UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 17, 2019

INTUITIVE SURGICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-30713 (Commission File Number) 77-0416458 (I.R.S. Employer Identification No.)

1020 Kifer Road

Sunnyvale, California 94086 (Address of principal executive offices) (zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

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

Item 2.02. Results of Operations and Financial Condition.

On October 17, 2019, Intuitive Surgical, Inc. ("Intuitive") issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is furnished hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section and shall not be deemed to be incorporated by reference into any filing of Intuitive under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

d) Exhibits.

99.1Press release issued by Intuitive Surgical, Inc., dated October 17, 2019.104Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

INTUITIVE SURGICAL, INC.

Date: October 17, 2019

By: /s/ Marshall L. Mohr

Name: Marshall L. Mohr *Title:* Executive Vice President and Chief Financial Officer

INTUITIVE ANNOUNCES THIRD QUARTER EARNINGS

SUNNYVALE, CALIF. October 17, 2019 - Intuitive (the "Company") (Nasdaq: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced financial results for the quarter ended September 30, 2019.

Q3 Highlights

- Worldwide da Vinci procedures grew nearly 20% compared with the third quarter of 2018, driven primarily by growth in U.S. general surgery procedures and worldwide urologic procedures.
- The Company shipped 275 da Vinci Surgical Systems, an increase of 19% compared with 231 in the third quarter of 2018.
- The Company grew its da Vinci Surgical System installed base to 5,406 systems as of September 30, 2019, an increase of 12% compared with 4,814 as of the end of the third quarter of 2018.
- Third quarter 2019 revenue of \$1,128 million grew 23% compared with \$921 million for the third quarter of 2018.
- Third quarter 2019 GAAP net income was \$397 million, or \$3.33 per diluted share, compared with \$293 million, or \$2.45 per diluted share, for the third quarter of 2018. Third quarter 2019 GAAP net income includes \$51 million, or \$0.43 per diluted share, of income tax benefit related to the enactment of Swiss tax reform.
- Third quarter 2019 non-GAAP* net income was \$409 million, or \$3.43 per diluted share, compared with \$337 million, or \$2.83 per diluted share, for the third quarter of 2018.
- The Company sold the first three IonTM endoluminal systems in the third quarter of 2019. The Ion endoluminal system is the Company's new flexible, robotic-assisted, catheter-based platform, which is designed to navigate through very small lung airways to reach peripheral nodules for biopsies.
- In July 2019, the Company received U.S. Food and Drug Administration clearance for the SureForm 45 Curved-Tip stapler, a single-use, fully wristed stapling instrument with a curved tip, and SureForm 45 Gray reload, a new, single-use cartridge that contains multiple staggered rows of implantable staples and a stainless steel knife. These have particular utility in thoracic procedures and round out our SureForm 45 portfolio.
- In August 2019, the Company acquired Schölly Fiberoptic's robotic endoscope business, which the Company believes will strengthen the supply chain and increase manufacturing capacity for imaging products.

Q3 Financial Summary

Gross profit, income from operations, net income, net income per diluted share, and diluted shares are reported on a GAAP and non-GAAP* basis. The non-GAAP* measures are described below and are reconciled to the corresponding GAAP measures at the end of this release.

Third quarter 2019 revenue was \$1,128 million, an increase of 23% compared with \$921 million in the third quarter of 2018. Higher third quarter revenue was driven by increased procedures and systems placements.

Third quarter 2019 instrument and accessory revenue increased by 25% to \$606 million, compared with \$486 million for the third quarter of 2018, primarily driven by nearly 20% growth in da Vinci procedure volume.

Third quarter 2019 systems revenue increased by 23% to \$339 million, compared with \$275 million for the third quarter of 2018. The Company shipped 275 da Vinci Surgical Systems in the third quarter of 2019, compared with 231 in the third quarter of 2018. The third quarter 2019 system shipments included 92 systems shipped under operating lease and usage-based arrangements, compared with 58 during the third quarter of 2018.

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Third quarter 2019 GAAP income from operations increased to \$366 million, compared with \$313 million in the third quarter of 2018. Third quarter 2019 non-GAAP* income from operations increased to \$462 million, compared with \$391 million in the third quarter of 2018.

