

**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 11, 2017**

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

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 1.01 Entry into a Material Definitive Agreement.

On August 11, 2017, an indirect wholly owned subsidiary (the "Avadel Licensee") of Avadel Pharmaceuticals plc (the "Company") entered into an exclusive right of negotiation agreement (the "Exclusivity Agreement") with Serenity Pharmaceuticals, LLC ("Serenity"). Under the Exclusivity Agreement, Serenity agreed to negotiate exclusively with the Avadel Licensee regarding the proposed transaction described below (the "Proposed Transaction") until the earliest to occur of (i) 11:59 p.m. (U.S. East Coast Time) on September 7, 2017, or, under certain circumstance as described below, 11:59 p.m. (U.S. East Coast Time) on September 14, 2017 (such date, the "Expiration Date"), (ii) receipt by either party of a written notice from the other party that such other party is terminating negotiations with respect to the proposed Exclusive License Agreement (as defined below), or (iii) the date the proposed Exclusive License Agreement is executed.

If the Avadel Licensee continues to engage with Serenity in good faith negotiations relating to the Proposed Transaction and circumstances beyond the control of the parties make it unlikely that the parties will execute and deliver the Exclusive License Agreement by 11:59 p.m. on September 7, 2017, then, if at such time it is reasonable to assume that continuation of such negotiations will result in the execution and delivery by the parties of the Exclusive License Agreement by 11:59 p.m. on September 14, 2017, then the Expiration Date shall be extended to that later date.

Under the Proposed Transaction, Serenity would grant to the Avadel Licensee an exclusive license, under certain rights of Serenity in and to certain intellectual property (the "IP Rights"), to develop and commercialize the drug desmopressin acetate (the "Drug") in the United States, Canada, and their respective territories and possessions (the "Territory") for the treatment of certain medical conditions characterized by abnormalities or disorders in voiding and other urinary functions of a subject to control urination (the "Field") pursuant to a proposed exclusive license and assignment agreement in substantial form and substance as set forth on an exhibit to the Exclusivity Agreement (the "Exclusive License Agreement"). In addition, under the Exclusive License Agreement, Serenity would assign to the Avadel Licensee the New Drug Application for the Drug approved by the U.S. Food and Drug Administration (the "NDA"), and certain supply agreements relating to the Drug (the "Supply Agreements").

Either Serenity or the Avadel Licensee may terminate the Exclusivity Agreement at any time prior to the Expiration Date by notice to the other party; however, if Serenity receives an unsolicited offer for an alternative transaction on terms that are superior to the Proposed Transaction, Serenity will provide Avadel with the opportunity to match such offer within five (5) Business Days of being notified by Serenity of such alternative transaction.

Under the Exclusivity Agreement, the Avadel Licensee will deposit Five Million U.S. Dollars (US\$5,000,000) (the "Escrow Amount") with an escrow agent, to be held and transferred by the escrow agent as follows:

- (a) If the parties execute and deliver the Exclusive License Agreement prior to the Expiration Date, the Escrow Amount will be transferred to Serenity in partial satisfaction of any upfront payment to be made by the Avadel Licensee to Serenity under the Exclusive License Agreement.

(b) If the Exclusivity Agreement is terminated by the Avadel Licensee without Cause (as defined below with respect to such termination by the Avadel Licensee) or by Serenity with Cause (as defined below with respect to such termination by Serenity), or the parties fail to execute and deliver the Exclusive License Agreement by the Expiration Date (notwithstanding Serenity's good faith efforts to do so and provided that the Exclusive License Agreement is in substantial form and substance as set forth on the exhibit to the Exclusivity Agreement), then the Escrow Amount will be transferred to Serenity, and the Avadel Licensee will also pay to Serenity an additional amount of Five Million U.S. Dollars (US\$5,000,000). The sum of the Escrow Amount and the additional \$5,000,000 payment to be transferred by the Avadel Licensee to Serenity (*i.e.*, an aggregate of \$10,000,000) will be consideration, in part, to Serenity for granting the Avadel Licensee the exclusive negotiating rights under the Exclusivity Agreement.

(c) If the Exclusivity Agreement is terminated by the Avadel Licensee with Cause or by Serenity without Cause, then the full amount of the Escrow Amount will be returned to the Avadel Licensee; and in addition, if Serenity terminates the Exclusivity Agreement without Cause, then Serenity will pay to the Avadel Licensee the additional amount of Ten Million U.S. Dollars (US\$10,000,000), as consideration for the Avadel Licensee's time, effort, and resources to evaluate, pursue, and negotiate the Proposed Transaction.

