | 66.0 |
| Effect of exchange rate changes on cash and cash equivalents | 0.9 | (1.2) |
| Net increase in cash and cash equivalents | 265.9 | 100.8 |
| Cash and cash equivalents, beginning of period | 714.6 | 600.3 |
| Cash and cash equivalents, end of period | \$980.5 | \$701.1 |
| 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, 2015, 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, 2015, which was filed with the SEC on February 2, 2016. The results of operations for the first three months of fiscal year 2016 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 (“ASU”) No. 2014-09, Revenue from Contracts with Customers. This 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. This 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 evaluating the effect that the updated standard will have on its Consolidated Financial Statements and related disclosures.

In February 2016, FASB issued ASU No. 2016-02, Leases (Topic 842), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). For lessees, leases will continue to be classified as either operating or financing in the income statement. This ASU becomes effective for the Company in the first quarter of fiscal year 2019 and early adoption is permitted. This ASU is required to be applied with a modified retrospective approach and requires application of the new standard at the beginning of the earliest comparative period presented. The Company generally does not finance purchases of equipment or other capital, but does lease some of its facilities. The Company’s customers do finance purchases of da Vinci systems and ancillary products, including directly with the Company. It is currently unknown whether this ASU will change customer buying patterns or

behaviors. The Company is evaluating the effect that this ASU will have on its Consolidated Financial Statements and related disclosures.

In March 2016, FASB issued ASU No. 2016-09, Improvements to Employee Share-based Payment Accounting. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This ASU requires that excess tax benefits and deficiencies be recognized as income tax benefit or expense in the income statement, and therefore, the Company anticipates increased income tax expense volatility after adoption of this ASU. The Company currently plans to implement this ASU as required in the first quarter of fiscal year 2017. The Company is evaluating the effect that this ASU will have on its Consolidated Financial Statements and related disclosures.

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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, 2015 that are of significance, or potential significance to the Company.

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 reported as cash and cash equivalents, short-term, or long-term investments as of March 31, 2016, and December 31, 2015 (in millions):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value | Reported as: | | |
|---|-------------------|------------------------------|-------------------------------|---------------|------------------------------------|-------------------------------|------------------------------|
| | | | | | Cash and Cash Equivalents | Short- term Investments | Long- term Investments |
| March 31, 2016 | | | | | | | |
| Cash | \$ 213.3 | \$ — | \$ — | \$213.3 | \$213.3 | \$ — | \$ — |
| Level 1: | | | | | | | |
| Money market funds | 656.7 | — | — | 656.7 | 656.7 | — | — |
| U.S. treasuries & corporate equity securities | 264.3 | 1.0 | (1.2) | 264.1 | — | 62.0 | 202.1 |
| Subtotal | 921.0 | 1.0 | (1.2) | 920.8 | 656.7 | 62.0 | 202.1 |
| Level 2: | | | | | | | |
| Commercial paper | 88.3 | — | — | 88.3 | 76.9 | 11.4 | — |
| Corporate securities | 1,190.0 | 5.4 | (0.3) | 1,195.1 | 1.3 | 393.1 | 800.7 |
| U.S. government agencies | 685.9 | 1.7 | (0.1) | 687.5 | 12.3 | 219.7 | 455.5 |
| Non-U.S. government securities | 28.8 | — | — | 28.8 | — | 10.3 | 18.5 |
| Municipal securities | 665.9 | 1.5 | (0.1) | 667.3 | 20.0 | 131.4 | 515.9 |
| Subtotal | 2,658.9 | 8.6 | (0.5) | 2,667.0 | 110.5 | 765.9 | 1,790.6 |
| Total assets measured at fair value | \$ 3,793.2 | \$ 9.6 | \$ (1.7) | \$3,801.1 | \$980.5 | \$ 827.9 | \$ 1,992.7 |
| December 31, 2015 | | | | | | | |
| Cash | \$ 202.6 | \$ — | \$ — | \$202.6 | \$202.6 | \$ — | \$ — |
| Level 1: | | | | | | | |
| Money market funds | 430.6 | — | — | 430.6 | 430.6 | — | — |
| U.S. treasuries & corporate equity securities | 253.6 | — | (1.8) | 251.8 | 50.6 | 52.4 | 148.8 |
| Subtotal | 684.2 | — | (1.8) | 682.4 | 481.2 | 52.4 | 148.8 |
| Level 2: | | | | | | | |
| Commercial paper | 76.4 | — | — | 76.4 | 3.8 | 72.6 | — |
| Corporate securities | 1,131.0 | 0.8 | (3.0) | 1,128.8 | — | 384.5 | 744.3 |
| U.S. government agencies | 618.5 | — | (1.5) | 617.0 | 27.0 | 194.8 | 395.2 |
| Non-U.S. government securities | 28.8 | — | (0.1) | 28.7 | — | 10.3 | 18.4 |
| Municipal securities | 611.9 | 0.6 | (0.6) | 611.9 | — | 130.6 | 481.3 |
| Subtotal | 2,466.6 | 1.4 | (5.2) | 2,462.8 | 30.8 | 792.8 | 1,639.2 |

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Total assets measured at fair value \$ 3,353.4 \$ 1.4 \$ (7.0) \$ 3,347.8 \$ 714.6 \$ 845.2 \$ 1,788.0

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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 March 31, 2016 (in millions):

| | Amortized Fair | |
|------------------------------|----------------|------------|
| | Cost | Value |
| Mature in less than one year | \$ 937.0 | \$ 937.4 |
| Mature in one to five years | 1,984.0 | 1,992.7 |
| Total | \$ 2,921.0 | \$ 2,930.1 |

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 three months ended March 31, 2016, 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 the 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 gain (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 \$0.9 million and \$3.3 million for the three months ended March 31, 2016, and 2015, respectively. The amounts reclassified to expenses related to the hedged transactions and the ineffective portions of cash flow hedges were not material for the periods presented.