Third quarter 2019 GAAP net income was \$397 million, or \$3.33 per diluted share, compared with \$293 million, or \$2.45 per diluted share, for the third quarter of 2018. As a result of the enactment of Swiss tax reform, third quarter 2019 GAAP net income included a tax benefit from the re-measurement of Swiss deferred tax assets of \$51 million, or \$0.43 per share. This benefit is excluded from non-GAAP net income.

Third quarter 2019 non-GAAP* net income was \$409 million, or \$3.43 per diluted share, compared with \$337 million, or \$2.83 per diluted share, for the third quarter of 2018.

The Company ended the third quarter of 2019 with \$5.4 billion in cash, cash equivalents, and investments, an increase of \$282 million during the quarter, primarily driven by cash generated from operations.

"We are pleased with performance in the quarter, reflected in our support of customers in procedures performed and system placements. Intuitive is committed to enabling care givers in their pursuit of better outcomes while lowering their total cost of treatment," said Intuitive CEO Gary Guthart.

Additional supplemental financial and procedure information has been posted to the Investor Relations section of the Intuitive website at: <u>https://isrg.gcs-web.com/</u>.

Webcast and Conference Call Information

Intuitive will hold a teleconference at 1:30 p.m. PDT today to discuss the third quarter 2019 financial results. The call is being webcast by Nasdaq OMX and can be accessed at Intuitive's website at <u>www.intuitive.com</u> or by dialing (800) 288-8975 or (612) 332-0335.

About Intuitive

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery. At Intuitive, we believe that minimally invasive care is life-enhancing care. Through ingenuity and intelligent technology, we expand the potential of physicians to heal without constraints.

Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings, and develops, manufactures, and markets the da Vinci[®] surgical system and the IonTM endoluminal system.

Da Vinci[®], da Vinci SP[®], IonTM, and SureFormTM are trademarks or registered trademarks of Intuitive Surgical, Inc.

For more information, please visit the Company's website at www.intuitive.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the Company's pursuit of better outcomes while lowering their total cost of treatment and the potential for the acquisition of Schölly Fiberoptic's robotic endoscope business to strengthen the Company's supply chain and increase manufacturing capacity for imaging products. These forward-looking statements are necessarily estimates reflecting the best judgment of the Company's management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to, the following: the timing and success of product development and market acceptance of developed products, including, but not limited to, Intuitive's Ion endoluminal system, da Vinci SP surgical system, and 3rd generation stapling platform; the impact of global and regional economic and credit market conditions on healthcare spending; competition in the medical device industry and in the specific markets of surgery in which the Company and the safety of the Company's products and adequacy of training; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which the Company is or may become a party; the Company's reliance on sole and single source suppliers; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships, including the joint

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venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd.; the Company's completion of and ability to successfully integrate the acquisition of Schölly Fiberoptic's robotic endoscope business; healthcare reform legislation in the United States and its impact on hospital spending, reimbursement, and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; 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; the Company's ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; changes in tariffs, trade barriers, and regulatory requirements; and other risk factors identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, as updated by the Company's other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "targeted," and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, except as required by law.

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*About Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with accounting principles generally accepted in the United States ("GAAP"), the Company uses the following non-GAAP financial measures: non-GAAP gross profit, non-GAAP income from operations, non-GAAP net income, non-GAAP net income per diluted share ("EPS"), and non-GAAP diluted shares. The presentation of this financial information is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP.

The Company uses these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. The Company believes that these non-GAAP financial measures provide meaningful supplemental information regarding its performance and liquidity by excluding items such as intangible asset charges, share-based compensation ("SBC") expenses, and other special items. Intangible asset charges consist of non-cash charges, such as the amortization of intangible assets, as well as in-process R&D charges. The Company believes that both management and investors benefit from referring to these non-GAAP financial measures in assessing its performance and when planning, forecasting, and analyzing future periods. These non-GAAP financial measures also facilitate management's internal comparisons to its historical performance and liquidity. The Company believes these non-GAAP financial measures are useful to investors, because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making, and (2) they are used by institutional investors and the analyst community to help them analyze the performance of the Company's business.

