

INTUITIVE SURGICAL INC

Form 8-K

October 31, 2018

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 29, 2018

INTUITIVE SURGICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware 000-30713 77-0416458
(State or other jurisdiction (Commission (I.R.S. Employer
of incorporation) File Number) 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 7.01.Regulation FD Disclosure.

On October 29, 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow 154 new surgical robots, which could include da Vinci Surgical Systems of Intuitive Surgical, Inc. (the “Company”), to be sold during this period in China. Da Vinci Surgical Systems sales under the quota are uncertain, as they are dependent on hospitals completing a tender process and receiving associated approvals. The tender process could be lengthy, and the Company does not expect to sell any systems under this quota in 2018.

Forward-Looking Statements

This report contains forward-looking statements, including statements regarding systems sales under the China National Health Commission quota, the tender process, and the Company’s expectations regarding timing of sales. 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 uncertainty regarding the timing and extent of purchases of da Vinci Surgical Systems under the 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, competitive products that will share the quota, and regulatory clearances for da Vinci Xi products in China; the impact of global and regional economic and credit market conditions on healthcare spending; 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; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; the Company’s ability to expand into foreign markets; 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 or 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 report. The Company undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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 31, 2018 By: /s/ Jamie E. Samath

Name: Jamie E. Samath

Title: Vice President, Corporate Controller, and Principal Accounting Officer