For purposes of the Exclusivity Agreement, "Cause" means:

(i) with respect to termination by the Avadel Licensee with Cause, (a) the receipt by the Avadel Licensee of an opinion of counsel, which counsel shall be reasonably acceptable to Serenity, that the Avadel Licensee will not have freedom to commercialize the Drug in the United States as contemplated by the draft Exclusive License Agreement because of intellectual property rights held by third parties, (b) a change affecting the IP Rights, the NDA, or the Supply Agreements that would have a material and adverse effect on the contemplated commercialization by the Avadel Licensee of the Drug in the United States, (c) a material misstatement or omission by Serenity in its disclosures to the Avadel Licensee about the IP Rights, the NDA, or the Supply Agreements, (d) the bankruptcy or insolvency of Serenity, (e) the breach of Serenity's covenant to negotiate exclusively with the Avadel Licensee, or (f) Serenity does not agree to execute the Exclusive License Agreement in substantial form and substance as set forth on the exhibit to the Exclusivity Agreement by the Expiration Date (notwithstanding the Avadel Licensee's good faith effort to do so); and

(ii) with respect to termination by Serenity with Cause, (a) a material adverse change in the business, operations, or financial condition of Avadel, (b) a material misstatement or omission by the Avadel Licensee in its disclosures to Serenity about the Avadel Licensee or the Avadel Licensee's intentions with respect to the Proposed Transaction, that has a material and adverse effect on the Proposed Transaction or (c) the bankruptcy or insolvency of the Avadel Licensee.

The form of Exclusive License Agreement attached as an exhibit to the Exclusivity Agreement provides that:

- Serenity will grant the Avadel Licensee an exclusive license to commercialize, develop and manufacture the Drug for use in the Field throughout the Territory. The Avadel Licensee may sublicense the licensed rights in Canada immediately and in the U.S. beginning two years after the effective date of the license, in all cases subject to Serenity's prior written consent which may not be unreasonably withheld, conditioned, or delayed.
- The Avadel Licensee will use its commercially reasonable efforts at all times to commercialize the rights licensed to it under the Exclusive License Agreement. The Avadel Licensee is responsible for the costs associated with all regulatory activities, including development activities undertaken to support obtaining or maintaining regulatory approvals. Within 120 days of the effective date of the Exclusive License Agreement, the Avadel Licensee will provide Serenity with a plan with respect to the commercialization of the Drug in the Field in the Territory.
- Within 180 days following the effective date of the Exclusive License Agreement, the Avadel Licensee will notify Serenity of its decision to undertake development of the Drug for the "Nocturia Indication" (*i.e.*, nocturia due to nocturnal polyuria) in Canada and the PNE Indication (*i.e.*, bed-wetting) in the United States and/or Canada. Serenity will have the right to develop and commercialize the Drug for the PNE Indication in the Territory and the Nocturia Indication in Canada if the Avadel Licensee decides not to undertake such development.
- The Avadel Licensee will be required to pay Serenity an initial payment upon execution of the Exclusive License Agreement, and royalty payments based on net sales of the products in the Territory.
- The Avadel Licensee will indemnify Serenity for losses arising out of its (a) gross negligence or willful misconduct by the Avadel Licensee in connection with its performance or obligations arising under the Exclusive License Agreement, (b) any material breach of obligations, representations, warranties or covenants by the Avadel Licensee under the Exclusive License Agreement, (c) development and commercialization activities in respect of the Drug undertaken by the Avadel Licensee, (d) failure by the Avadel Licensee to comply with applicable laws, and (e) any allegation that personal injury or death, or damage to property was caused by a manufacturing defect in the Drug manufactured by the Avadel Licensee or its third-party suppliers.

- Serenity will indemnify the Avadel Licensee for losses arising out of its (a) gross negligence or willful misconduct by Serenity in connection with its performance or obligations arising under the Exclusive License Agreement, (b) any material breach of obligations, representations, warranties or covenants by Serenity under the Exclusive License Agreement, (c) development and commercialization activities in respect of the Drug undertaken by Serenity, and (d) failure by Serenity to comply with applicable laws.