Other Derivatives Not Designated as Hedging Instruments

Other derivatives not designated as hedging instruments consist primarily of forward contracts that the Company uses to hedge intercompany balances and other monetary assets or liabilities denominated in currencies other than the USD, primarily the EUR, GBP, JPY, KRW, 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 months ended March 31, 2016, and 2015, 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 | |
|----------------------------------|---|-------------------|---|-------------------|
| | March 31, 2016 | December 31, 2015 | March 31, 2016 | December 31, 2015 |
| Notional amounts: | | | | |
| Forward contracts | \$ 106.8 | \$ 89.1 | \$ 90.5 | \$ 128.7 |
| Gross fair value recorded in: | | | | |
| Prepaid and other current assets | \$ 0.7 | \$ 2.0 | \$ 0.4 | \$ 2.6 |
| Other accrued liabilities | \$ 2.4 | \$ 0.5 | \$ 1.0 | \$ 0.2 |

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NOTE 4. BALANCE SHEET DETAILS AND OTHER FINANCIAL INFORMATION

Inventory

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

| | March 31, December 31, | |
|-----------------|------------------------|----------|
| | 2016 | 2015 |
| Raw materials | \$ 51.1 | \$ 53.3 |
| Work-in-process | 8.1 | 10.2 |
| Finished goods | 103.8 | 104.4 |
| Total inventory | \$ 163.0 | \$ 167.9 |

Supplemental Cash Flow Information

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

| | Three Months Ended March 31, 2016 2015 | |
|---|--|-------|
| Equipment transfers from inventory to property, plant and equipment | \$13.2 | \$7.2 |

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 | |
|-------------------------------------|-------------------|----------------------|
| | March 31, 2016 | December 31, 2015 |
| Gross lease receivable | \$88.3 | \$ 67.1 |
| Unearned income | (4.0) | (3.4) |
| Allowance for credit loss | (2.3) | (0.4) |
| Net investment in sales-type leases | 82.0 | 63.3 |
| Reported as: | | |
| Prepays and other current assets | 21.3 | 16.1 |
| Intangible and other assets, net | 60.7 | 47.2 |
| Total, net | \$82.0 | \$ 63.3 |

Contractual maturities of gross lease receivables at March 31, 2016, are as follows (in millions):

| | Amount |
|------------|---------|
| 2016 | \$ 17.6 |
| 2017 | 24.7 |
| 2018 | 23.6 |
| 2019 | 14.8 |
| 2020 | 6.1 |
| Thereafter | 1.5 |
| Total | \$ 88.3 |

NOTE 6. CONTINGENCIES

The Company is involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, intellectual property, insurance, contract disputes, employee related, and other matters. Certain of these lawsuits and claims are described in further detail below. It is not possible to predict what the outcome of these matters will be and the Company cannot guarantee that any resolution will be reached on commercially reasonable terms, if at all. With the exception of the charges recorded related to the Company's estimate of the probable loss associated with the tolled product liability claims described below, the Company has determined that an estimate of either probable losses or range of loss related to material pending or threatened

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litigation matters cannot be determined as of March 31, 2016. Nevertheless, it is possible that future legal costs (including settlements, judgments, legal fees, and other related defense costs) could have a material adverse effect on the Company's business, financial position, 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 allegedly making 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. The case is moving forward on the claims that remain, and discovery is ongoing. The plaintiffs moved for class certification on September 1, 2015, the Company filed its opposition on October 15, 2015, and the plaintiffs filed their reply on November 16, 2015. On January 21, 2016, the court held a hearing on the motion, which remains pending. 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 plaintiff seeks to recover, on the Company's behalf, 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. The plaintiff 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 plaintiffs filed an opposition on October 9, 2014, and the Company filed its

reply on October 30, 2014. The court denied the Company's motion to dismiss on November 16, 2015, and the case is moving forward. Discovery is ongoing and no trial date has been set. On January 26, 2016, the Company moved to stay this lawsuit in favor of Public School Teachers' Pension and Retirement Fund of Chicago v. Guthart et al. (see below for additional description). Plaintiff opposed the motion to stay on February 16, 2016, the Company filed its reply on March 1, 2016, and a hearing was set for June 16, 2016. While the motion was pending, however, the Company and the plaintiff reached an agreement in principle under which the plaintiff will file a motion to intervene in the Public School Teachers' Pension and Retirement Fund of Chicago action and will withdraw his opposition to the stay motion. On March 17, 2016, the parties jointly requested that the court not rule on the stay motion while the agreement in principle is being implemented, because the agreement will resolve the motion. 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.

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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 on the grounds that 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 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 of the proceedings 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 filed a demurrer (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. 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 court later amended the case schedule, and trial is currently set for September 15, 2016. The Company plans to file a motion for summary judgment, and/or other dispositive motions, in advance of this date. 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 86 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. In total, plaintiffs seek damages on behalf of 55 patients who had da Vinci Surgeries in 22 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,

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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 also engaged in well-funded national advertising efforts seeking patients dissatisfied with da Vinci Surgery. The Company has received a significant number of such claims from plaintiffs' attorneys that it believes are a result of these advertising efforts. A substantial number of claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor ("MCS") instruments which 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. 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 2014 that, while it denies any and all liability, in light of the costs and risks of litigation, settlement of certain claims was appropriate. During the years ended December 31, 2015 and 2014, the Company recorded pre-tax charges of \$13.8 million and \$82.4 million, respectively, to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements. During the three months ended March 31, 2016, and 2015, the Company recorded pre-tax charges of \$1.9 million and \$7.2 million, respectively, related to these product liability claims.

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 March 31, 2016, and December 31, 2015, a total of \$24.8 million and \$24.4 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 a decedent's surgery on such decedent's behalf (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. On July 27, 2015, plaintiff filed a motion for reconsideration with the Court of Appeal; the Court of Appeal denied the motion for reconsideration on August 10, 2015. On September 9, 2015, plaintiff filed a Petition for Review with the Washington State Supreme Court. On February 10, 2016, the Washington Supreme Court issued an order granting the plaintiff's Petition for Review. Oral argument on the appeal before the Washington Supreme Court is set for June 7, 2016.

In December 2012, the Company was named as a defendant in a product liability action filed in the Superior Court of California, Santa Clara County (Michelle Zarick et al. v. Intuitive Surgical, Inc., No. 12-237723). In Zarick, plaintiff asserts product liability claims against the Company as a result of injuries purportedly suffered during a hysterectomy, which was conducted with the use of the da Vinci Surgical System. The plaintiff in Zarick asserts that her injuries were caused, in whole or in part, by the Company's purported failure to properly train, warn, and instruct the surgeon and by the malfunction of da Vinci surgical equipment during her surgery. The lawsuit seeks damages for lost earnings, past medical expenses, and pain and suffering, as well as punitive damages. A trial began on April 5, 2016. In pretrial filings, the plaintiff asserted damages of \$300 million for lost earnings, past medical expenses, pain and suffering, loss of consortium as well as punitive damages. At trial, the Judge held that the plaintiff had not established a basis for punitive damages. In closing argument, the plaintiff asked the jury to award between \$15 million to \$30 million. The Company believes the claims are without merit. Based on currently available information, the Company believes that it is reasonably possible that an unfavorable judgment could be rendered in this matter.

