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): December 16, 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)	(IRS 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

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 December 16, 2019, Avadel Pharmaceuticals plc (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved Nouress™, a cysteine hydrochloride injection. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act, 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Exhibits

(d) Exhibits

99.1	Press release issued by the Company on December 16, 2019, furnished herewith.

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.

December 16, 2019

AVADEL PHARMACEUTICALS PLC

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

Exhibit 99.1

Avadel Pharmaceuticals Receives U.S. FDA Approval for Nouress™ (AV001), a Cysteine Hydrochloride Injection for Treating Neonate Patients Requiring Total Parental Nutrition (TPN)

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USPTO issues Orange Book-listed patent for Nouress

DUBLIN, Ireland, December 16, 2019 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating narcolepsy, announced today that the U.S. Food and Drug Administration (FDA) has approved Nouress™ (AV001), a cysteine hydrochloride injection, a critical drug for treating neonatal patients requiring total parenteral nutrition (TPN).

In addition, Avadel announced today that the United States Patent and Trademark Office (USPTO) recently issued United States Patent No. 10,493,051 covering cysteine solutions, including the approved Nouress product. This patent is listed in the Orange Book for Nouress and is set to expire in March of 2039. Avadel has additional U.S. patent applications pending for Nouress.

“We are pleased to receive FDA approval for Nouress, which validates our strategy of developing innovative medicines for patients,” said Greg Divis, Chief Executive Officer of Avadel. “Nouress is the fourth FDA approved product in our sterile injectable hospital business. The cash flow generated by this legacy business is supporting the clinical development costs from our lead program, FT218, which is currently expected to announce topline data from the pivotal Phase 3 REST-ON trial in the second quarter of 2020. We believe that as a once-nightly formulated sodium oxybate, FT218, if approved by the FDA, has the potential to take a significant share of the twice-nightly sodium oxybate market, which is currently valued at an estimated annualized rate of $1.7 billion[1].”

Avadel is currently evaluating the timing and process for a commercial launch of Nouress in the United States. In this regard, a competitor received FDA approval earlier this year for its cysteine hydrochloride injection and more recently was granted a U.S. patent, which Avadel is assessing along with other market factors.

Due to a historical lack of reliable supply, U.S. markets previously imported cysteine hydrochloride injection from Canada under special FDA rules allowing shortage drugs to be sourced abroad if no domestic supplies are available. With FDA approvals of Nouress and another U.S. company’s cysteine hydrochloride injection earlier this year, Avadel expects domestic supply of cysteine hydrochloride injection will be sufficient to support the entire U.S. market, which, under FDA regulations, should preclude further import or U.S. marketing of unapproved cysteine hydrochloride injection products. Under these potential market conditions, the U.S. annual market for cysteine hydrochloride could be greater than $50 million.

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company’s primary focus is the development and potential FDA approval of 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.

Footnote:
1. Annualized Xyrem revenues from Jazz Pharmaceuticals Q3 2019 earnings press release, November 5, 2019

Cautionary Disclosure Regarding Forward-Looking Statements
This press release includes "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 our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof (if applicable).

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks, including the risk that Nouress is not launched in 2020 or at all and the risk that a third party claims Nouress infringes its patent(s), and, as a result, there can be no assurance that actual results of our research, development and commercialization activities and the results of our 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 our forward-looking statements include the risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, which we filed with the Securities and Exchange Commission on March 15, 2019 and subsequent 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. We do not undertake any obligation to publicly update or revise the forward-looking statements contained in this Annual Report.

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