
**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): **September 1, 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.

License Agreement

On September 1, 2017, Avadel Specialty Pharmaceuticals, LLC (the "Avadel Licensee"), an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc (the "Company"), entered into an Exclusive License and Assignment Agreement (the "License Agreement") with Serenity Pharmaceuticals, LLC ("Serenity"). The License Agreement is subject to review by the U. S. Government under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") and will not become effective until the expiration of any applicable waiting period thereunder.

Under the terms of the License Agreement, Serenity granted 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"). In addition, under the License Agreement, Serenity granted to the Avadel Licensee certain rights of Serenity in 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 License Agreement further provides that:

- 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, 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 to commercialize the rights licensed to it under the 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 following the effective date of the 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 License Agreement, the Avadel Licensee will notify Serenity of its decision to undertake development of the Drug for the "Nocturia Indication" (*i.e.*, adult night-time non-incontinent urination) 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 Nocturia Indication in Canada and the PNE Indication in the Territory if the Avadel Licensee decides not to undertake such development.
 - The Avadel Licensee will pay Serenity an up-front payment of \$50 million upon the effective date of the License Agreement. Pursuant to the exclusive right of negotiation agreement (the "Exclusivity Agreement"), dated as of August 11, 2017 and amended on September 1, 2017 as described below, the full amount of such up-front payment will be held in escrow pending such effective date. The Avadel Licensee will also pay Serenity \$20 million when the Drug first becomes available for commercial sale.
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- Serenity is eligible to receive milestone payments as follows: up to \$40 million (the "Cumulative Sales Milestone Payments") in the aggregate based on achievement of cumulative sales milestones of \$50 million to \$200 million and up to \$180 million in the aggregate based on achievement of 12-month sales milestones of \$300 million to \$1.5 billion. Upon a change in control, Serenity will be eligible to receive a payment in the low to mid-double digit millions, reduced by portions of any Cumulative Sales Milestone Payments previously paid. In addition, Serenity is eligible to receive royalties in a tiered mid-double digit range, subject to adjustment in certain circumstances.
- The Avadel Licensee will indemnify Serenity for losses arising out of (a) gross negligence or willful misconduct by the Avadel Licensee in connection with its performance or obligations arising under the License Agreement, (b) any material breach of obligations, representations, warranties or covenants by the Avadel Licensee under the 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 any damage to any 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 (a) gross negligence or willful misconduct by Serenity in connection with its performance or obligations arising under the License Agreement, (b) any material breach of obligations, representations, warranties or covenants by Serenity under the 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 License Agreement includes various other representations, warranties, covenants, indemnities and other provisions customary for similar transactions.

The foregoing summary of the License Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the complete text of the License 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 Agreement. The License Agreement, in redacted form subject to such confidential treatment request, will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2017.

Amendment to Exclusivity Agreement

On September 1, 2017, the Avadel Licensee and Serenity amended the Exclusivity Agreement. The Exclusivity Agreement was described in Item 1.01 of the Company's Form 8-K filed August 17, 2017. Under the amendment, the \$5,000,000 previously deposited into escrow by the Avadel Licensee will continue to be held in escrow and the Avadel Licensee will deposit into escrow an additional \$47,000,000. Upon the expiration of the HSR Act waiting period, as certified to the escrow agent by T.R. Winston & Co., LLC (financial advisor to Serenity), and the resulting effectiveness of the License Agreement, \$50,000,000 of the aggregate of \$52,000,000 in escrow will be used to pay the up-front payment to Serenity due upon such effectiveness (as described above in this current report on Form 8-K) and \$2,000,000 will be paid to Serenity as a reimbursement of its costs and expenses of the transaction.

The foregoing summary of the amendment to the Exclusivity Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the complete text of the amendment to the Exclusivity Agreement. The amendment to the Exclusivity Agreement 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 September 5, 2017, the Company issued a press release regarding the License 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 Exhibits 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 may include 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 as a result 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 the results contemplated in such forward-looking statements. These risks include the following: (i) our internal analyses may overstate the market opportunity in the United States and Canada for the drug desmopressin acetate (the "**Drug**"), which we have licensed from Serenity Pharmaceuticals, LLC, or we may not effectively exploit such market opportunity; (ii) significant safety or drug interaction problems could arise with respect to the Drug; (iii) we may not successfully increase awareness of nocturia and the potential benefits of the Drug; (iv) we may encounter problems with the manufacture or supply of the Drug; (v) patents and proprietary rights associated with the Drug may not provide adequate protection; (vi) our costs to complete the commercialization of the Drug could be more than planned and/or may not provide the intended positive financial results; (vii) the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (viii) 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," 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; 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. Except as may be required by law, we disclaim any obligation to publicly update any 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 September 5, 2017
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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
Phillandas T. Thompson
Senior Vice President, General Counsel and Corporate Secretary

Date: September 5, 2017

99.1 Press release of Avadel Pharmaceuticals plc dated as of September 5, 2017



Avadel Pharmaceuticals Enters into Exclusive License Agreement for Noctiva™

*Noctiva is the only FDA-approved product indicated for
the treatment of nocturia*

Dublin, Ireland – September 5, 2017 – Avadel Pharmaceuticals plc (NASDAQ: AVDL) ("Avadel"), today announced that it has entered into a license agreement with Serenity Pharmaceuticals, LLC ("Serenity"). The agreement grants Avadel the sole right to commercialize and further develop Noctiva in the United States and Canada. Noctiva is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected intranasal delivery system. It is the first and only product approved by the U.S. Food and Drug Administration ("FDA") for the treatment of nocturia due to nocturnal polyuria.