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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. (“Illinois Union”) seeks to rescind the Life Sciences Products-Completed Operations Liability Policy issued by plaintiff to the Company, which provides coverage for product 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 Specialty Insurance Co. (“Navigators”) 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. On October 20, 2015, the Company filed a complaint alleging breach of contract and bad faith against Illinois Union and Navigators in an action entitled Intuitive Surgical Inc. v. Illinois Union Insurance Co., et al., No. 5:15-cv-4834, based on the defendants failure to indemnify the Company for losses incurred in the defense and settlement of certain product liability claims brought against the Company during the insurance policy period March 1, 2013 to March 1, 2014. The Company’s breach of contract and bad faith action against the insurers has been consolidated with the insurers’ rescission actions for all purposes except for trial, leaving open for a later date as to whether the cases will be consolidated for trial as well. Both Illinois Union and Navigators have moved to dismiss the Company’s complaint in that action. On March 15, 2016, Illinois Union and Navigators filed motions for summary judgment, which the Company plans to oppose. 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.

On March 3, 2015, the Company also filed a cross-complaint for breach of contract and declaratory judgment against Ironshore Specialty Insurance Co. (“Ironshore”) based on Ironshore’s failure to indemnify the Company for losses incurred in the defense and settlement of certain product liability claims made 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. Ironshore and the Company reached a settlement that resolved completely the Company’s cross-complaint against Ironshore and Ironshore’s counterclaim against the Company and, on December 28, 2015, the Court dismissed the claims between the Company and Ironshore with prejudice. The settlement did not have a material effect on the Company’s Consolidated Financial Statements.

NOTE 7. STOCKHOLDERS’ EQUITY

Stock Repurchase Program

Since March 2009, the Company has had a stock repurchase program authorized by the Board of Directors (the “Board”). As of March 31, 2016, the Board has authorized an aggregate amount of up to \$4.0 billion for repurchases of the Company’s outstanding common stock, of which the most recent authorization occurred in January 2015 when the Board increased the authorization for

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stock repurchase by \$1.0 billion. As of March 31, 2016, the remaining amount of share repurchases authorized by the Board was approximately \$808.2 million.

The Company repurchased approximately 16,000 shares and 30,000 shares of the Company's common stock during the three months ended March 31, 2016, and 2015, respectively. The following table provides the average price per share and the value of share repurchased during the three months ended March 31, 2016, and 2015 (in millions, except per share amounts):

| | Three Months Ended March 31, | |
|-----------------------------|---------------------------------|----------|
| | 2016 | 2015 |
| Average price per share | \$516.54 | \$495.45 |
| Value of shares repurchased | \$8.1 | \$14.7 |

Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss), net of tax, for the three months ended March 31, 2016, and 2015, are as follows (in millions):

| | Three Months Ended March 31, 2016 | | | | |
|--|---|--|--|------------------------------|---------|
| | Unrealized Gains (Losses) on Hedge Instruments | Unrealized Gains (Losses) on Available-for-Sale Securities | Foreign Currency Translation Gains (Losses) | Employee Benefit Plans | Total |
| Beginning balance | \$1.5 | \$ (4.2) | \$ (3.3) | \$ (3.5) | \$(9.5) |
| Other comprehensive income before reclassifications | (2.5) | 10.4 | 3.5 | — | 11.4 |
| Amounts reclassified from accumulated other comprehensive income | (0.7) | — | — | 0.1 | (0.6) |
| Net current-period other comprehensive income (loss) | (3.2) | 10.4 | 3.5 | 0.1 | 10.8 |
| Ending balance | \$(1.7) | \$ 6.2 | \$ 0.2 | \$ (3.4) | \$1.3 |

| | Three Months Ended March 31, 2015 | | | | |
|--|---|--|--|------------------------------|---------|
| | Unrealized 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 | 4.3 | 4.9 | (1.7) | 0.4 | 7.9 |
| Amounts reclassified from accumulated other comprehensive income | (3.6) | (0.5) | — | 0.1 | (4.0) |
| Net current-period other comprehensive income (loss) | 0.7 | 4.4 | (1.7) | 0.5 | 3.9 |
| Ending balance | \$1.8 | \$ 4.2 | \$ (3.8) | \$ (3.4) | \$(1.2) |

NOTE 8. SHARE-BASED COMPENSATION

As of March 31, 2016, approximately 1.3 million shares of common stock were reserved for future issuance under the Company's stock plans. A maximum of 0.6 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 three months ended March 31, 2016, is presented as follows (in millions, except per share amounts):

Stock Options
Outstanding

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| | Number Outstanding Share | Weighted Average Exercise Price Per Share |
|------------------------------|--------------------------------|---|
| Balance at December 31, 2015 | 4.2 | \$ 421.00 |
| Options granted | 0.2 | \$ 536.61 |
| Options exercised | (0.6) | \$ 399.79 |
| Options forfeited/expired | (0.1) | \$ 507.69 |
| Balance at March 31, 2016 | 3.7 | \$ 428.68 |

As of March 31, 2016, options to purchase an aggregate of 2.7 million shares of common stock were exercisable at a weighted-average price of \$405.80 per share.

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Restricted Stock Units Information

A summary of RSU activity for the three months ended March 31, 2016, is presented as follows (in millions, except per share amounts):

| | Shares | Weighted Average Grant Date Fair Value |
|---------------------------------------|--------|--|
| Unvested balance at December 31, 2015 | 0.4 | \$ 485.55 |
| Granted | 0.3 | \$ 535.65 |
| Vested | (0.1) | \$ 482.86 |
| Canceled | — | \$ 505.26 |
| Unvested balance at March 31, 2016 | 0.6 | \$ 510.62 |

During the three months ended March 31, 2016, approximately 9,000 RSUs were canceled.

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (“ESPP”), employees purchased approximately 0.1 million shares for \$18.1 million and 0.1 million shares for \$17.8 million during the three months ended March 31, 2016, and 2015, respectively.

