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): March 14, 2024

INTUITIVE SURGICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-30713**	**77-0416458**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 ☐

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 March 14, 2024, Intuitive Surgical, Inc. ("Intuitive") issued a press release announcing U.S. Food and Drug Administration clearance of its fifth-generation robotic system, da Vinci 5. A copy of the press release is furnished hereto as Exhibit 99.1.

Intuitive will hold a teleconference at 5:45 a.m. PDT on Monday, March 18, 2024, to discuss the da Vinci 5 features and benefits and our launch plans. The call will be webcast and can be accessed on Intuitive's website at *www.intuitive.com* or by dialing (844) 291-6362 using the access code 5898411. The webcast replay of the call will be made available on our website at *www.intuitive.com* within 24 hours after the end of the live teleconference and will be accessible for at least 30 days.

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 March 14, 2024.
104	Cover 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: March 14, 2024

By: */S/ JAMIE E. SAMATH*

Name: Jamie E. Samath
Title: Senior Vice President and Chief Financial Officer

Contact: Global Public Affairs
+1-202-997-7373

Intuitive Announces FDA Clearance of Fifth-Generation Robotic System, da Vinci 5

Da Vinci 5 builds on decades of Intuitive technology and millions of robotic procedures

Sunnyvale, Calif., March 14, 2024 – Intuitive (NASDAQ:ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, announced today that the U.S. Food and Drug Administration (FDA) provided 510(k) clearance for da Vinci 5, the company's next-generation multiport robotic system.

"We are pleased to receive FDA clearance for our fifth-generation robotic system, da Vinci 5," said Gary Guthart, CEO. "Intuitive is committed to meaningful improvements in surgery that enable better patient outcomes, enhance the patient and care team experiences, and ultimately lower the total cost of care. After more than a decade of careful research, design, development, and testing, we believe da Vinci 5 will deliver on these goals and help drive the future of robotic-assisted surgery."

Da Vinci 5 builds on Intuitive's da Vinci Xi's highly functional design, which surgeons and care teams around the world have used in more than 7 million procedures to date. The system includes more than 150 enhancements, including:

- **Improved accuracy and precision:** Da Vinci 5's design and engineering enhancements, including new surgeon controllers and powerful vibration and tremor controls, make it the smoothest and most precise system Intuitive has developed to date.
- **Next-generation 3D display and image processing:** Da Vinci 5 is equipped with Intuitive's highest quality and most natural 3D imaging system, enabling surgeons to see more today, and supporting future generations of surgical endoscopes and vision software as those technologies evolve.
- **First-of-its-kind force-sensing technology:** Da Vinci 5 introduces Force Feedback technology and optional instruments that enable the system to measure, and surgeons to feel, subtle forces exerted on tissue during surgery —something no other surgical technology in any modality offers. In preclinical trials with surgeons at all experience levels, Force Feedback demonstrated up to 43 percent less force exerted on tissue, which may translate to less trauma on tissue. The ability to measure this force adds an important new data stream to surgical data science, which can bring future analytical insights supported through artificial intelligence. Force Feedback instruments, which are optional for use with da Vinci 5, are cleared for use in the same procedures as da Vinci Xi, except pediatric and cardiac procedures, and a specific contraindication for the Force Feedback needle driver for use in suturing during hysterectomy and myomectomy procedures.
- **Meaningful throughput and workflow enhancements**: Da Vinci 5 has innovative features that are designed to help increase surgeon autonomy and streamline surgeon and care team workflow. For example, da Vinci 5 has integrated key OR technologies, including insufflation and an electrosurgical unit. The system also includes an optimized user interface, with settings that are accessible by the broader surgical team and by the surgeon directly from the head-in menu. Surgeons have access to other key settings while head-in to help them stay focused on the surgical field.