Key Highlights:

- **Deal Includes \$50 million upfront payment; funded by cash on hand, and a near term expected improvement in the Company's effective tax rate.**
- **Current nocturia-treated patient pool estimated at over \$2B with no FDA approved treatment options until now, and market growth potential¹.**
- **Long-term growth opportunity with current intellectual property through mid-2030, and potential opportunities to extend patent life.**
- **Balance sheet remains strong with no bank debt, and adequate cash to fund ongoing operations, including completion of the Company's REST-ON Phase III trial.**

Nocturia is a medical condition that affects approximately 40 million² people in the United States, and represents a high unmet medical need. Nocturia results in frequent nighttime urination, which may prevent patients from experiencing a normal, restful sleep cycle. Nocturia is associated with a number of co-morbidities and health-related consequences, including an increase in the risk of nighttime falls and fractures, loss of sleep, decreased work productivity, impaired daytime functioning and compromised quality of life³.

¹ Data on file.

² Sources: (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.

³ Data on file.



Mike Anderson, Avadel's Chief Executive Officer, said, "Licensing Noctiva is an important step in our strategic growth plan and positions Avadel as a fully-integrated specialty pharmaceutical company, with a profitable base and a significant ongoing Phase III trial. Noctiva is the first and only FDA approved product to treat nocturia due to nocturnal polyuria, and aligns with our mission of offering patients unique and differentiated branded products. Noctiva has the potential to deliver significant value to Avadel, the large, underserved patient population who suffer from nocturia and our shareholders."

Dr. Samuel Herschkowitz, Chief Executive Officer of Serenity, said, "Approximately \$200 million has been invested in order to develop and gain FDA approval for Noctiva, which is the first drug therapy shown to be safe and effective for the treatment of nocturia. The clinical program for Noctiva included four Phase 3 studies and two long-term safety trials and demonstrated significant reductions in the mean number of nocturic episodes, and improved quality of life⁴. We believe Avadel is the right partner with the experience, capability and commitment to bring Noctiva to market for the benefit of patients, providers and payors."

Terms of the final agreement, which can be found in detail on Avadel's 8-K filed with the S.E.C. on September 5, 2017, include an upfront payment of \$50 million, \$20 million due at the earlier of full scale commercial launch or June 30, 2018, performance-based milestones tied to specific Noctiva net sales thresholds and a tiered royalty rate structure based upon achievement of annual net sales. As a result of the licensing agreement, the Company expects an improvement in its effective tax rate, as expenses associated with the launch will partially offset U.S. taxable income. Avadel's strong balance sheet, with \$173 million in cash and marketable securities and no bank debt at June 30, 2017, means the Company is able to self-fund the licensing acquisition of Noctiva and subsequent near-term commercialization plans.

The transaction is set to close upon expiration of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. T.R. Winston & Company, LLC, served as financial and strategic advisor to Serenity.

Conference Call:

Avadel will host a conference call and live audio webcast on Wednesday, September 6, 2017 at 8:30 am EDT to discuss this transaction. Interested parties may access the conference call by dialing (844) 388-0559 (U.S. & Canada) or (216) 562-0393 (International) and entering Conference ID# 79911607. The live audio webcast and slide presentation may be accessed via the Investors section of the Avadel Pharmaceuticals website at www.avadel.com. A replay of the webcast will be available on the website for 90 days.

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.

⁴ New Drug Application for Noctiva. Data on file.

**About Noctiva™:**

Noctiva is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Noctiva™ is a preservative-free intranasal formulation of desmopressin, administered as a single spray in one nostril 30 minutes before bedtime, and is approved in two dosage forms of 0.83 mcg and 1.66 mcg. (Full Prescribing Information available [here](#)).

Important Safety Information and Indication for Noctiva (desmopressin acetate)**WARNING: HYPONATREMIA:**

- Noctiva can cause hyponatremia, which may be life-threatening if severe.
- Noctiva is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, with illnesses that cause fluid or electrolyte imbalances, or those using loop diuretics or systemic or inhaled glucocorticoids.
- Ensure serum sodium is normal before starting or resuming Noctiva. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age or older and in patients at increased risk of hyponatremia.
- If hyponatremia occurs, Noctiva may need to be temporarily or permanently discontinued.

Noctiva should not be used in patients with symptomatic congestive heart failure or uncontrolled hypertension because fluid retention can worsen these underlying conditions. Use of Noctiva should be discontinued temporarily in patients with certain nasal conditions such as colds or allergies until those conditions have resolved.



Noctiva is also not recommended for the treatment of nocturia in pregnant women. Nocturia is usually related to normal physiologic changes in pregnancy that do not require treatment with Noctiva. Noctiva should not be used in children.

The most common side effects of Noctiva in clinical trials included nasal discomfort, cold symptoms (nasopharyngitis), nasal congestion, sneezing, high or increased blood pressure, back pain, nose bleeds, bronchitis and dizziness.

Safe Harbor: *This press release may include 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," "potentially," "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 as a result 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 the results contemplated in such forward-looking statements. These risks include the following: (i) our internal analyses may overstate the market opportunity in the United States and Canada for the drug desmopressin acetate (the "Drug"), which we have licensed from Serenity Pharmaceuticals, LLC, or we may not effectively exploit such market opportunity; (ii) significant safety or drug interaction problems could arise with respect to the Drug; (iii) we may not successfully increase awareness of nocturia and the potential benefits of the Drug; (iv) we may encounter problems with the manufacture or supply of the Drug; (v) patents and proprietary rights associated with the Drug may not provide adequate protection; (vi) our costs to complete the commercialization of the Drug could be more than planned and/or may not provide the intended positive financial results; (vii) the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (viii) 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," 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; 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. Except as may be required by law, we disclaim any obligation to publicly update any forward-looking statements to reflect events after the date of this press release.*

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