

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 5, 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 7.01 Regulation FD Disclosure.**

On or about September 5, 2017, Avadel Pharmaceuticals plc (the "Company") posted on its website (at <http://Investors.Avadel.com>) a slide presentation intended to be used in connection with an investor conference call on September 6, 2017. That slide presentation is furnished as Exhibit 99.1 to this current report on Form 8-K.

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 Slide Presentation of Avadel Pharmaceuticals plc dated as of September 6, 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: September 5, 2017

---





Avadel Pharmaceuticals plc

Noctiva™ Investor Call

September 6, 2017

September 6, 2017

---

*Safe Harbor: This investor slide presentation 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 these slides are presented. 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 investor slide presentation.*



*We strive to commercialize unique and differentiated products that address unmet medical needs in targeted specialty patient populations.*

**2012**

- Acquired Éclat Pharmaceuticals & its pipeline of Unapproved Marketed Drugs (UMD) products
- Departure from contract drug delivery focus

**2013 - 2014**

- FDA approved
- Bloxiverz®
  - Vazculep®

**2016**

- FDA approved Akovaz®
- Acquired FSC Pediatrics
- Initiated REST-ON Phase III Trial

**2017**

- Reincorporated in Ireland
- Noctiva™

September 6, 2017







- First & Only FDA-Approved Treatment for nocturia due to nocturnal polyuria*
- An estimated 40 million Americans suffer from nocturia\**
- Less than 10% patients are being treated\**

\* Data on file  
For full prescribing information please see our appendix

September 6, 2017

4





*Noctiva is a unique, patent-protected specialty product that diversifies our revenue streams, reduces dependence on branded generics and will deliver value to Avadel investors, employees, health care professionals and most importantly - patients.*



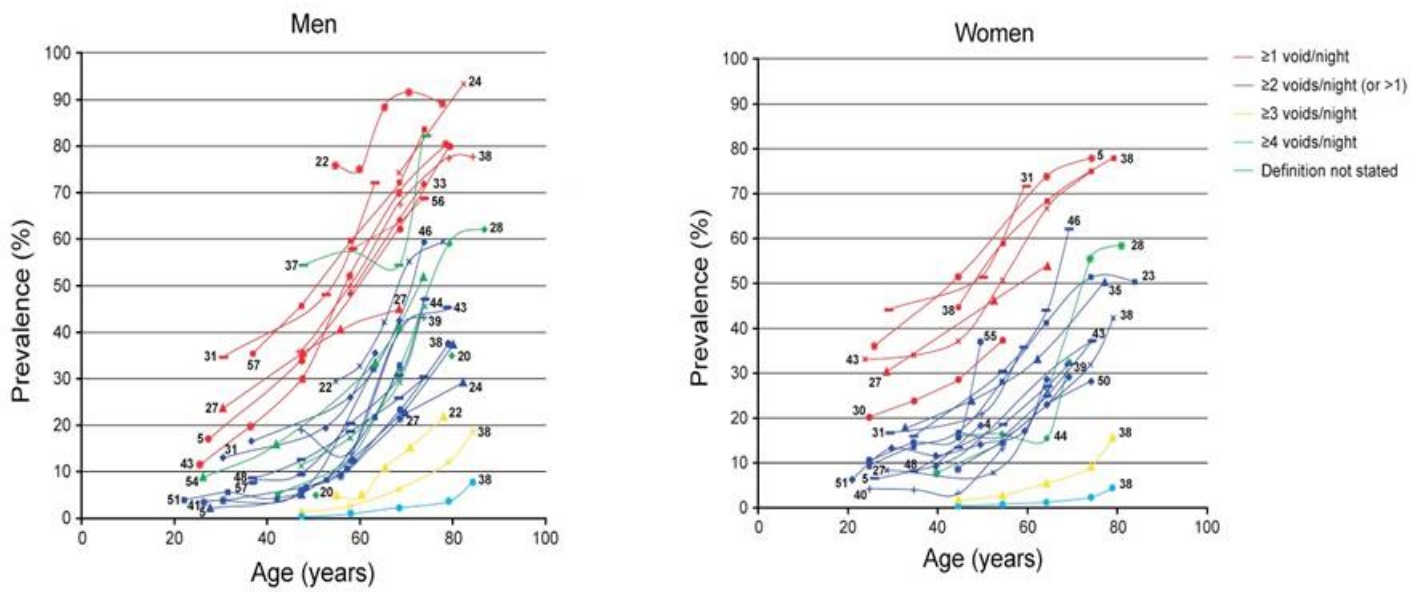
September 6, 2017

- Nocturia is an under recognized significant medical condition with substantive consequences, morbidities and diminished quality of life
- In clinical practice, nocturia is often treated ineffectively
- Patients & healthcare providers recognize pressing need for a safe & clinically meaningful therapy



September 6, 2017





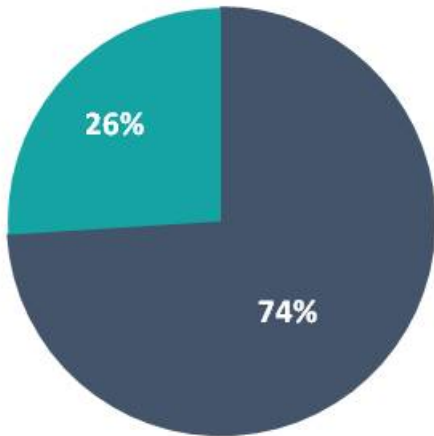
Bosch JLHR and Weiss JP: The prevalence and causes of nocturia. J Urol 184: Aug 2010

