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): **August 9, 2019** (August 8, 2019)

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**001-37977**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Block 10-1 **Blanchardstown Corporate Park, Ballycoolin** **Dublin 15, Ireland** (Address of Principal Executive Offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

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. ☐

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

Title of each class	**Ticker symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares* Ordinary Shares**	AVDL	NASDAQ Stock Market LLC (NASDAQ Global Market)

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

** Nominal value $0.01 per share. Not for trading, but only in connection with the listing of American Depositary Shares.

Item 8.01 Other Events.

On August 8, 2019, Avadel Pharmaceuticals plc issued a press release, a copy of which is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release dated August 8, 2019, issued by Avadel Pharmaceuticals plc

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.

AVADEL PHARMACEUTICALS PLC

By: /s/ Phillandas T. Thompson
Phillandas T. Thompson
Senior Vice President, General Counsel and Corporate Secretary

Date: August 9, 2019

Exhibit 99.1

Avadel Pharmaceuticals Receives New PDUFA Date for AV001 of December 15, 2019

PDUFA Action Extended 3 Months; Launch Remains on Track for 1Q 2020

DUBLIN, Ireland, Aug. 8, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) Action Date relating to the New Drug Application (NDA) for AV001, a sterile injectable product designed for use in the hospital setting, by three months to December 15, 2019. The NDA for AV001 was originally accepted in May 2019 under the FDA's Priority Review program with a statutory six-month review.

This three-month extension relates to recent submissions Avadel made in response to FDA requests for additional analytical information. The FDA determined that these submissions constitute a major amendment and will require additional time to review.

"We have remained in contact with the FDA since filing the AV001 NDA and look forward to continuing our constructive dialog with the Agency," said Greg Divis, Chief Executive Officer of Avadel. "Should FDA approve AV001, the three-month extension does not impact our planned timeline for the U.S. launch, which we currently anticipate occurring in the first quarter of 2020. As such, all our operational and launch planning remain on-track."

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. The Company's primary focus is on the development and potential FDA approval for FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. For more information, please visit www.avadel.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements (which may be identified by words such as "will," "look forward," "should," "planned" and "anticipate") are not statements of historical facts regarding AV001, the FDA review process relating thereto including the expected timing of that process, and the possible commercial launch of AV001. All forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA may determine that there are deficiencies in the NDA for AV001 or may never approve the NDA for AV001, AV001 may not have the therapeutic benefits the Company anticipates, the commercial launch of AV001 could be delayed, AV001 may not achieve commercial acceptance, other companies may develop competing products which may receive FDA approval before AV001, and the other risks detailed in Avadel's filings with the SEC, including, without limitation, its Form 10-K, Forms 10-Q and other reports on Forms 8-K, all of which can be obtained on the SEC website at www.sec.gov. Avadel assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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