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 18, 2018

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)

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

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

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 18, 2018, Intuitive Surgical, Inc. ("Intuitive") issued a press release announcing its financial results for the quarter ended September 30, 2018. 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.

Exhibit No.	Description
99.1	Press release issued by Intuitive Surgical, Inc., dated October 18, 2018.

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.

By: /s/ Marshall L. Mohr

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

Date: October 18, 2018

INTUITIVE SURGICAL ANNOUNCES THIRD QUARTER EARNINGS

SUNNYVALE, CALIF. October 18, 2018 - Intuitive Surgical, Inc. ("Intuitive") (Nasdaq: ISRG), a global technology leader in robotic-assisted, minimally invasive surgery, today announced financial results for the quarter ended September 30, 2018.

Q3 Highlights

- Worldwide da Vinci procedures grew approximately 20% compared with the third quarter of 2017, driven primarily by growth in U.S. general surgery procedures and worldwide urologic procedures.
- The Company shipped 231 da Vinci Surgical Systems compared with 169 in the third quarter of 2017.
- Third quarter 2018 revenue of \$921 million grew approximately 14% compared with \$808 million for the third quarter of 2017. Third quarter 2017 revenue included \$21 million that had previously been deferred in connection with a customer trade-out program that the Company had offered certain first quarter 2017 customers.
- Third quarter 2018 GAAP net income was \$293 million, or \$2.45 per diluted share, compared with \$299 million, or \$2.56 per diluted share, for the third quarter of 2017.
- Third quarter 2018 non-GAAP* net income was \$337 million, or \$2.83 per diluted share, compared with \$325 million, or \$2.78 per diluted share, for the third quarter of 2017. The customer trade-out program mentioned above increased third quarter 2017 GAAP and non-GAAP* net income per diluted share by approximately \$0.09. Third quarter 2017 GAAP and non-GAAP* net income benefited from \$68 million, or \$0.59 per diluted share, related to certain tax benefits.
- The Company shipped the first three da Vinci SP[®] Surgical Systems in the third quarter of 2018. The da Vinci SP system is the Company's latest surgical system platform which delivers the surgical instruments and camera through a single port for narrow access surgery.
- In August 2018, the Company submitted a premarket notification to the U.S. Food and Drug Administration ("FDA") for the IonTM endoluminal system, the Company's new flexible robotic-assisted, catheter-based platform, designed to navigate through very small lung airways to reach peripheral nodules for biopsies.

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 2018 revenue was \$921 million, an increase of approximately 14% compared with \$808 million in the third quarter of 2017. Third quarter 2017 revenue included \$21 million of revenue that had previously been deferred in connection with a customer trade-out program that the Company had offered certain first quarter 2017 customers.

Third quarter 2018 instrument and accessory revenue increased by approximately 21% to \$486 million, compared with \$401 million for the third quarter of 2017, primarily driven by approximately 20% growth in da Vinci procedure volume.

Third quarter 2018 systems revenue increased by approximately 5% to \$275 million, compared with \$262 million for the third quarter of 2017. The Company shipped 231 da Vinci Surgical Systems in the third quarter of 2018, compared with 169 in the third quarter of 2017. The third quarter 2018 system shipments included 58 systems shipped under operating lease arrangements, compared with 20 during the third quarter of 2017. Third quarter 2017 systems revenue included revenue related to the customer trade-out program mentioned above.

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Third quarter 2018 GAAP income from operations increased to \$313 million, compared with \$281 million in the third quarter of 2017. Third quarter 2018 non-GAAP* income from operations increased to \$391 million, compared with \$349 million in the third quarter of 2017.

Third quarter 2018 GAAP net income was \$293 million, or \$2.45 per diluted share, compared with \$299 million, or \$2.56 per diluted share, for the third quarter of 2017.

Third quarter 2018 non-GAAP* net income was \$337 million, or \$2.83 per diluted share, compared with \$325 million, or \$2.78 per diluted share, for the third quarter of 2017. The customer trade-out program mentioned above, including the associated deferral of product costs and income tax effect, increased GAAP and non-GAAP* net income per diluted share by approximately \$0.09. Third quarter 2017 GAAP and non-GAAP* net income benefited from \$68 million, or \$0.59 per diluted share, related to certain tax benefits.

The Company ended the third quarter of 2018 with \$4.6 billion in cash, cash equivalents, and investments, an increase of \$311 million during the quarter, primarily driven by cash generated from operations.

Commenting on the announcement, Gary Guthart, President and CEO of Intuitive, said, "We are pleased with our strong third quarter procedure growth, da Vinci system placements, and the financial results that follow. With our customers, we remain dedicated to the pursuit of our shared mission to improve the availability and quality of minimally invasive surgery."

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 2018 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) 230-1096 or (612) 234-9960.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global technology leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures, and markets robotic technologies designed to improve clinical outcomes and help patients return more quickly to active and productive lives. The Company's mission is to extend the benefits of minimally invasive surgery to the broadest possible base of patients. Intuitive Surgical - Taking surgery beyond the limits of the human handTM.