Share-based Compensation Expense

The following table summarizes share-based compensation expense for the three months ended March 31, 2016, and 2015 (in millions):

| | Three Months Ended March 31, | |
|--|---------------------------------------|--------|
| | 2016 | 2015 |
| Cost of sales - products | \$5.7 | \$5.3 |
| Cost of sales - services | 3.0 | 3.5 |
| Total cost of sales | 8.7 | 8.8 |
| Selling, general and administrative | 24.2 | 23.1 |
| Research and development | 9.9 | 9.3 |
| Share-based compensation expense before income taxes | 42.8 | 41.2 |
| Income tax benefit | 13.2 | 13.5 |
| Share-based compensation expense after income taxes | \$29.6 | \$27.7 |

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 March 31, | | | |
|---|---------------------------------|---|----------|---|
| | 2016 | | 2015 | |
| Stock Option Plans | | | | |
| Risk free interest rate | 1.2 | % | 1.6 | % |
| Expected term (in years) | 4.4 | | 4.5 | |
| Expected volatility | 29 | % | 28 | % |
| Weighted average fair value at grant date | \$138.69 | | \$135.61 | |
| Employee Stock Purchase Plan | | | | |
| Risk free interest rate | 0.6 | % | 0.3 | % |
| Expected term (in years) | 1.2 | | 1.2 | |
| Expected volatility | 33 | % | 33 | % |
| Weighted average fair value at grant date | \$156.87 | | \$145.52 | |

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NOTE 9. INCOME TAXES

Income tax expense for the three months ended March 31, 2016, was \$48.1 million, or 26.1% of income before taxes, compared with \$37.7 million, or 28.0% of income before taxes for the three months ended March 31, 2015. 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 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 months ended March 31, 2016, included the tax benefit from the U.S. federal Research and Development ("R&D") credit. The effective tax rate for the three months ended March 31, 2015, did not reflect the tax benefit of federal R&D credit as it expired at the end of 2014 and was reinstated retroactively in December 2015.

As of March 31, 2016, the Company had total gross unrecognized tax benefits of approximately \$99.0 million compared with approximately \$92.4 million as of December 31, 2015, representing a net increase of approximately \$6.6 million for the three months ended March 31, 2016. 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 months ended March 31, 2016, and 2015 (in millions, except per share amounts):

| | Three Months Ended March 31, 2016 2015 | |
|--|---|--------|
| Numerator: | | |
| Net income | \$136.4 | \$97.0 |
| Denominator: | | |
| Weighted-average shares outstanding used in basic calculation | 37.7 | 36.7 |
| Add: dilutive effect of potential common shares | 0.8 | 1.0 |
| Weighted-average shares used in computing diluted net income per share | 38.5 | 37.7 |
| Net income per share: | | |
| Basic | \$3.62 | \$2.64 |
| Diluted | \$3.54 | \$2.57 |

Share-based compensation awards of approximately 1.0 million and 1.9 million weighted-average shares were outstanding for the three months ended March 31, 2016, and 2015, respectively, 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 March 31, 2016, and results of operations for the three months ended March 31, 2016, and 2015, 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, 2015.

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to 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 healthcare spending; health care reform legislation in the United States and its impact on hospital spending, reimbursement, insurance deductibles, and fees 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 healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; 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, 2015, 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, EndoWrist® Stapler 30, 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 patients, typically resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering relative to minimally invasive surgery ("MIS"), where MIS is available. For over two and a half decades, MIS has reduced trauma to patients by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures, 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), 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. 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 and da Vinci Xi Surgical Systems 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. For the da Vinci Si and da Vinci Xi platforms, we offer advanced energy instrumentation, including the EndoWrist One Vessel Sealer and EndoWrist Stapler products 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.

Procedures

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

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, within the prevailing economics of healthcare providers. da Vinci Surgical Systems are used primarily in gynecologic surgery, general surgery, urologic 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 healthcare providers. Target procedures in gynecology include da Vinci Hysterectomy (“dVH”), for both cancer and benign procedures, and sacrocolpopexy. Target procedures in general surgery include hernia repair (both ventral and inguinal), colorectal procedures, and cholecystectomy. Target procedures in urology include da Vinci Prostatectomy (“dVP”) and partial nephrectomy. 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. Patients need to 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 2015, approximately 652,000 surgical procedures were performed with the da Vinci Surgical System, compared with approximately 570,000 and 523,000 procedures performed in 2014 and 2013, respectively. Approximately 176,000 procedures were performed during the three months ended March 31, 2016, up approximately 17% compared to the three months ended March 31, 2015. The growth in our overall procedure volume in 2015 and the first quarter

of 2016 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 499,000 in 2015, compared with approximately 449,000 in 2014, and approximately 422,000 in 2013. U.S. procedure volume for the three months ended March 31, 2016 increased approximately 15% compared to the three months ended March 31, 2015. Gynecology is our largest U.S. surgical specialty and the procedure volume was approximately 238,000 in 2015, compared with 235,000 in 2014 and 240,000 in 2013. General surgery is our second largest and fastest growing specialty in the U.S. with procedure volume that grew to approximately 140,000 in 2015 compared with

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approximately 107,000 in 2014 and 81,000 in 2013. U.S. urology procedure volume was approximately 102,000 in 2015, compared with approximately 91,000 in 2014 and 85,000 in 2013.

Procedures Outside of the U.S.

Overall procedures outside of the U.S. (“OUS”) grew to approximately 153,000 in 2015, compared with approximately 121,000 in 2014 and approximately 101,000 in 2013. OUS procedure volume for the three months ended March 31, 2016 increased approximately 22% compared to the three months ended March 31, 2015. Procedure growth in most OUS markets was driven largely by dVP volume, which grew to approximately 79,000 in 2015, compared with approximately 65,000 in 2014, and approximately 56,000 in 2013. Partial nephrectomy, general surgery, and gynecologic oncology procedures also contributed to OUS procedure growth.

See “Recent Business Events and Trends” for further discussion on U.S. and OUS procedures.

Business Model

Overview

We generate revenue from both the initial capital sales of da Vinci Surgical Systems and from subsequent sales of instruments, accessories and service, as recurring revenue. 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 purchase 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

Recurring revenue has generally grown at a faster rate than system revenue in the last few fiscal years. Recurring revenue increased to \$1.7 billion or 70% of total revenue in 2015, compared with \$1.5 billion, or 70% of total revenue in 2014, and \$1.4 billion, or 63% of total revenue in 2013. Recurring revenue for the three months ended March 31, 2016 was \$446.6 million, or 75% of revenue, compared with \$391.1 million, or 74% of revenue for the three months ended March 31, 2015. The growth of recurring revenue and its increasing proportion of total revenue largely reflect continued procedure adoption on a growing base of installed da Vinci Surgical Systems. The installed base of da Vinci Surgical Systems has grown to approximately 3,660 at March 31, 2016.

Procedure Mix / Products

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. Our fully featured da Vinci Xi system with advanced instruments including the EndoWrist One Vessel Sealer, EndoWrist Stapler products, and our Table Motion product target the more complex procedure segment. Lower priced products, including the three-arm da Vinci Si-e System, refurbished da Vinci Si, and lower priced Single-Site instruments are targeted towards less complex procedures.