Non-GAAP gross profit. The Company defines non-GAAP gross profit as gross profit, excluding intangible asset charges, expenses related to SBC, and litigation charges and recoveries.

Non-GAAP income from operations. The Company defines non-GAAP income from operations as income from operations, excluding intangible asset charges, certain acquisition-related items for the re-measurement of contingent consideration, expenses related to SBC, and litigation charges and recoveries.

Non-GAAP net income and EPS. The Company defines non-GAAP net income as net income (loss), excluding intangible asset charges, non-cash impairment charges and recoveries, certain acquisition-related items for the re-measurement of contingent consideration, expenses related to SBC, litigation charges and recoveries, adjustments attributable to noncontrolling interest in joint venture, net of the related tax effects, and tax adjustments, including the excess tax benefits or deficiencies associated with SBC arrangements, the one-time impact of the enactments of the 2017 Tax Act and the 2019 Swiss tax reform, and the net tax effects related to intra-entity transfers of non-inventory assets. The Company excludes the one-time impact of the enactments of the 2017 Tax Act and the 2019 Swiss tax reform, because they are discrete in nature, and excludes the excess tax benefits or deficiencies associated with SBC arrangements as well as the tax effects associated with non-cash amortization of deferred tax assets related to intra-entity non-inventory transfers, because the Company does not believe these items correlate with the on-going results of its core operations. The tax effects of the non-GAAP items are determined by applying a calculated non-GAAP effective tax rate, which is commonly referred to as the with-and-without method. Without excluding these tax effects, investors would only see the gross effect that these non-GAAP adjustments had on the Company's operating results. The Company's calculated non-GAAP effective tax rate is generally higher than its GAAP effective tax rate. The Company defines non-GAAP EPS as non-GAAP net income divided by non-GAAP diluted shares, which are calculated as GAAP weighted average outstanding shares plus dilutive potential shares outstanding during the period.

There are a number of limitations related to the use of non-GAAP measures versus measures calculated in accordance with GAAP. Non-GAAP gross profit, non-GAAP income from operations, non-GAAP net income, and non-GAAP EPS exclude items such as intangible asset charges, re-measurement of contingent consideration, SBC, excess tax benefits or deficiencies associated with SBC arrangements, and non-cash amortization of deferred tax assets related to intra-entity transfer of non-inventory assets, which are primarily recurring items. SBC has been, and will continue to be for the foreseeable future, a significant recurring expense in the Company's business. In addition, the components of the costs that the Company excludes in its calculation of non-GAAP net income and non-GAAP EPS may differ from the components that its peer companies exclude when they report their results of operations. Management addresses these limitations by providing specific information regarding the GAAP amounts excluded from non-GAAP net income and non-GAAP EPS and evaluating non-GAAP net income and non-GAAP EPS together with net income (loss) and net income (loss) per share calculated in accordance with GAAP.

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INTUITIVE SURGICAL, INC. UNAUDITED QUARTERLY CONDENSED CONSOLIDATED STATEMENTS OF INCOME (IN MILLIONS, EXCEPT PER SHARE DATA)