  Together, these innovations will continue to streamline workflow in the OR and potentially save valuable time, without compromising patient safety. This can enable more efficient use of a hospital's human and capital resources.
- **Expanded computing power and advanced data capabilities:** Da Vinci 5 has more than 10,000 times the computing power of da Vinci Xi. This enables innovative new system capabilities and advanced digital experiences, now and in the future, including integration with Intuitive's My Intuitive app, SimNow (virtual reality simulator), Case Insights (computational observer), and Intuitive Hub (edge computing system).
- **Greater surgeon comfort:** The system features a redesigned console capable of customizable positioning, allowing surgeons to find their best fit for surgical viewing and comfort, including the ability to sit completely upright. The surgeon can make any necessary adjustments while their head is in the console, with options designed to fit different body types, including surgeons who are pregnant.

Da Vinci 5 will initially be available to a small number of customers in the U.S. who collaborated with Intuitive during the development period and those with mature robotic surgery programs. Intuitive will work with surgeons at these initial sites to generate additional data on the system's use before a wider commercial introduction.

"We strive to provide customers with technology that meets their needs and solves important problems," said Intuitive's Chief Medical Officer, Myriam J. Curet, M.D. "We intend to launch da Vinci 5 more broadly in the U.S. and globally after we learn from and work with an initial smaller number of customers directly."

Da Vinci 5 is the latest addition to the da Vinci family, which includes multiport systems da Vinci X and da Vinci Xi, and the single-port system da Vinci SP. These offer surgeons and hospitals their choice of highly capable, proven solutions from Intuitive.

"We design our systems so we can integrate new functions, capabilities, indications, and instrumentation over time," said Curet. "Our careful attention to customers' long-term needs and goals has led our systems to become the hospital standard, and we expect to continue developing and innovating da Vinci 5 and da Vinci Xi over the coming years."

Intuitive will hold a teleconference at 5:45 a.m. PDT on Monday, March 18, 2024, to discuss the da Vinci 5 features and benefits and our launch plans. The call will be webcast and can be accessed on Intuitive's website at *www.intuitive.com* or by dialing (844) 291-6362 using the access code 5898411. The webcast replay of the call will be made available on our website at *www.intuitive.com* within 24 hours after the end of the live teleconference and will be accessible for at least 30 days.

About Intuitive Surgical, Inc.

Intuitive (NASDAQ:ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic surgery. Our technologies include the da Vinci surgical system and the Ion endoluminal system. By uniting advanced systems, progressive learning, and value-enhancing services, we help physicians and their teams optimize care delivery to support the best outcomes possible. At Intuitive, we envision a future of care that is less invasive and profoundly better, where disease is identified early and treated quickly, so that patients can get back to what matters most.

About da Vinci Surgical Systems

There are several models of the da Vinci Surgical System. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery and 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.

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

Important Safety Information

For Important Safety Information, indications for use, risks, full cautions and warnings, please refer to associated da Vinci 5 user manual(s).

Forward-Looking Statements

This press release 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. Forward-looking statements relate to expectations concerning matters that are not historical facts. 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. These forward-looking statements are necessarily estimates reflecting the 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 include, but are not limited to, statements related to the future development of current products, the potential effects of improved patient and hospital workflow experiences, the expected operational plans of the Company, and the future compatibility of current products with new technologies. These forward-looking statements should be considered in light of various important factors, including, but not limited to, the following: the overall macroeconomic environment, including

the levels of inflation and interest rates; the conflict in Ukraine; the conflict between Israel and Hamas; disruption to the Company's supply chain, including increased difficulties in obtaining a sufficient supply of materials in the semiconductor and other markets; delays in surgeon training; the risk of the Company's inability to comply with complex FDA and other regulations, which may result in significant enforcement actions; regulatory approvals, clearances, certifications, and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; healthcare reform legislation in the U.S. 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; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery and diagnostics in which the Company operates; risks associated with the Company's operations and any expansion outside of the United States; unanticipated manufacturing disruptions or the inability to meet demand for products; the Company's reliance on sole-sourced and single-sourced suppliers; the results of legal proceedings to which the Company is or may become a party, including, but not limited to, product liability claims; adverse publicity regarding the Company and the safety of the Company's products and adequacy of training; changes in tariffs, trade barriers, and regulatory requirements; and other risks and uncertainties. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release and which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as updated by the Company's other filings with the Securities and Exchange Commission. The Company's actual results may differ materially and adversely from those expressed in any forward-looking statement, and the Company undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.