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): **February 17, 2021**

Medtronic Public Limited Company
(Exact Name of Registrant as Specified in its Charter)

Ireland	**1-36820**	**98-1183488**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

20 On Hatch, Lower Hatch Street
Dublin 2, Ireland
(Address of principal executive offices)

+353 1 438-1700
(Registrant's telephone number, including area code)

Not Applicable
Former name or former address, if changed since last report

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Ordinary Shares, $0.0001 par value per share	**MDT**	**New York Stock Exchange**
Floating Rate Senior Notes due 2021	**MDT/21**	**New York Stock Exchange**
0.00% Senior Notes due 2022	**MDT/22B**	**New York Stock Exchange**
0.375% Senior Notes due 2023	**MDT/23B**	**New York Stock Exchange**
0.000% Senior Notes due 2023	**MDT/23C**	**New York Stock Exchange**
0.25% Senior Notes due 2025	**MDT/25**	**New York Stock Exchange**
0.000% Senior Notes due 2025	**MDT/25A**	**New York Stock Exchange**
1.125% Senior Notes due 2027	**MDT/27**	**New York Stock Exchange**
0.375% Senior Notes due 2028	**MDT/28**	**New York Stock Exchange**
1.625% Senior Notes due 2031	**MDT/31**	**New York Stock Exchange**
1.00% Senior Notes due 2031	**MDT/31A**	**New York Stock Exchange**
0.750% Senior Notes due 2032	**MDT/32**	**New York Stock Exchange**
2.250% Senior Notes due 2039	**MDT/39A**	**New York Stock Exchange**
1.50% Senior Notes due 2039	**MDT/39B**	**New York Stock Exchange**
1.375% Senior Notes due 2040	**MDT/40A**	**New York Stock Exchange**
1.75% Senior Notes due 2049	**MDT/49**	**New York Stock Exchange**
1.625% Senior Notes due 2050	**MDT/50**	**New York Stock Exchange**

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 February 17, 2021, Medtronic plc (the "Company") issued a press release announcing its voluntary global recall of its Valiant Navion™ Thoracic Stent Graft System. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The Company is providing the following additional details related to its voluntary global recall of its Valiant Navion™ Thoracic Stent Graft System. Medtronic does not expect this voluntary global recall to have a material impact on its total company financials. The company's Valiant Navion™ revenue, prior to this recall, represented less than 0.5% of total Company revenue.

As a substitute for the Valiant Navion™, Medtronic is working to ramp production of its previous generation product, the Valiant Captivia™ Thoracic Stent Graft System, over the coming weeks and resume selling this product in markets globally. The Company expects to have Valiant Captivia™ inventory available in most markets in late March or early April and expects to reach full production capacity in September.

The Company has booked a $19 million reserve to cover the estimated cost of scrapping its Valiant Navion™ inventory. This charge will appear in the company's third quarter of fiscal year 2021 cost of products sold, which the company will report on February 23, 2021. The company does not expect to adjust its third quarter earnings for this charge.

While it is difficult to estimate the revenue impact of this global recall at this time, based on current assumptions, the Company estimates that its current quarter, the fourth quarter of fiscal year 2021, Aortic, Peripheral and Venous (APV) division revenue, which is reported within the Cardiac and Vascular Group, could be negatively affected by approximately $40 million. Similarly, based on current assumptions, the company also estimates that its APV revenue could be negatively affected by approximately $25 to $35 million per quarter in fiscal year 2022, decreasing through the fiscal year.