	Three months ended						
	Se	otember 30, 2019	Ju	ne 30, 2019	September 30, 2018		
Revenue:							
Instruments and accessories	\$	606.2	\$	578.5	\$	486.3	
Systems		338.6		343.8		274.6	
Services		183.4		176.6		160.0	
Total revenue		1,128.2		1,098.9		920.9	
Cost of revenue:							
Product		277.3		283.4		225.1	
Service		65.3		56.5		53.5	
Total cost of revenue		342.6		339.9		278.6	
Gross profit		785.6		759.0		642.3	
Operating expenses:							
Selling, general and administrative		284.0		279.2		221.4	
Research and development		135.9		120.8		107.6	
Total operating expenses		419.9		400.0		329.0	
Income from operations		365.7		359.0		313.3	
Interest and other income, net		33.3		32.8		21.9	
Income before taxes		399.0		391.8		335.2	
Income tax expense (1)		0.3		75.4		43.4	
Net income		398.7		316.4		291.8	
Less: net income (loss) attributable to noncontrolling interest in joint venture		1.9		(1.9)		(0.7)	
Net income attributable to Intuitive Surgical, Inc.	\$	396.8	\$	318.3	\$	292.5	
Net income per share attributable to Intuitive Surgical, Inc.:							
Basic	\$	3.44	\$	2.76	\$	2.57	
Diluted (2)	\$	3.33	\$	2.67	\$	2.45	
Weighted average shares outstanding:							
Basic		115.4		115.4		114.0	
Diluted		119.3		119.3		119.2	
(1) Income tax expense includes the effect of the following items:							
Excess tax benefits related to share-based compensation arrangements	\$	(28.8)	\$	(11.3)	\$	(24.1)	
One-time tax benefit related to the enactment of Swiss tax reform (2) Diluted net income per share includes the effect of the following items:	\$	(51.3)	\$	_	\$	_	
Excess tax benefits related to share-based compensation arrangements	\$	0.24	\$	0.09	\$	0.20	
One-time tax benefit related to the enactment of Swiss tax reform	\$	0.43	\$	_	\$	—	

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INTUITIVE SURGICAL, INC. UNAUDITED NINE MONTHS ENDED CONDENSED CONSOLIDATED STATEMENTS OF INCOME (IN MILLIONS, EXCEPT PER SHARE DATA)

		Nine mo Septer		
		2019		2018
Revenue:				
Instruments and accessories	\$	1,737.0	\$	1,422.7
Systems		929.9		786.5
Services		533.9		468.5
Total revenue		3,200.8	<u> </u>	2,677.7
Cost of revenue:		-,		_,
Product		807.1		654.7
Service		179.5		154.6
Total cost of revenue		986.6		809.3
Gross profit		2,214.2		1,868.4
Operating expenses:				
Selling, general and administrative (1)		836.6		702.8
Research and development		400.7		298.2
Total operating expenses		1,237.3		1,001.0
Income from operations (2)		976.9		867.4
Interest and other income, net		93.6		53.3
Income before taxes		1,070.5		920.7
Income tax expense (3)		51.4		87.0
• •				
Net income		1,019.1		833.7
Less: net loss attributable to noncontrolling interest in joint venture		(2.5)		(1.7)
Net income attributable to Intuitive Surgical, Inc.	\$	1,021.6	\$	835.4
Net income per share attributable to Intuitive Surgical, Inc.:				
Basic	\$	8.86	\$	7.37
Diluted (4)	\$	8.56	\$	7.04
Weighted average shares outstanding:			:	
Basic		115.3		113.4
Diluted		119.4		118.6
(1) Solling, general and administrative includes the effect of the following item:				
(1) Selling, general and administrative includes the effect of the following item: Litigation charges	\$	0.2	\$	45.2
(2) Income from operations includes the effect of the following item:	Ŷ	0.2	Ψ	10.2
Intangible asset charges	\$	51.5	\$	22.2
(3) Income tax expense includes the effect of the following items:				
Excess tax benefits related to share-based compensation arrangements	\$	(112.8)	\$	(100.4
One-time tax benefit related to the enactment of Swiss tax reform	\$	(51.3)	\$	
(4) Diluted net income per share includes the effect of the following items:			¢	/
Litigation charges, net of tax	\$		\$	(0.29
Intangible asset charges, net of tax	\$	(0.38)	\$	(0.15
Excess tax benefits related to share-based compensation arrangements One-time tax benefit related to the enactment of Swiss tax reform	\$	0.94 0.43	\$ \$	0.85

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

	September 30, 2019			ecember 31, 2018
Cash, cash equivalents, and investments	\$	5,430.6	\$	4,834.4
Accounts receivable, net		639.0		682.3
Inventory		579.6		409.0
Property, plant, and equipment, net		1,136.8		812.0
Goodwill		304.7		240.6
Deferred tax assets		424.1		428.6
Other assets		616.5		439.8
Total assets	\$	9,131.3	\$	7,846.7
Accounts payable and other accrued liabilities	\$	1,018.6	\$	831.9
Deferred revenue		335.6		327.3
Total liabilities		1,354.2		1,159.2
Stockholders' equity		7,777.1		6,687.5
Total liabilities and stockholders' equity	\$	9,131.3	\$	7,846.7

