# 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 12, 2018

# 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** (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 Ž

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.  $\check{Z}$ 

#### Item 1.01 Entry into a Material Definitive Agreement.

#### Purchase Agreement

On February 12, 2018, Avadel Pharmaceuticals plc (the "<u>Company</u>"), together with its subsidiaries Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC ("<u>FSC Therapeutics</u>"), and Avadel US Holdings, Inc. ("<u>Holdings</u>"), as the "<u>Sellers</u>," entered into an asset purchase agreement (the "<u>Purchase Agreement</u>") with Cerecor, Inc. ("<u>Cerecor</u>"). Pursuant to the Purchase Agreement, the Sellers agreed to sell to Cerecor, and Cerecor agreed to purchase, four pediatric commercial stage assets – Karbinal<sup>TM</sup> ER, Cefaclor, Flexichamber<sup>TM</sup> and AcipHex<sup>®</sup> Sprinkle<sup>TM</sup>, together with certain associated business assets – which are held by FSC Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively "<u>FSC</u>"). The Company acquired FSC in February 2016 from Deerfield CSF, LLC ("<u>Deerfield CSF</u>") and certain of its affiliates.

Under the Purchase Agreement, Cerecor will assume the Company's remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist of the following (collectively, the "<u>Assumed Obligations</u>"): (i) a quarterly payment of \$262,500 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of \$2,625,000; (ii) a payment in January 2021 of \$15,262,500; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through February 5, 2026 ("<u>FSC Product Royalties</u>"), in an aggregate amount of up to approximately \$10,300,000. Cerecor will also assume certain contracts and other obligations related to the acquired assets, and in that connection Holdings will pay Cerecor certain make-whole payments associated with obligations Cerecor is assuming related to a certain supply contract related to Karbinal<sup>™</sup> ER.

The transactions under the Purchase Agreement require the consent of Deerfield CSF. Such consent of Deerfield CSF is expected to be delivered at the closing, subject to the delivery by the Company and Holdings of their guarantee, in favor of Deerfield CSF, of the payment by Cerecor of the Assumed Obligations, including certain minimum annual FSC Product Royalties through February 5, 2026 (the "<u>Minimum Royalties</u>"). As a further condition to the closing under the Purchase Agreement, Cerecor is required to deliver the guarantee of its majority shareholder, in favor of Holdings, of the payment by Cerecor of the Assumed Obligations, including the Minimum Royalties. The Purchase Agreement includes various other representations, warranties, covenants, and indemnities customary for a transaction of its size and nature.

The foregoing summary of the Purchase Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the complete text of the Purchase Agreement. The Company intends to submit a FOIA Confidential Treatment Request with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 for certain portions of the Purchase Agreement. The Purchase Agreement, in redacted form subject to such confidential treatment request, will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

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The Purchase Agreement contains representations and warranties made by the parties as of specific dates and solely for their benefit. The representations and warranties reflect negotiations between the parties and are not intended as statements of fact to be relied upon by the Company's shareholders or any other person or entity other than the parties to the Purchase Agreement; in certain cases such representations and warranties represent risk allocation decisions among the parties and may be modified or qualified by correspondence or confidential disclosures made between the parties in connection with the negotiation of the Purchase Agreement (which disclosures would not be reflected in the Purchase Agreement itself, may not be true as of any date other than the date made, or may apply standards of materiality in a way that is different from what may be viewed as material by stockholders). Accordingly, the representations and warranties may not describe the actual state of affairs at the date they were made or at any other time, and stockholders should not rely on such representations and warranties as statements of fact. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Purchase Agreement.

## License and Development Agreement

In connection with the closing of the transactions under the Purchase Agreement, the Company and Cerecor will enter into a license and development agreement (the "License and Development Agreement"), pursuant to which, among other things:

- Avadel will provide Cerecor with four product formulations utilizing Avadel's LiquiTime<sup>™</sup> technology, and will complete pilot bioequivalence studies for such product formulations within 18 months;
- · Cerecor will reimburse Avadel for development costs of the four LiquiTime<sup>™</sup> products in excess of \$1 million in the aggregate;
- Upon transfer of the four product formulations, Cerecor will assume all remaining development costs and responsibilities for the product development, clinical studies, NDA applications and associated filing fees; and
- Upon regulatory approval and commercial launch of any LiquiTime<sup>™</sup> products, Cerecor will pay Avadel quarterly royalties based on a percentage of net sales of any such products in the mid-single digits.

The foregoing summary of the License and Development Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the complete text of the License and Development Agreement. The Company intends to submit a FOIA Confidential Treatment Request with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 for certain portions of the License and Development Agreement. The License and Development Agreement, in redacted form subject to such confidential treatment request, will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

The Company expects the closing of the transactions contemplated by the Purchase Agreement to occur on or before February 28, 2018, subject to the satisfaction of the conditions described above and certain customary closing conditions.

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## Item 7.01 Regulation FD Disclosure.

On February 12, 2017, the Company issued a press release regarding the Purchase Agreement with Cerecor and the proposed License and Development Agreement with Cerecor. That press release is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

The information in Item 7.01 of this current report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall such information be incorporated by reference into any registration statement or other filing pursuant to the Securities Act of 1933, except as may be expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits.