The information in this Item 7.01 of this 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 of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties, including risks related to, the impact COVID-19 has had and is expected to continue to have on our business, operations and production, as well as demand for our offerings, and on our employees, medical professional and the healthcare system, communities in which we operate, and our financial results and condition, competitive factors, difficulties and delays inherent in the development, manufacturing, marketing and sale of medical products, government regulation and general economic conditions and other risks and uncertainties described in the Company's periodic reports on file with the U.S. Securities and Exchange Commission including the most recent Annual Report on Form 10-K of the Company, as filed with the U.S. Securities and Exchange Commission. In some cases, you can identify these statements by forward-looking words, such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "looking ahead," "may," "plan," "possible," "potential," "project," "should," "will," and similar words or expressions, the negative or plural of such words or expressions and other comparable terminology. Actual results may differ materially from anticipated results. Medtronic does not undertake to update its forward-looking statements or any of the information contained in this Current Report on Form 8-K, including to reflect future events or circumstances.

Item 9.01 Exhibits

Exhibit Number	Description
99.1	Press release of Medtronic plc, dated February 17, 2021

SIGNATURES

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

MEDTRONIC PUBLIC LIMITED COMPANY

Date: February 17, 2021

By /s/ Karen L. Parkhill

Karen L. Parkhill

Executive Vice President and Chief Financial Officer

NEWS RELEASE

Contacts:

Ben Petok
Public Relations
+1-612-297-0501

Ryan Weispfenning
Investor Relations
+1-763-505-4626

FOR IMMEDIATE RELEASE

MEDTRONIC ANNOUNCES VOLUNTARY RECALL OF UNUSED VALIANT NAVION™ THORACIC STENT GRAFT SYSTEM

DUBLIN – February 17, 2021 – Medtronic plc (NYSE:MDT), the global leader in medical technology, has voluntarily issued a global recall of unused Medtronic Valiant Navion™ thoracic stent graft system and informed physicians to immediately cease use of the device until further notice.

In accordance with its commitment to patient safety – and in consultation with independent physicians – Medtronic initiated this action in response to information recently obtained from the Valiant Evo Global Clinical Trial indicating that three patients in the Valiant Evo Global Clinical Trial were observed to have stent fractures, two of which have confirmed type IIIb endoleaks. One patient death was reported.

Following these observations, an independent imaging laboratory reviewed all available images from patients enrolled in the Valiant Evo Global Clinical Trial. Upon further analysis of the images, seven (7) out of 87 patients were observed to have stent ring enlargement beyond the design specification. Those observations require further assessment to determine potential clinical importance.

Medtronic is currently conducting a comprehensive technical root cause investigation, including further review of follow-up clinical trial imaging and commercial complaints and imaging.

“There is nothing more important than the safety and well-being of patients,” said Nina Goodheart, senior vice president and president, Structural Heart & Aortic, which is reported as part of the Cardiac Vascular Group at Medtronic. “We treat matters of product safety with the highest priority and urgency. Our decision to implement this voluntary recall is necessary to ensure the utmost patient safety. As our investigation continues, we are committed to timely communication with physicians and regulatory bodies.”

Medtronic has contacted the U.S. Food and Drug Administration (FDA), along with other regulatory bodies around the world, to share information related to this issue. Medtronic will continue working directly with regulatory authorities on this global voluntary recall.

Patient Management Recommendations

Patients with a Medtronic Valiant Navion thoracic stent graft system should consult their physician with any questions.

As part of the voluntary recall of unused product, physicians were sent written communication from Medtronic directing them to immediately cease use of the Medtronic Valiant Navion thoracic stent graft system and instructions for returning unused product to Medtronic.

Medtronic advises physicians to retrospectively review all available images of patients treated with Valiant Navion thoracic stent graft system with specific attention to stent fractures and type IIIb endoleaks and contact Medtronic if any imaging findings are observed.

Medtronic urges physicians to follow best clinical practices and evaluate patients with at least annual follow-up according to the imaging recommendations in the Medtronic Valiant Navion thoracic stent graft system Instructions for Use (IFU).

As always, physicians are asked to notify Medtronic of any adverse events or product safety issues associated with use of any Medtronic product, which also should be reported to the FDA's MedWatch Adverse Event Reporting program. Outside of the U.S. adverse events or product safety issues associated with use of any Medtronic product should be reported to the appropriate competent authority.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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