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INTUITIVE SURGICAL, INC. UNAUDITED RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES (IN MILLIONS, EXCEPT PER SHARE DATA)

	Three months ended					Nine months ended				
	Se	ptember 30, 2019	Jı	ıne 30, 2019		September 30, 2018		September 30, 2019		September 30, 2018
GAAP gross profit	\$	785.6	\$	759.0	\$	642.3	\$	2,214.2	\$	1,868.4
Share-based compensation expense		17.8		16.0		14.3		48.9		39.0
Intangible asset charges		8.8		8.7		1.8		25.7		4.1
Non-GAAP gross profit	\$	812.2	\$	783.7	\$	658.4	\$	2,288.8	\$	1,911.5
GAAP income from operations	\$	365.7	\$	359.0	\$	313.3	\$	976.9	\$	867.4
Share-based compensation expense		88.9		81.6		70.1		246.6		190.8
Intangible asset charges		10.7		10.6		9.0		51.5		22.2
Litigation charges				—		(1.8)		—		45.2
Acquisition-related items		(3.0)		4.1		—		4.1		_
Non-GAAP income from operations	\$	462.3	\$	455.3	\$	390.6	\$	1,279.1	\$	1,125.6
GAAP net income attributable to Intuitive Surgical, Inc.	\$	396.8	\$	318.3	\$	292.5	\$	1,021.6	\$	835.4
Share-based compensation expense		88.9		81.6		70.1		246.6		190.8
Intangible asset charges		10.7		10.6		9.0		51.5		22.2
Litigation charges		—		—		(1.8)		—		45.2
Impairment charges (recoveries)		—		(0.8)		—		0.7		—
Acquisition-related items		(3.0)		4.1				4.1		—
Tax adjustments (1)		(83.2)		(22.1)		(32.8)		(206.8)		(141.7)
Adjustments attributable to noncontrolling interest in joint venture		(1.4)		(4.2)		_		(9.4)		_
Non-GAAP net income attributable to Intuitive Surgical, Inc.	\$	408.8	\$	387.5	\$	337.0	\$	1,108.3	\$	951.9
GAAP net income per share attributable to Intuitive Surgical, Inc diluted	\$	3.33	\$	2.67	\$	2.45	\$	8.56	\$	7.04
Share-based compensation expense		0.75		0.68		0.59		2.07		1.61
Intangible asset charges		0.09		0.09		0.08		0.43		0.19
Litigation charges						(0.02)				0.38
Impairment charges (recoveries)		_		_		_		0.01		_
Acquisition-related items		(0.03)		0.03				0.03		_
Tax adjustments (1)		(0.70)		(0.18)		(0.27)		(1.74)		(1.19)
Adjustments attributable to noncontrolling interest in joint venture		(0.01)		(0.04)				(0.08)		_
Non-GAAP net income per share attributable to Intuitive Surgical, Inc diluted	\$	3.43	\$	3.25	\$	2.83	\$	9.28	\$	8.03

(1) For the three months ended September 30, 2019, tax adjustments included: (a) excess tax benefits associated with share-based compensation arrangements of (28.8) million, or (0.24) per diluted share; (b) a tax benefit from the re-measurement of Swiss deferred tax assets of (51.3) million, or (0.43) per share; (c) tax impact related to intra-entity transfers of non-inventory assets of (10.2) million, or (0.09) per diluted share; and (d) other tax adjustments effects determined by applying a calculated non-GAAP effective tax rate of (13.3) million, or (0.12) per diluted share.

For the nine months ended September 30, 2019, tax adjustments included: (a) excess tax benefits associated with share-based compensation arrangements of (112.8) million, or (0.94) per diluted share; (b) a tax benefit from the re-measurement of Swiss deferred tax assets of (51.3) million, or (0.43) per share; (c) tax impact related to intra-entity transfers of non-inventory assets of (30.6) million, or (0.26) per diluted share; and (d) other tax adjustments effects determined by applying a calculated non-GAAP effective tax rate of (73.3) million, or (0.63) per diluted share.

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