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, hernia repairs, cholecystectomies, 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.

Distribution Channels

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

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Intuitive Surgical da Vinci System Leasing

Since 2013, we have entered into sales-type and operating lease arrangements directly with certain qualified customers as a way to offer customers flexibility in how they acquire 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 months ended March 31, 2016, and 2015, we shipped 31 and 11 systems under lease arrangements, respectively, of which 19 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. We believe this has been an effective program and has been well received by our customers and we plan to continue with our system leasing program in the future. Operating lease revenue for the three months ended March 31, 2016, and 2015, was \$3.5 million and \$1.2 million, respectively. As of March 31, 2016, 62 da Vinci systems were installed at customers under operating lease arrangements.

Regulatory Activities

Clearances and Approvals

We have obtained the clearances required to market our multiport products associated with all generations of our da Vinci Surgical Systems (Standard, S, Si, and Xi systems) for our targeted surgical specialties within the U.S. and most of the European markets in which we operate. 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. We received regulatory clearances for the da Vinci Xi Surgical System in South Korea in October 2014 and in Japan in March 2015. The regulatory status of the da Vinci Xi Surgical System in other OUS 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 in April 2014. Later in 2014, 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 in Europe and received FDA clearance in January 2016 for our integrated table motion product. In March 2016, we received FDA 510(k) clearances in the U.S. for Single-Site instruments and the 30mm EndoWrist stapler products for the da Vinci Xi Surgical System (see the complete description of the EndoWrist Stapler 30 in the New Product Introductions Section). In March 2016, we also received CE mark clearances in Europe for Single-Site instruments and the 30mm EndoWrist stapler products for the da Vinci Xi Surgical System. 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. Since this clearance, we have largely completed modifications to the da Vinci Single Port Surgical System to integrate it into the da Vinci Xi product family as a dedicated single port patient console compatible with existing da Vinci Xi surgeon consoles, vision carts, and other equipment. We plan to seek additional FDA clearance(s) for this da Vinci Xi version of 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 the da Vinci Single Port Surgical System in 2016, particularly in transoral, transabdominal, and transanal 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. National reimbursement

status was received for dVP procedures in Japan effective April 2012 and for da Vinci partial nephrectomy procedures in April 2016. With our support, Japanese surgical societies are seeking reimbursement for additional procedures through the MHLW's Senshin Iryo processes as well as alternative reimbursement processes. Senshin Iryo approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years. There can be no assurance that we will gain additional Senshin Iryo reimbursements for the procedures or at the times we have targeted. 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.

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

Recent Business Events and Trends

Procedures

Overall. During the three months ended March 31, 2016, total da Vinci procedures grew approximately 17%, compared with growth of approximately 13% for the three months ended March 31, 2015. U.S. procedure growth during the three months ended March 31, 2016 was approximately 15%, compared with approximately 11% for the three months ended March 31, 2015. First quarter 2016 U.S. procedure growth was largely attributable to growth in general surgery procedures, most notably hernia repair and colorectal procedures as well as growth in dVP and in gynecologic oncology procedures.

Procedure volume OUS for the three months ended March 31, 2016, as well as the three months ended March 31, 2015, grew approximately 22%, driven by continued growth in dVP urology procedures and earlier stage growth in kidney cancer and colorectal procedures. Year over year procedure growth also likely benefited from an additional calendar day associated with leap year.

The 2016 OUS procedure growth rate reflects continued da Vinci adoption in Asian markets, including China, Japan, and South Korea. Procedure growth was variable by country in Europe, with solid performance in the United Kingdom and Germany offsetting slower growth in the Nordic countries. While we are encouraged by procedure adoption in China, future system placements and our ability to sustain procedure growth are dependent on obtaining additional importation authorizations and hospitals completing the central purchasing tender under the authorization. The most recent authorization expired at the end of 2015. The timing and magnitude of future authorizations, which may enable future system placements, is not certain. In Japan, procedure growth rates are likely to be paced by the timing of procedure reimbursement approvals for procedures in addition to dVP and partial nephrectomy.

U.S. Gynecology. Gynecology is our largest U.S. surgical specialty and the procedure volume was approximately 238,000 in 2015, compared with 235,000 in 2014 and 240,000 in 2013. Our US gynecology procedure volume expanded modestly during the three months ended March 31, 2016 as compared with the same period in 2015. We believe that overall U.S. benign gynecologic surgery volume (robotic and other modalities) has been pressured in recent years by factors including, but not limited to, a trend by payers toward encouraging conservative disease management, larger patient deductibles and co-pays associated with the Affordable Care Act, and FDA actions regarding the use of power morcellation in uterine surgeries. Combining robotic, laparoscopic, and vaginal approaches, MIS represents about 80% of the U.S. benign hysterectomy market, and thus the rate of migration from open surgeries to MIS has slowed. We believe that in 2015 and the first quarter of 2016 an increasing portion of dVH procedures with uncertain oncologic characteristics were referred to gynecologic oncologists. A high proportion of gynecologic oncologists utilize the da Vinci surgical systems to perform procedures which may account for the slight increase in total dVH procedures in 2015 and first quarter of 2016.

U.S. General Surgery. General surgery is our second largest and fastest growing specialty in the U.S. with procedure volume that grew to approximately 140,000 in 2015, compared with approximately 107,000 in 2014, and 81,000 in 2013. 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. U.S. general surgery procedures grew in excess of 30% in 2014, 2015, and the first quarter of 2016 with growth shifting from cholecystectomy to hernia repair, colorectal resections, and other general surgery procedures. Ventral and inguinal hernia, combined, contributed the most incremental general surgery procedures in 2015 and the first quarter of 2016.

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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. While we believe hernia repair procedures represent a significant opportunity with the potential to drive growth in future periods, given the differences in complexity among hernia patient populations and varying surgeon opinion regarding optimal surgical technique, 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 via different modalities of surgery.

Adoption of da Vinci for colorectal procedures, which includes 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 our recently launched technologies such as the da Vinci Xi Surgical System, EndoWrist Stapler, EndoWrist Vessel Sealer, and Integrated Table Motion.