About the da Vinci Surgical System

There are several models of the da Vinci surgical system. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery. Da Vinci systems offer surgeons high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels and forceps) that are designed to help with precise dissection and reconstruction deep inside the body.

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

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

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the Company's dedication to the pursuit of a shared mission to improve the availability and quality of minimally invasive surgery. 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 impact of global and regional economic and credit

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market conditions on healthcare spending; 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; the timing and success of product development and market acceptance of developed products, including, but not limited to, the recently launched SP surgical system and 3rd generation stapling platform; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body, including, but not limited to, the recently submitted premarket notification to the FDA for the IonTM endoluminal system; 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 the Company operates; 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; product liability and other litigation claims; adverse publicity regarding the Company and the safety of the Company's products and adequacy of training; 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 under the heading "Risk Factors" in the Company's report on Form 10-K for the year ended December 31, 2017, 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," "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, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update or release any revisions to 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.

Non-GAAP income from operations. The Company defines non-GAAP income from operations as income from operations excluding intangible asset charges, 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 excluding intangible asset charges; expenses related to SBC; litigation charges and recoveries, net of the related tax effects; and tax adjustments including the excess tax benefits or deficiencies associated with share-based compensation arrangements, the provisional income tax expense related to the Tax Cuts and Jobs Act ("2017 Tax Act"), and the net tax effects related to intra-entity transfers of non-inventory assets. The Company excludes income tax expense related to the 2017 Tax Act because of its one-time nature as well as the excess tax benefits or deficiencies associated with share-based compensation arrangements and the tax effects associated with non-cash amortization of deferred tax assets related to intra-entity non-inventory transfers as 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, SBC, excess tax benefits or deficiencies associated with share-based compensation 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 net income and net income 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								
In millions (except per share data)	Sept	tember 30, 2018	J	June 30, 2018	September 30, 2017				
Revenue:		2010		2010		2017			
Instruments and accessories	\$	486.3	\$	476.1	\$	401.2			
Systems		274.6	•	277.4	•	262.0			
Services		160.0		155.8		144.6			
Total revenue		920.9		909.3		807.8			
Cost of revenue:									
Product		225.1		228.1		195.4			
Service		53.5		48.9		44.3			
Total cost of revenue		278.6		277.0		239.7			
Gross profit		642.3		632.3		568.1			
Operating expenses:									
Selling, general and administrative (1)		221.4		259.8		204.1			
Research and development		107.6		95.1		83.4			
Total operating expenses		329.0		354.9		287.5			
Income from operations		313.3		277.4		280.6			
Interest and other income, net		21.9		18.2		10.8			
Income before taxes		335.2		295.6		291.4			
Income tax expense (benefit) (2)		43.4		41.0		(7.2)			
Net income		291.8		254.6		298.6			
Less: net loss attributable to noncontrolling interest in joint venture		(0.7)		(0.7)		_			
Net income attributable to Intuitive Surgical, Inc.	\$	292.5	\$	255.3	\$	298.6			
Net income per share attributable to Intuitive Surgical, Inc.:									
Basic	\$	2.57	\$	2.25	\$	2.67			
Diluted (3)	\$	2.45	\$	2.15	\$	2.56			
Weighted average shares outstanding:									
Basic		114.0		113.5		111.8			
Diluted		119.2		118.5		116.8			
Diffica		115.2		110.5		110.0			
(1) Selling, general and administrative includes the effect of the following item:									
Litigation charges (recoveries)	¢	(1.0)	¢	42.5	¢	0.7			
(2) Income tax expense (benefit) includes the effect of the following items:	\$	(1.8)	3	42.5	\$	9.7			
Certain one-time tax benefit	¢	(4.6)	¢		¢	(60.4)			
Excess tax benefits related to share-based compensation arrangements	\$	(4.6)		(21.0)	\$	(68.4)			
(3) Diluted net income per share includes the effect of the following items:	\$	(24.1)	\$	(21.6)	\$	(19.7)			
Litigation recoveries (charges), net of tax	<i>•</i>	0.07	¢	(0.05)	¢	(0.0=)			
Certain one-time tax benefit	\$	0.01	\$	(0.27)	\$	(0.05)			
Excess tax benefits related to share-based compensation arrangements	\$	0.04	\$		\$	0.59			
units for the second of the second compensation unungenerits	\$	0.20	\$	0.18	\$	0.17			

