
**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): January 9, 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))

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

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 January 9, 2019, Intuitive Surgical, Inc. (“Intuitive”) issued a press release announcing certain unaudited preliminary fourth quarter and full year 2018 financial results. A copy of the press release is furnished hereto as Exhibit 99.1.

Additional unaudited preliminary revenue and procedure information is provided in the tables attached hereto as Exhibit 99.2, which has also been posted to the Investor Relations section of the Intuitive website at: <https://isrg.gcs-web.com/>.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, 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.

The following exhibits are furnished with this report on Form 8-K:

Exhibit No.	Description
99.1	<u>Press release issued by Intuitive Surgical, Inc., dated January 9, 2019.</u>
99.2	<u>Unaudited preliminary revenue and procedure information, as of January 9, 2019.</u>

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: January 9, 2019

By: /s/ Marshall L. Mohr

Name: Marshall L. Mohr

Title: Executive Vice President and Chief Financial Officer

Contact: Investor Relations
(408) 523-2161

INTUITIVE SURGICAL ANNOUNCES PRELIMINARY FOURTH QUARTER AND FULL YEAR 2018 RESULTS

SUNNYVALE, CALIF. January 9, 2019 - Intuitive Surgical, Inc. (“Intuitive”) (Nasdaq: ISRG), the pioneer and a global technology leader in robotic-assisted, minimally invasive surgery, today announced certain unaudited preliminary fourth quarter and full year 2018 financial results ahead of its participation at the 37th Annual JP Morgan Healthcare Conference on January 9-10, 2019, in San Francisco, California.

Financial and Operational Highlights

- Fourth quarter 2018 worldwide da Vinci procedures increased approximately 19% compared with the fourth quarter of 2017. Full year 2018 worldwide da Vinci procedures increased approximately 18% compared with 2017. The annual number of da Vinci procedures performed was in excess of 1 million for the first time in 2018, with more than 6 million procedures having been performed to-date.
- Preliminary fourth quarter 2018 revenue of \$1.047 billion grew approximately 17% compared with \$0.892 billion for the fourth quarter of 2017. Preliminary 2018 revenue of \$3.724 billion grew approximately 19% compared with \$3.138 billion for 2017.
- The Company shipped 290 da Vinci Surgical Systems in the fourth quarter of 2018 compared with 216 in the fourth quarter of 2017. The Company shipped 926 da Vinci Surgical Systems in 2018, compared with 684 systems in 2017.
- In the fourth quarter of 2018, the Company established the Intuitive Foundation whose mission is to reduce the global burden of disease and suffering through research, education, and philanthropy aimed at better outcomes for patients around the globe. The Company contributed \$25 million to the Intuitive Foundation during the quarter.
- In October 2018, the China National Health Commission announced a new quota to allow the sale of 154 new surgical robots into China through 2020, which includes da Vinci Surgical Systems. In December 2018, the Company also obtained clearance for the da Vinci Xi Surgical System in China.
- The Intuitive-Fosun joint venture in China began direct operations for da Vinci products and services in January 2019.
- The Company began direct operations for da Vinci products and services in Taiwan in December 2018.

Preliminary Results

The Company expects revenue for the fourth quarter of 2018 of approximately \$1.047 billion, an increase of approximately 17% compared with \$0.892 billion for the fourth quarter of 2017. The Company expects 2018 revenue of approximately \$3.724 billion, an increase of approximately 19% compared with \$3.138 billion for 2017. These unaudited results are preliminary and prior to the completion of the Company’s annual independent audit and therefore are subject to adjustment.

Preliminary fourth quarter 2018 instrument and accessory revenue increased approximately 18% to approximately \$539 million compared with \$457 million for the fourth quarter of 2017. Preliminary full year 2018 instrument and accessory revenue increased approximately 20% to approximately \$1.962 billion compared with \$1.637 billion for 2017. Fourth quarter and full year 2018 instrument and accessory revenue growth was driven primarily by da Vinci procedure growth.

Da Vinci procedures increased approximately 19% for the fourth quarter of 2018 compared with the fourth quarter of 2017. Approximately 1,037,000 surgical procedures were performed with the da Vinci Surgical System in 2018, an increase of approximately 18% compared with approximately 877,000 procedures performed in 2017. The growth in overall 2018 procedure volume was primarily driven by growth in U.S. general surgery procedures and worldwide urologic procedures. The Company expects total da Vinci procedures to grow approximately 13% to 17% in 2019.

Preliminary fourth quarter 2018 da Vinci Surgical Systems revenue increased approximately 20% to approximately \$341 million from \$285 million for the fourth quarter of 2017. Preliminary systems revenue for 2018 increased approximately 21% to approximately \$1.127 billion compared with \$0.928 billion in 2017. The Company shipped 290 da Vinci Surgical Systems in the fourth quarter of 2018, compared with 216 systems in the fourth quarter of 2017. The fourth quarter 2018 da Vinci Surgical Systems shipments included 84 shipped under operating lease and usage-based arrangements, compared with 40 in the fourth quarter of 2017. The Company shipped 926 da Vinci Surgical Systems in 2018, compared with 684 systems in 2017.