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, cholecystectomies generally have lower reimbursement rates than more complex procedures and many cholecystectomies are lower complexity procedure which can generally be executed in a minimally invasive manner via multiport laparoscopy. For this reason, it is difficult to estimate to what degree or timing that we may capture these procedures. During 2014, total U.S. da Vinci cholecystectomies grew at a lower rate than in previous years, and in 2015 and the first quarter of 2016, they modestly declined. In recent quarters, declines in Single-Site cholecystectomies have been largely offset by higher multiport cholecystectomy volumes.

dVP. U.S. dVP is the largest urology procedure in the U.S. with 66,000 dVPs performed in 2015, compared with 60,000 in 2014, and 58,000 in 2013. U.S. dVP procedures for the three months ended March 31, 2016 grew at rates consistent with 2015. As the U.S. standard of care for the surgical treatment of prostate cancer, we expect that the number of dVP procedures performed in the U.S. will fluctuate with the overall prostatectomy market. We believe the return to growth in dVP in 2014 and our current growth rate reflects surgical procedures being performed for men who may have previously deferred definitive treatment. dVP adoption outside of the U.S. is at various stages of adoption, with lower market penetration in certain large markets in Western Europe and Asia. We believe growth in these global markets is being driven by increased acceptance among surgeons and health systems, supported by expanded global evidence validating the clinical and economic value of dVP.

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, hospital 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 markets outside of the U.S. for our Xi System and related instruments. 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 Auris Surgical Robotics, Inc., Cambridge Medical Robotics Ltd, IMRIS Inc., Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc., MedRobotics Corp., meerecompany Inc., Medtronic PLC, Olympus Corp., Samsung Corporation, TransEnterix, Inc., and Titan Medical, Inc., as well as other economic and geopolitical factors.

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 MIS 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 45 products and received clearances for these products from June 2014 to August 2014. We received FDA clearance for the Integrated Table Motion for the da Vinci Xi Surgical System in the U.S. in January 2016. We received FDA

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clearance for the Single-Site instruments and the 30mm EndoWrist stapler products for the da Vinci Xi Surgical System in March 2016. In March 2016, we also received CE mark clearances in Europe for Single-Site instruments and the 30mm EndoWrist stapler products for the da Vinci Xi Surgical System.

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. We received regulatory clearances for the da Vinci Xi Surgical System in South Korea in October 2014 and in Japan in March 2015. The regulatory status of the da Vinci Xi Surgical System in other OUS markets varies by country.

da Vinci Xi Integrated Table Motion. The Integrated Table Motion coordinates the movements of the da Vinci robot arms with an advanced operating room table, the TruSystem® 7000dV sold by Trumpf Medical™, to enable shifting a patient's position in real-time while the da Vinci surgical robotic arms remains docked. This gives operating room teams the capabilities to optimally position the operating table so that gravity exposes anatomy during multi-quadrant da Vinci System procedures, maximize reach and access to target anatomy enabling surgeons to interact with tissue at an ideal working angle, and reposition the table during the procedure to enhance anesthesiologists' care of the patient. In June 2015, we received CE mark clearance for our integrated table motion product in Europe. Initial cases were successfully completed using the integrated table motion technology in the third quarter of 2015, and we began a phased introduction in Europe during the fourth quarter of 2015. We received FDA clearance for the da Vinci Xi integrated table motion product in January 2016 and began our U.S. launch.

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) and in January 2015, we began to ship the replacement product for the da Vinci Si. In January 2015, we also 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.

EndoWrist Stapler 30. In March 2016, we received FDA clearance in the U.S. for the EndoWrist Stapler 30 instrument with Blue, Green, White, and Gray 30 mm reloads for use with the da Vinci Xi Surgical System. It is intended to deliver particular utility with fine tissue interaction in lobectomy and other thoracic procedures. The EndoWrist Stapler 30 is a wristed, stapling instrument intended for resection, transection and/or creation of anastomoses.

First Quarter 2016 Financial Highlights

Total revenue increased by 12% to \$594.5 million during the three months ended March 31, 2016, compared with \$532.1 million during the three months ended March 31, 2015.

- Approximately 176,000 da Vinci procedures were performed during the three months ended March 31, 2016, an increase of approximately 17% compared to 151,000 for the three months ended March 31, 2015.

Instrument and accessory revenue increased by 16% to \$322.1 million during the three months ended March 31, 2016, compared with \$277.2 million during the three months ended March 31, 2015.

Recurring revenue increased by 14% to \$446.6 million during the three months ended March 31, 2016, representing 75% of total revenue, compared with \$391.1 million during the three months ended March 31, 2015, representing 74% of total revenue.

Systems revenue increased by 5% to \$147.9 million during the three months ended March 31, 2016, compared with \$141.0 million during the three months ended March 31, 2015. A total of 110 da Vinci Surgical Systems were shipped during the three months ended March 31, 2016, compared with 99 during the three months ended March 31, 2015.

As of March 31, 2016, we had a da Vinci Surgical System installed base of approximately 3,660 systems, consisting of 2,431 in the U.S., 616 in Europe, 441 in Asia, and 172 in the rest of the world.

Gross profit as a percentage of revenue increased to 68.1% for the three months ended March 31, 2016, compared with 63.3% for the three months ended March 31, 2015.

Operating income increased by 37% to \$179.0 million during the three months ended March 31, 2016, compared with \$130.4 million during the three months ended March 31, 2015. Operating income included \$42.8 million and \$41.2 million of share-based compensation expense related to employee stock plans during the three months ended March 31, 2016, and 2015, respectively.

As of March 31, 2016, we had \$3.8 billion in cash, cash equivalents and investments. Cash, cash equivalents and investments increased by \$453.3 million, compared with December 31, 2015, primarily driven by proceeds from employee stock option exercises and cash provided by operating activities.

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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 March 31, | | | | | |
|-------------------------------------|------------------------------|--------------------|---|---------|--------------------|---|
| | 2016 | % of total revenue | | 2015 | % of total revenue | |
| Revenue: | | | | | | |
| Product | \$470.0 | 79 | % | \$418.2 | 79 | % |
| Service | 124.5 | 21 | % | 113.9 | 21 | % |
| Total revenue | 594.5 | 100 | % | 532.1 | 100 | % |
| Cost of revenue: | | | | | | |
| Product | 151.6 | 26 | % | 153.5 | 29 | % |
| Service | 37.9 | 6 | % | 41.8 | 8 | % |
| Total cost of revenue | 189.5 | 32 | % | 195.3 | 37 | % |
| Product gross profit | 318.4 | 53 | % | 264.7 | 50 | % |
| Service gross profit | 86.6 | 15 | % | 72.1 | 13 | % |
| Gross profit | 405.0 | 68 | % | 336.8 | 63 | % |
| Operating expenses: | | | | | | |
| Selling, general and administrative | 172.8 | 29 | % | 162.0 | 31 | % |
| Research and development | 53.2 | 9 | % | 44.4 | 8 | % |
| Total operating expenses | 226.0 | 38 | % | 206.4 | 39 | % |
| Income from operations | 179.0 | 30 | % | 130.4 | 24 | % |
| Interest and other income, net | 5.5 | 1 | % | 4.3 | 1 | % |
| Income before taxes | 184.5 | 31 | % | 134.7 | 25 | % |
| Income tax expense | 48.1 | 9 | % | 37.7 | 7 | % |
| Net income | \$136.4 | 22 | % | \$97.0 | 18 | % |

Total Revenue

Total revenue was \$594.5 million for the three months ended March 31, 2016, compared with \$532.1 million for the three months ended March 31, 2015, driven by 14% higher recurring revenue and 5% higher systems revenue.

