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): September 11, 2020

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.)

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 11, 2020, Jordan Dubow, M.D. notified Avadel Pharmaceuticals plc (the "Company") of his decision to resign from his position as Chief Medical Officer of the Company, effective September 30, 2020.

Item 8.01 Other Events.

On September 14, 2020, the Company issued a press release announcing Dr. Dubow's resignation. A copy of this press release is filed as Exhibit 99.1 to this report on Form 8-K.

The Company and Dr. Dubow intend to enter into a consulting agreement providing for Dr. Dubow to consult for the Company, including on matters relating to the submission, acceptance and subsequent review of the Company's new drug application for FT218. It is expected that Dr. Dubow will be eligible to receive performance-based incentive cash compensation commensurate with that which he was otherwise eligible to receive for 2020 and retain a portion of his outstanding equity awards.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the Company on September 14, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: September 14, 2020

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: Vice President, Deputy General Counsel and Corporate Secretary

Exhibit 99.1

Avadel Pharmaceuticals Announces FT218 Leadership Transition

- *Jordan Dubow, M.D. stepping down as CMO and will continue as a consultant to the Company through the FT218 NDA submission and review*
- *Seasoned industry veteran and Avadel Board member, Mark McCamish, M.D., Ph.D., to work with management and provide direct leadership of the FT218 program*

DUBLIN, Ireland, September 14, 2020 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy, announced today that Jordan Dubow, M.D. will be stepping down as Chief Medical Officer to pursue another opportunity. He will continue in a consultancy role in order to support the Company through the filing, review and anticipated approval of the new drug application (NDA) for FT218 with the FDA. Mark McCamish, M.D., Ph.D., an Independent Director on Avadel's Board of Directors and an accomplished industry executive with over 30 years of drug development experience, will assume a direct leadership role for the FT218 filing working with Avadel CEO Greg Divis, Dr. Dubow and the rest of the team to ensure continuity of the FT218 program, including the completeness and timeliness of the NDA submission.

"We thank Jordan for his hard work and dedication as our Chief Medical Officer, including the important role he played in the acceleration of and reporting the data from our pivotal Phase 3 REST-ON study that produced robust and statistically significant results across all primary endpoints. With that phase complete, we believe the addition of Mark's extensive experience and direct leadership of the FT218 filing serves to strengthen our internal and external teams, which include world class capabilities in the fields of clinical development, regulatory affairs and CMC. As a result, I have the utmost confidence in our team and I am confident this change will not impact the timing of our planned NDA filing," said Mr. Divis. "We continue to be excited by the market potential for FT218, if approved. As we execute our market preparation activities, we will continue to evaluate all strategic options, including sale, merger, out-licensing or commercialization to maximize shareholder value."

"I want to thank Greg, the Avadel team, and the Board for their support of my personal decision to take a new role outside of Avadel that is focused on developing gene therapies," stated Dr. Dubow. "I am excited by and proud of the progress we made in advancing the development program for FT218 and the potential for this once-nightly formulation of sodium oxybate to have a positive impact on the lives of narcolepsy patients suffering from excessive daytime sleepiness and cataplexy. I look forward to continuing to support the program and the Avadel team in my new capacity and remain highly confident in the clinical data for FT218, the timing of the NDA filing and its commercial potential."

"The Board and I are committed to supporting the Avadel team through the NDA preparation and review process for FT218. Since joining the Board, I have been actively overseeing the development and regulatory plan of FT218. I remain confident that the team is well positioned to finish the filing without delay," stated Dr. McCamish. "If approved, FT218 would be the first once-nightly therapy to address both excessive daytime sleepiness and cataplexy in patients with narcolepsy. As a result, the Avadel Board remains confident in the potential for FT218 to be an important treatment option for narcolepsy patients, and disrupt the estimated $1.7 billion[1] twice-nightly sodium oxybate market."

Dr. McCamish, who joined the Avadel Board of Directors in December 2019, is an internationally recognized expert in drug development, regulatory affairs and manufacturing. Most recently, he was the President and Chief Executive Officer of Forty Seven, Inc. (Nasdaq: FTSV), moving magrolimab through early development into registration trials, which led to Gilead's acquisition of the company for $5 billion in April 2020. Prior to Forty Seven, Inc., Dr. McCamish was the Global Head of Biopharmaceutical Development at Sandoz International, a Novartis company where he led the filing of ten BLAs in the last three years of his tenure.

About FT218

FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. In March of 2020, the Company completed the REST-ON study, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company's primary focus is the development and FDA approval of FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy. For more information, please visit www.avadel.com.

Footnote: 1. Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020

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. Such forward-looking statements include, but are not limited to, the planned submission of the FT218 NDA to the FDA and commercial launch of FT218, if approved. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "could," "believe," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project," "next steps" 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, and, as a result, there can be no assurance that actual results (including, without limitation, the continued advancement and development of FT218 and benefits and cost savings from the sale of our hospital products) 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 risk that we do not file the NDA for FT218 on a timely basis or at all, the risk that the FDA does accept such NDA or does not approve FT218, and the risk that the impact of the current COVID-19 pandemic on our financial results and results of operations could be greater than we anticipate and 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, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 2020 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

Contacts:

Investor Contacts

Tom McHugh
Chief Financial Officer
Phone: (636) 449-1843
Email: tmchugh@avadel.com

Tim McCarthy
LifeSci Advisors, LLC
Phone: (212) 915.2564
Email: tim@lifesciadvisors.com

Media Contact

Patrick Bursey
LifeSci Communications, LLC
Phone: (646) 970-4688
Email: pbursey@lifescicomms.com