Preliminary fourth quarter 2018 service revenue of approximately \$167 million increased approximately 11% compared with \$150 million in the fourth quarter of 2017. Preliminary 2018 service revenue increased approximately 11% to approximately \$635 million compared with \$573 million in 2017.

Commenting on the announcement, Gary Guthart, President and CEO of Intuitive, said, “We are pleased with our fourth quarter procedure growth, system placements, and the financial results that follow. We are committed to advancing intelligent minimally invasive care through the combination of human understanding, smart systems and instruments, and digital insights.”

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

The Company is scheduled to present at the 2019 JP Morgan Healthcare Conference on January 10, 2019, at 9:00 a.m. Pacific Time. The Company is scheduled to report its fourth quarter 2018 results during a conference call on January 24, 2019, at which point the Company will discuss the 2018 financial results in more detail. Dial-in and webcast access information for both of these events are also available in the Investor Relations section of the Intuitive website.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq: ISRG), headquartered in Sunnyvale, California, is the pioneer and a global technology leader in robotic-assisted, minimally invasive surgery. Intuitive develops, manufactures, and markets the da Vinci surgical system. The Company strives to make surgery more effective, less invasive, and easier on surgeons, patients, and their families.

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® is trademark 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 unaudited preliminary financial and operational results for the fourth quarter and full year 2018, expected procedure growth in 2019, the mission of the Intuitive Foundation, systems sales under the China National Health Commission quota, and

the Company's commitment to advancing intelligent minimally invasive care through the combination of human understanding, smart systems and instruments, and digital insights. 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: completion of the Company's final closing procedures, final adjustments and other developments that may arise in the course of audit procedures; the uncertainty regarding the timing and extent of purchases of da Vinci Surgical Systems under the China National Health Commission quota, which may be adversely impacted by Provincial approvals in China, hospital tendering processes, tariffs assessed on certain medical equipment manufactured in the United States, and competitive products that will share the quota; the impact of global and regional economic and credit 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 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 premarket notification to the FDA for the Ion™ 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," "should," "would," "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.

Intuitive Surgical, Inc.
Unaudited Preliminary Quarterly and Annual Revenue Data and Metrics

	Three Months Ended			Twelve Months Ended		
	December 31, 2018	December 31, 2017	Change	December 31, 2018	December 31, 2017	Change
Revenue (\$Millions)						
Instruments and Accessories	\$ 539.3	\$ 457.1	18 %	\$ 1,962.0	\$ 1,636.9	20 %
Systems	340.6	284.5	20 %	1,127.1	928.4	21 %
Services	166.6	150.4	11 %	635.1	572.9	11 %
Total Revenue	\$ 1,046.5	\$ 892.0	17 %	\$ 3,724.2	\$ 3,138.2	19 %
System Unit Shipments by Geography						
United States	175	130	35 %	581	417	39 %
Europe	55	47	17 %	169	122	39 %
Asia	40	34	18 %	116	108	7 %
Other Markets	20	5	300 %	60	37	62 %
Total Systems*	290	216	34 %	926	684	35 %
System Unit Shipments by Model						
Si-e Systems	—	1	(100)%	—	4	(100)%
Single Console Si Systems	15	19	(21)%	50	98	(49)%
Dual Console Si Systems	1	—	—	2	7	(71)%
Single Console X Systems	49	47	4 %	181	73	148 %
Dual Console X Systems	2	4	(50)%	10	5	100 %
Single Console Xi Systems	147	106	39 %	479	356	35 %
Dual Console Xi Systems	64	39	64 %	189	141	34 %
SP Systems	12	—	—	15	—	—
Total Systems*	290	216	34 %	926	684	35 %
* Systems Shipped under Operating Leases (Included above in Total Unit Shipments)	84	40	110 %	229	108	112 %
Other Metrics						
System Average Selling Price (\$Millions)	\$ 1.46	\$ 1.47	(1)%	\$ 1.45	\$ 1.47	(1)%
Inst & Accy Revenue/Procedure (\$Thousands)	\$ 1.89	\$ 1.91	(1)%	\$ 1.89	\$ 1.87	1 %
System Installed Base	4,986	4,409	13 %	4,986	4,409	13 %

Intuitive Surgical, Inc.
Unaudited Preliminary Trended Annual Procedure Data

	Approximate Procedures (Thousands)			Percentage Change	
	2018	2017	2016	2018	2017
<u>United States</u>					
General Surgery	325	246	186	32%	32%
Gynecology	265	252	246	5%	2%
Urology	128	118	109	8%	8%
Other	35	28	22	25%	27%
Total United States	753	644	563	17%	14%
Total Outside of the United States	284	233	190	22%	23%
Total Worldwide	1,037	877	753	18%	16%

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This report contains forward-looking statements. Such statements relate to unaudited preliminary trended annual procedure data, unaudited preliminary fourth quarter and full year 2018 revenue data and metrics, and other related subjects. The unaudited preliminary results are prior to the completion of Intuitive Surgical's final closing procedures and the independent audit and are therefore subject to adjustment. These forward-looking statements are based on Intuitive Surgical's current plans and expectations and are subject to risks and uncertainties that could cause actual events and results to vary significantly from those implied by such statements. Please refer to Intuitive Surgical's reports and filings with the Securities and Exchange Commission for a further discussion of these risks and uncertainties.