We sell our products and services in Euros and British Pounds in those European markets where we have direct distribution channels, and in Japanese Yen and Korean Won. Revenue denominated in foreign currencies as a percentage of total revenue was approximately 19% and 17% for the three months ended March 31, 2016 and 2015, respectively.

Revenue generated in the U.S. accounted for 72% of total revenue for the three months ended March 31, 2016 and 2015, respectively. We believe that U.S. 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 U.S. infrastructure. We have been investing in our business in the OUS market and our OUS procedures have grown faster in proportion to U.S. procedures. In future years, we expect our OUS 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 months ended March 31, 2016, and 2015 (in millions, except percentages and unit shipments):

| | Three Months Ended March 31, | |
|--|---------------------------------|---------|
| | 2016 | 2015 |
| Revenue | | |
| Instruments and accessories | \$322.1 | \$277.2 |
| Systems | 147.9 | 141.0 |
| Total product revenue | 470.0 | 418.2 |
| Services | 124.5 | 113.9 |
| Total revenue | \$594.5 | \$532.1 |
| Recurring revenue | \$446.6 | \$391.1 |
| % of total revenue | 75 | % 74 |
| United States | \$430.7 | \$382.4 |
| OUS | 163.8 | 149.7 |
| Total revenue | \$594.5 | \$532.1 |
| % of Revenue - United States | 72 | % 72 |
| % of Revenue - OUS | 28 | % 28 |
| Unit Shipments by Region: | | |
| United States unit shipments | 74 | 63 |
| OUS unit shipments | 36 | 36 |
| Total unit shipments* | 110 | 99 |
| Unit Shipments by Model: | | |
| da Vinci Si-e - Single console unit shipments (3 arm) | 1 | 2 |
| da Vinci Si - Single console unit shipments (4 arm) | 24 | 19 |
| da Vinci Si - Dual console unit shipments | — | 3 |
| da Vinci Xi - Single console unit shipments | 66 | 48 |
| da Vinci Xi - Dual console unit shipments | 19 | 27 |
| Total unit shipments* | 110 | 99 |
| Unit Shipments involving System Trade-ins: | | |
| Unit shipments involving trade-ins of da Vinci standard Surgical Systems | 1 | 3 |
| Unit shipments involving trade-ins of da Vinci S Surgical Systems | 22 | 25 |
| Unit shipments involving trade-ins of da Vinci Si Surgical Systems | 17 | 13 |
| Total unit shipments involving trade-ins | 40 | 41 |
| Unit shipments not involving trade-ins | 70 | 58 |
| Total unit shipments* | 110 | 99 |

*Systems shipped on operating leases (included in total unit shipments) 19 9

Product Revenue

Product revenue increased 12% to \$470.0 million for the three months ended March 31, 2016, compared with \$418.2 million for the three months ended March 31, 2015.

Instrument and accessory revenue increased 16% to \$322.1 million for the three months ended March 31, 2016, compared with \$277.2 million for the three months ended March 31, 2015. The increase in instrument and accessory revenue was driven by procedure growth of approximately 17%. First quarter 2016 U.S. procedure growth was approximately 15% compared to 11% in the first quarter 2015 and was driven by a higher general surgery procedure volume, particularly in hernia repair and colorectal

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procedures, dVP growth, and gynecology growth. OUS procedure growth was approximately 22% for both the first quarter of 2016 and 2015 driven by continued growth in dVP and earlier stage growth in kidney cancer and colorectal procedures.

Systems revenue was \$147.9 million during the three months ended March 31, 2016, compared to \$141.0 million during the three months ended March 31, 2015. Higher system revenue resulted from higher first quarter 2016 revenue associated with operating lease activities and slightly higher average selling prices. During the first quarter of 2016, a total of 110 total systems were shipped compared to 99 during the first quarter of 2015. By geography, 74 systems were shipped into the U.S., 13 into Europe, 18 into Asia, and 5 into other markets during the first quarter of 2016, compared with 63 systems shipped into the U.S., 18 into Europe, 14 into Asia, and 4 into other markets during the first quarter of 2015. During the first quarter 2016, 19 of the 110 systems were shipped under operating lease arrangements compared to 9 of 99 systems shipped during the first quarter of 2015. Operating lease revenue was \$3.5 million in the first quarter of 2016 compared with \$1.2 million in the first quarter of 2015. The increase in U.S. systems shipments was driven by higher procedure growth in 2016 and market interest in the da Vinci Xi System that was launched in the second quarter of 2014.

The da Vinci Surgical System average selling price (“ASP”), excluding the impact of systems shipped under operating leases, was approximately \$1.50 million for the three months ended March 31, 2016, compared with \$1.48 million for the three months ended March 31, 2015.

Service Revenue

Service revenue increased by 9% to \$124.5 million for the three months ended March 31, 2016, compared with \$113.9 million for the three months ended March 31, 2015. 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 months ended March 31, 2016, was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue.

Gross Profit

Product gross profit for the three months ended March 31, 2016, increased 20% to \$318.4 million, representing 67.7% of product revenue, compared with \$264.7 million, representing 63.3% of product revenue, for the three months ended March 31, 2015. The higher first quarter 2016 product gross profit was primarily driven by higher product revenue. There was no medical device excise tax included in product gross profit for the three months ended March 31, 2016, compared with \$4.2 million for the three months ended March 31, 2015. The Consolidated Appropriations Act, 2016 includes a two-year moratorium on the medical device excise tax such that medical device sales in 2016 and 2017 will be exempt from the excise tax.

The higher product gross profit margin for the three months ended March 31, 2016, as compared with the same period in 2015, was primarily driven by product cost reduction on some of our newer products and manufacturing operations efficiency improvements, medical device excise tax in the first quarter of 2015, and higher product recall charges incurred in the first quarter of 2015.