The Exclusive License Agreement includes various other representations, warranties, covenants, indemnities and other provisions customary for transactions of this nature.

The foregoing summary of the Exclusivity Agreement, including the description of the form of Exclusive License Agreement attached thereto as an exhibit, does not purport to be complete and is subject to, and qualified in its entirety by, the Exclusivity Agreement, and the form of Exclusive License Agreement attached thereto as an exhibit. The Avadel Licensee 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, as amended, for certain portions of the form of Exclusive License Agreement attached as an exhibit to the Exclusivity Agreement. The Exclusivity Agreement, with the form of Exclusive License Agreement attached as an exhibit and subject to confidential treatment, will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2017.

Item 7.01 Regulation FD Disclosure.

On August 17, 2017, the Company issued a press release regarding the Exclusivity Agreement with Serenity. 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.

Forward-Looking Statements

This Current Report on Form 8-K 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. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements 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 of our research, development and commercialization activities and our results of operations will not differ materially from our expectations. These risks include the following: (i) inability to finalize terms or otherwise fail to meet expectations regarding the timing and completion of the definitive license agreement with Serenity under circumstances requiring us to pay a termination fee of \$10,000,000 to Serenity; (ii) the amount of the costs, fees, expenses and charges related to the negotiation of a definitive license agreement; (iii) risks related to the need for management to divert attention from the Company's ongoing business operations due to the negotiation of the definitive license agreement; and (iv) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2016, in particular under the captions "Forward-Looking Statements" and "Risk Factors." Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of Avadel Pharmaceuticals plc dated as of August 17, 2017

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 17, 2017

[99.1 Press release of Avadel Pharmaceuticals plc dated as of August 17, 2017](#)



Avadel Pharmaceuticals Enters into Exclusive Negotiations with Serenity Pharmaceuticals for Noctiva™

Dublin, Ireland – August 17, 2017 – Avadel Pharmaceuticals plc (NASDAQ: AVDL) ("Avadel"), today announced that it has entered into an agreement for the right to exclusively negotiate with Serenity Pharmaceuticals, LLC ("Serenity"), for the sole rights to commercialize and further develop Noctiva in the United States and Canada.

Noctiva is a proprietary low-dose formulation of, and delivery system for, the drug desmopressin acetate. It was specifically developed to meet the needs of nocturia patients and was approved by the U.S. Food and Drug Administration ("FDA") on March 3, 2017. Noctiva is the first and only drug approved for the treatment of nocturia due to nocturnal polyuria in adults ages 18 and over who awaken two or more times per night to void. Nocturia is a condition that affects as many as 40 million adults in the United States¹. Noctiva is a metered dose intranasal formulation administered as a single spray in one nostril 30 minutes before bedtime and is approved in two dose forms of 0.83 mcg and 1.66 mcg (Full Prescribing Information available here²).

The exclusive negotiation period is expected to close on or before September 7, 2017. If Avadel terminates negotiations without cause, Avadel must pay \$10 million to Serenity; and if Serenity terminates negotiations without cause, Serenity must pay \$10 million to Avadel.

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (NASDAQ: AVDL) is a specialty pharmaceutical company that seeks to commercialize differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, by utilizing its proprietary drug delivery technology and in-licensing / acquiring new products; 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 and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: *This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Avadel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: (i) inability to finalize terms or otherwise fail to meet expectations regarding the timing and completion of the definitive license agreement with Serenity under circumstances requiring us to pay a termination fee of \$10,000,000 to Serenity; (ii) the amount of the costs, fees, expenses and charges related to the negotiation of a definitive license agreement; (iii) risks related to the need for management to divert attention from the Company's ongoing business operations due to the negotiation of the definitive license agreement; and (iv) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2016 (all of which filings are also available on the Company's website), in particular under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®, Vazculep® and Akovaz® products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; and our dependence on key personnel to execute our business plan. Avadel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.*

Contacts: **Michael F. Kanan**
 Chief Financial Officer
 Phone: (636) 449-1844
 E-mail: mkanan@avadel.com

Lauren Stival
 Sr. Director, Investor Relations and Corporate Communications
 Phone: (636) 449-5866
 Email: lstival@avadel.com

1Sources: (1) US census data 2016 estimates (2) Lee, L. K., et al. "Potential benefits of diagnosis and treatment..." International journal of clinical practice 70.1 (2016): 66-81.

2 https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201656lbl.pdf