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

	Nine months ended						
	September 30,						
In millions (except per share data)		2018	2017				
Revenue:							
Instruments and accessories	\$	1,422.7	\$	1,179.8			
Systems		786.5		643.9			
Services		468.5		422.5			
Total revenue		2,677.7		2,246.2			
Cost of revenue:							
Product		654.7		545.6			
Service		154.6		132.6			
Total cost of revenue		809.3		678.2			
Gross profit		1,868.4		1,568.0			
Operating expenses:							
Selling, general and administrative (1)		702.8		592.6			
Research and development		298.2		241.5			
Total operating expenses		1,001.0		834.1			
Income from operations		867.4		733.9			
Interest and other income, net		53.3		29.6			
Income before taxes		920.7		763.5			
Income tax expense (2)		87.0		61.1			
Net income		833.7		702.4			
Less: net loss attributable to noncontrolling interest in joint venture		(1.7)		—			
Net income attributable to Intuitive Surgical, Inc.	\$	835.4	\$	702.4			
Net income per share attributable to Intuitive Surgical, Inc.:			-				
Basic	\$	7.37	\$	6.29			
Diluted (3)	\$	7.04	\$	6.06			
Weighted average shares outstanding:							
Basic		113.4		111.6			
Diluted		118.6		115.9			
(1) Selling, general and administrative includes the effect of the following item:							
Litigation charges	\$	45.2	\$	18.7			
(2) Income tax expense includes the effect of the following items:							
Certain one-time tax benefit	\$	(4.6)	\$	(60.6)			
Excess tax benefits related to share-based compensation arrangements	\$	(100.4)	\$	(82.9)			
(3) Diluted net income per share includes the effect of the following items:							
Litigation charges, net of tax	\$	(0.29)	\$	(0.10)			
Certain one-time tax benefit	\$	0.04	\$	0.52			
Excess tax benefits related to share-based compensation arrangements	\$	0.85	\$	0.71			

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

In millions		September 30, 2018	December 31, 2017		
Cash, cash equivalents, and investments	\$	4,570.5	\$	3,846.5	
Accounts receivable, net		580.4		507.9	
Inventory		370.1		241.2	
Property, plant, and equipment, net		746.4		613.1	
Goodwill		236.1		201.1	
Deferred tax assets		411.5		72.0	
Other assets		403.6		295.0	
Total assets	\$	7,318.6	\$	5,776.8	
Accounts payable and other accrued liabilities	\$	723.0	\$	727.8	
Deferred revenue		307.1		268.6	
Total liabilities		1,030.1		996.4	
Stockholders' equity		6,288.5		4,780.4	
Total liabilities and stockholders' equity	\$	7,318.6	\$	5,776.8	

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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				
In millions (except per share data)		September 30, 2018	June 30, 2018		September 30, 2017		September 30, 2018		September 30, 2017		
GAAP gross profit	\$	642.3	\$	632.3	\$	568.1	\$	1,868.4	\$	1,568.0	
Share-based compensation expense		14.3		12.8		10.6		39.0		30.6	
Intangible asset charges		1.8		1.3		1.2		4.1		4.4	
Litigation charges		—		—		_				7.8	
Non-GAAP gross profit	\$	658.4	\$	646.4	\$	579.9	\$	1,911.5	\$	1,610.8	
GAAP income from operations	\$	313.3	\$	277.4	\$	280.6	\$	867.4	\$	733.9	
Share-based compensation expense		70.1		63.2		55.7		190.8		153.5	
Intangible asset charges		9.0		5.6		3.1		22.2		15.9	
Litigation charges (recoveries)		(1.8)		42.5		9.7		45.2		26.5	
Non-GAAP income from operations	\$	390.6	\$	388.7	\$	349.1	\$	1,125.6	\$	929.8	
GAAP net income attributable to Intuitive Surgical, Inc.	\$	292.5	\$	255.3	\$	298.6	\$	835.4	\$	702.4	
Share-based compensation expense		70.1		63.2		55.7		190.8		153.5	
Intangible asset charges		9.0		5.6		3.1		22.2		15.9	
Litigation charges (recoveries)		(1.8)		42.5		9.7		45.2		26.5	
Tax adjustments (1)		(32.8)		(39.2)		(42.2)		(141.7)		(146.5)	
Non-GAAP net income attributable to Intuitive Surgical, Inc.	\$	337.0	\$	327.4	\$	324.9	\$	951.9	\$	751.8	
GAAP net income per share attributable to Intuitive Surgical, Inc diluted	\$	2.45	\$	2.15	\$	2.56	\$	7.04	\$	6.06	
Share-based compensation expense		0.59		0.53		0.48		1.61		1.32	
Intangible asset charges		0.08		0.05		0.03		0.19		0.14	
Litigation charges (recoveries)		(0.02)		0.36		0.08		0.38		0.23	
Tax adjustments (1)		(0.27)		(0.33)		(0.37)		(1.19)		(1.26)	
Non-GAAP net income per share attributable to Intuitive Surgical, Inc diluted	\$	2.83	\$	2.76	\$	2.78	\$	8.03	\$	6.49	

(1) For the three months ended September 30, 2018, tax adjustments included: (1) excess tax benefits associated with share-based compensation arrangements of \$(24.1) million, or \$(0.20) per diluted share; (2) tax benefits related to intra-entity transfers of non-inventory assets of \$10.2 million, or \$0.09 per diluted share; and (3) other tax adjustments effects determined by applying a calculated non-GAAP effective tax rate of \$(18.9) million, or \$(0.16) per diluted share.

For the nine months ended September 30, 2018, tax adjustments included: (1) excess tax benefits associated with share-based compensation arrangements of \$(100.4) million, or \$(0.85) per diluted share; (2) tax benefits related to intra-entity transfers of non-inventory assets of \$30.6 million, or \$0.26 per diluted share; and (3) other tax adjustments effects determined by applying a calculated non-GAAP effective tax rate of \$(71.9) million, or \$(0.60) per diluted share.

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