## (d) Exhibits

99.1 Press release of Avadel Pharmaceuticals plc dated as of February 12, 2018.	99.1 Press release of Avadel Pharmaceuticals plc dated as of Fe	ebruary 12, 2018.
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## Cautionary Note Regarding Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements related to Avadel's sale of its pediatric assets to Cerecor and Avadel's ability to consummate the closing of such transaction, including the satisfaction of certain closing conditions including the delivery of certain third-party guarantees and consents, Avadel's ability to develop four new pediatric products under its license and development agreement with Cerecor, Avadel's business strategy and development plans, expected financial performance in future periods, expected timing of clinical, regulatory and commercial events, and other statements that are not historical facts. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Although we believe that the forward-looking statements contained in this report are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results will not differ materially from the expectations expressed in the forward-looking statements contained in this report. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements. Except as required by law, we specifically disclaim any obligation to update such forward-looking statements.

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## 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

Senior Vice President, General Counsel and Corporate Secretary

Date: February 12, 2018

99.1	Press release of Avadel Pharmaceuticals plc dated as of February 12, 2018.
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## Avadel Pharmaceuticals Announces Divestiture of Pediatric Business

Cerecor to acquire Avadel's pediatric assets Enters into license agreement to develop four LiquiTime™ or Micropump® products

**Dublin, Ireland – February 12, 2018** - Avadel Pharmaceuticals plc (NASDAQ: AVDL) ("Avadel" or "the Company") today announced that it has entered into an asset purchase agreement with Cerecor, Inc ("Cerecor") whereby Cerecor will acquire the Avadel pediatric portfolio. In connection with this transaction, Avadel and Cerecor will enter into a license and development agreement pursuant to which Avadel will develop up to four product formulations for Cerecor using Avadel's LiquiTime™ and Micropump® technologies. Under the asset purchase agreement, Cerecor will acquire the Company's four commercial pediatric products, Karbinal<sup>TM</sup> ER, Cefaclor for Oral Suspension, Flexichamber<sup>TM</sup> and AcipHex® Sprinkle<sup>TM</sup>, and Cerecor will assume Avadel's remaining payment obligations to Deerfield CSF, LLC, including a \$15 million note due in 2021 and its related interest payments, as well as a 15% annual royalty on net sales of the four pediatric products. The Company expects the deal to be accretive to EPS in 2018.

Mike Anderson, Avadel's Chief Executive Officer commented, "We made significant progress developing our pediatric business over the last two years. The script growth and revenue numbers were up substantially in 2017, particularly for Karbinal ER. However, after strategically evaluating our business objectives, we have made the decision to focus our efforts on expanding our urology, sleep and hospital based products. Our pediatric products align with Cerecor's objective to become a leading U.S. pediatric pharmaceutical company and with the addition of our sales team will expand their commercial footprint."

Mr. Anderson continued, "We will also enter into a license and development agreement to provide four new pediatric-focused product formulations using our Micropump and LiquiTime technologies to be selected by Cerecor. We believe they will be an excellent commercial partner and our team looks forward to working together during the development process."

Under the development agreement, Avadel expects to complete the initial bioequivalence studies within 18 months. Cerecor will reimburse Avadel for any costs associated with the development of the four products in excess of \$1 million and, upon transfer of the product formulations, will assume all remaining development costs and responsibilities associated with regulatory approval and marketing. If any products receive approval, Cerecor will pay Avadel quarterly royalties based on a percentage of net sales in the mid-single digits.

Avadel expects the transaction to close before February 28, 2018, subject to the satisfaction of certain closing conditions including the delivery of certain third-party guarantees and consents.

#### **About Avadel Pharmaceuticals plc:**

Avadel Pharmaceuticals plc (NASDAQ: AVDL) is a branded specialty pharmaceutical company that seeks to develop differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, in-licensing / acquiring new products and by utilizing its drug delivery technology; ultimately, helping patients adhere to their prescribed medical treatment and see better results. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri, United States and Lyon, France. For more information, please visit <u>www.avadel.com</u>.

Safe Harbor: This press release contains forward-looking statements, including, but not limited to, statements related to Avadel's sale of its pediatric assets to Cerecor and Avadel's ability to consummate the closing of such transaction, the accretive impact of such transaction on Avadel's results of operations, Avadel's ability to develop four new pediatric products under its development agreement with Cerecor, Avadel's business strategy and development plans, expected net sales growth of its marketed products, expected financial performance in future periods, expected timing of clinical, regulatory and commercial events, and other statements that are not historical facts. These forward-looking statements are based on Avadel's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks that Avadel's actual future financial and operating results may differ from its expectations or goals; Avadel's ability to grow net sales from existing products; the availability of coverage and adequate reimbursement and pricing from government and third-party payers and risks relating to Avadel's ability to successfully implement its business strategies; risks associated with drug development and regulatory approvals; potential delays in clinical trials, including due to enrollment rates or adverse events; risks that results from on-going or future clinical trials may be inconsistent with results from prior pre-clinical studies or clinical trials; risks in the ability to recruit, train and retain qualified personnel; competition, including potential generic competition; the ability to protect intellectual property and defend patents; regulatory obligations and oversight, including any changes in the legal and regulatory environment in which Avadel operates and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Avadel's filings and reports with the SEC. Avadel undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

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