

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or Section 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 24, 2022

**AVADEL PHARMACEUTICALS PLC**  
(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction  
of incorporation)

**001-37977**  
(Commission  
File Number)

**98-1341933**  
(IRS Employer  
Identification No.)

**10 Earlsfort Terrace**  
**Dublin 2, Ireland, D02 T380**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

Registrant's telephone number, including area code: **+353 1 920 1000**

**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 to 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(s)	Name of each exchange on which registered
American Depositary Shares*	AVDL	The Nasdaq Global Market
Ordinary Shares, nominal value \$0.01 per share**	N/A	

\*American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) Ordinary Share.

\*\* Not for trading, but only in connection with the listing of American Depositary Shares on The Nasdaq Global 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 May 24, 2022, Avadel Pharmaceuticals plc (the “Company”) received a proposed, final label and medication guide for FT218 from the U.S. Food & Drug Administration (“FDA”). In addition, the Company was notified by FDA that the FT218 New Drug Application (“NDA”) patent statement pertaining to US Patent No. 8,731,963 (the “REMS patent”) was deemed inappropriate by FDA. As such, FDA has requested the Company add a certification to the REMS patent to its NDA. FDA further confirmed, based on the final proposed label, that no additional patent certifications will be required.

Based upon the above, the Company anticipates tentative approval of the FT218 NDA with potential full approval on or before the expiration of the REMS patent on June 17, 2023. Full approval could occur sooner if the REMS patent is delisted from FDA’s Orange Book, a court determines the patent is invalid, not infringed or otherwise unenforceable, or a court determines that FDA erred in requesting a certification.

The Company believes in the potential of FT218 and its importance to the narcolepsy community. The Company is committed to pursuing all options for FT218 to realize its full value.

### *Forward-Looking Statements*

Statements contained under this Item 7.01 regarding matters that are not historical facts are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to the Company’s future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, expectations regarding the timing and outcome of FDA’s review of the NDA for FT218, the timing and likelihood of a potential full approval of the FT218 NDA, and the potential benefits of FT218.

Any forward-looking statements in this Current Report on Form 8-K are based on estimates and assumptions that are made within the bounds of the Company’s knowledge of its business and operations and that it considers reasonable. However, the Company’s business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the Company’s business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in the Company’s forward-looking statements include the risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2022, and subsequent SEC filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

*The information furnished under this Item 7.01 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.*

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**SIGNATURES**

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

Date: May 26, 2022

**AVADEL PHARMACEUTICALS PLC**

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: General Counsel & Corporate Secretary

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