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 March 31, 2016, and 2015, reflected share-based compensation expense of \$5.7 million and \$5.3 million, respectively. Product gross profit for the three months ended March 31, 2016, and 2015, included amortization expense of purchased intellectual property of \$2.2 million and \$3.3 million, respectively.

Service gross profit for the three months ended March 31, 2016, was \$86.6 million, or 69.6% of service revenue, compared with \$72.1 million, or 63.3% of service revenue for the three months ended March 31, 2015. The higher 2016 service gross profit was driven by higher service revenue reflecting a larger installed base of da Vinci Surgical Systems. First quarter 2016 service gross profit margin was higher than the first quarter of 2015, primarily reflecting improving efficiency and reduced costs associated with the repair of the da Vinci Xi System and endoscopes. Service

gross profit for the three months ended March 31, 2016, and 2015, reflected share-based compensation expense of \$3.0 million and \$3.5 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 March 31, 2016, increased by 7% to \$172.8 million, compared with \$162.0 million for the three months ended March 31, 2015. The first quarter selling, general, and administrative expenses were driven by higher OUS expenses associated with our expanded Asian and European teams, higher payroll and social

taxes associated with employee stock option exercises, higher headcount and incentive compensation, partially offset by lower first quarter 2016 pre-tax litigation charges of \$2.2 million compared with the \$7.2 million recorded in the first quarter of 2015. Share-based compensation expense for the three months ended March 31, 2016, and 2015, was approximately \$24.2 million and \$23.1 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.

Research and development expenses for the three months ended March 31, 2016, increased by 20% to \$53.2 million, compared with \$44.4 million for the three months ended March 31, 2015. The increase in research and development expenses for the three months ended March 31, 2016, as compared with the same periods in 2015, was primarily due to growth in our product development organization including earlier stage development in advanced imaging, advanced instrumentation, and next generation robotics, and higher incentive compensation costs. 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.

Share-based compensation expense charged to research and development expense was \$9.9 million and \$9.3 million for the three months ended March 31, 2016, and 2015, respectively.

Amortization expense related to purchased intellectual property was \$2.9 million for both the three months ended March 31, 2016, and 2015.

Interest and Other Income, Net

Interest and other income, net, for the three months ended March 31, 2016, and 2015, was \$5.5 million and \$4.3 million, respectively, primarily reflecting higher interest earned during the first quarter of 2016 on higher cash and investment balances.

Income Tax Expense

Income tax expense for the three months ended March 31, 2016, was \$48.1 million, or 26.1% of income before taxes, compared with \$37.7 million, or 28.0% of income before taxes for the three months ended March 31, 2015. 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. 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 months ended March 31, 2016 as compared to the same period of 2015 is mainly attributable to more favorable earnings mix, as well as tax benefit related to federal R&D credit which expired at the end of 2014 and was retroactively reinstated and made permanent in December 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.

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 \$3.3 billion at December 31, 2015, to \$3.8 billion at March 31, 2016. 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 March 31, 2016, \$1,087.4 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.

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Condensed Consolidated Cash Flow Data (unaudited)

The following table summarizes our cash flows for the three months ended March 31, 2016, and 2015 (in millions):

| | Three Months Ended March 31, 2016 2015 | |
|---|---|---------|
| Net cash provided by (used in) | | |
| Operating activities | \$208.5 | \$123.7 |
| Investing activities | (191.9) | (87.7) |
| Financing activities | 248.4 | 66.0 |
| Effect of exchange rates on cash and cash equivalents | 0.9 | (1.2) |
| Net increase in cash and cash equivalents | \$265.9 | \$100.8 |

Operating Activities

For the three months ended March 31, 2016, cash flow provided by operating activities of \$208.5 million exceeded our net income of \$136.4 million primarily for the following reasons:

1. Our net income included non-cash charges in the form of share-based compensation of \$42.7 million, deferred income taxes of \$28.9 million, depreciation and loss on disposal of property, plant, and equipment of \$18.3 million, accretion of discounts and amortization of premiums on investments of \$8.3 million, and amortization of intangible assets of \$5.1 million, partly offset by tax benefits from employee stock plans of \$7.5 million.

The non-cash charges outlined above were partly offset by changes in operating assets and liabilities that resulted in \$23.7 million of cash used by operating activities. Operating assets and liabilities are primarily comprised of accounts receivable, inventory, deferred revenue, other accrued liabilities, and prepaid expenses. Prepaids and other assets increased \$49.9 million primarily driven by higher lease receivable balances resulting from sales-type lease 2. arrangements entered into during the first quarter of 2016 and an increase in prepaid taxes due to timing of tax payments. Accrued compensation and employee benefits decreased \$39.7 million primarily due to the payments of 2015 incentive compensation. The unfavorable impact of these items on cash provided by operating activities was partly offset by decrease in accounts receivable of \$68.4 million, reflecting lower sales as compared to the seasonally stronger fourth quarter of 2015.

Investing Activities

Net cash used in investing activities during the three months ended March 31, 2016, included purchases of investments (net of proceeds from sales and maturities of investments) of \$182.3 million and acquisition of property and equipment of \$9.6 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 three months ended March 31, 2016, consisted primarily of the proceeds from stock option exercises and employee stock purchases of \$258.8 million and excess tax benefits of \$18.3 million, partly offset by \$20.6 million in taxes paid on behalf of employees related to net shares settlement of vested employee equity awards, and \$8.1 million used for the repurchase of shares through open market transactions.

Capital Expenditures

Our business is not capital intensive and we had no material commitments for capital expenditures as of the end of the first quarter of 2016.

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 the past, 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.

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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, 2015, 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 three months ended March 31, 2016, compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015.

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.

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, 2015, 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, 2015, 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.

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(c) Issuer Purchases of Equity Securities

The table below summarizes our stock repurchase activity for the quarter ended March 31, 2016:

| 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) |
|---|------------------------------------|------------------------------|--|---|
| January 1 to January 31, 2016 | — | \$ — | — | \$ 816.3 million |
| February 1 to February 29, 2016 | 15,557 | \$ 516.54 | 15,557 | \$ 808.2 million |
| March 1 to March 31, 2016 | — | \$ — | — | \$ 808.2 million |
| Total during quarter ended March 31, 2016 | 15,557 | | 15,557 | |

(1) Since March 2009, we have had an active stock repurchase program. As of March 31, 2016, the Board of Directors has authorized an aggregate 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 \$808.2 million represents the amount available to repurchase shares under the authorized repurchase program as of March 31, 2016.

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). |
| 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 March 31, 2016, 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: April 19, 2016