September 6, 2017

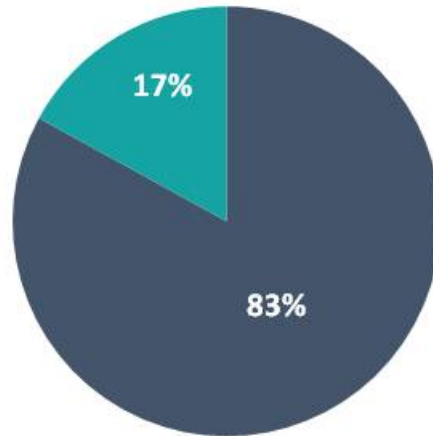
# Nocturia: Nocturnal Polyuria in Majority of Patients



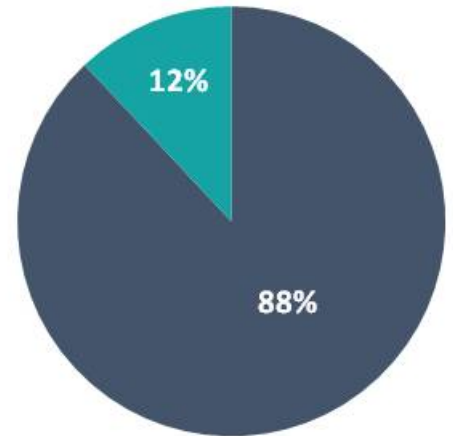
Europe<sup>1</sup>  
n=845



Japan<sup>2</sup>  
n=41\*



USA<sup>3</sup>  
n=934



■ NP   ■ Without NP

\*Males only

<sup>1</sup>Abrams et al. *NeuroUrol Urodyn* 2004;23:466. Abstract 48

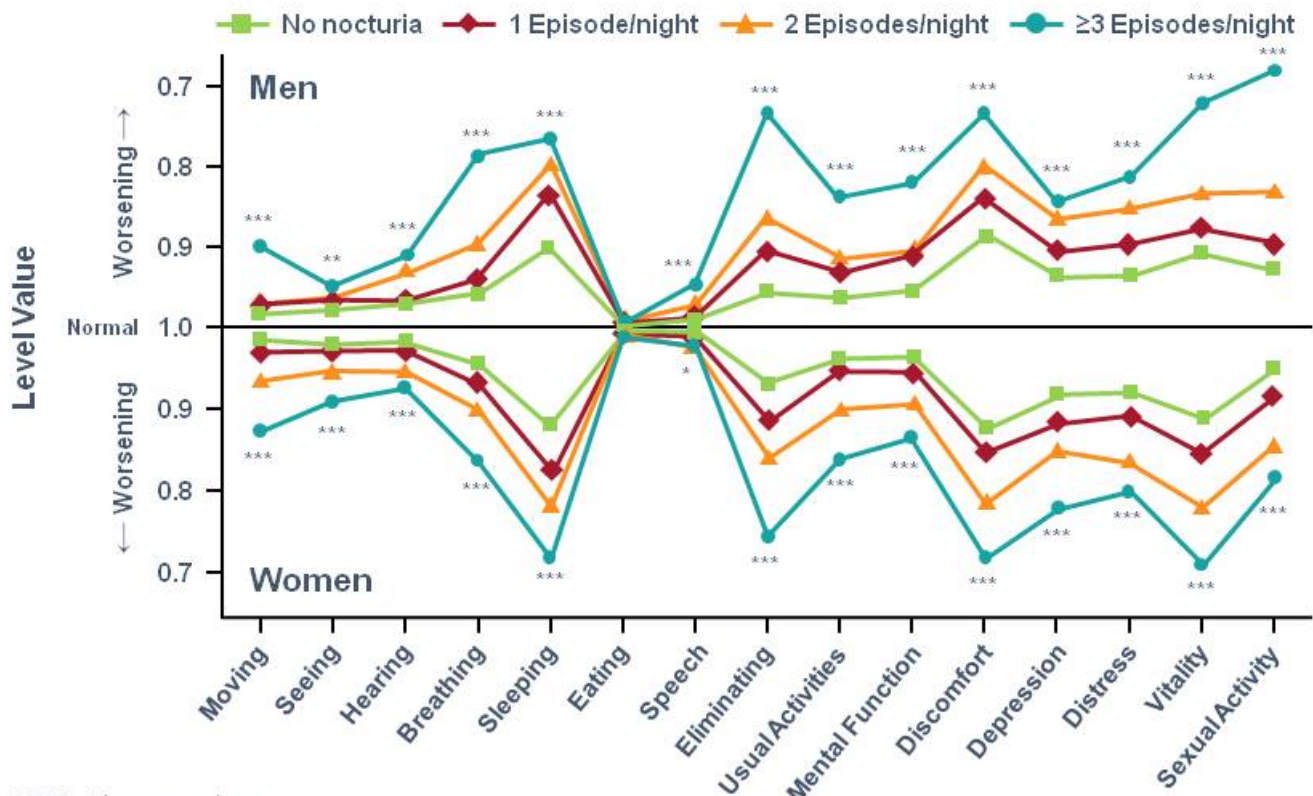
<sup>2</sup>Chang et al. *Urology* 2006;67:541-544.

<sup>3</sup>Weiss et al. *J Urol* 2009;181:538

September 6, 2017



# Nocturia: Quality of Life



n=3597 Finnish women and men

\*p < 0.05; \*\*p < 0.01; \*\*\*p < 0.001 (test for trend)

Tikkinen et al. *Eur Urol* 2010;57:488-496. 15D instrument: Sintonen. *Ann Med* 2001;33:328-336

September 6, 2017

## Nocturia: Severity & Bothersomeness

Nocturia episodes	Bother			
	None %	Small %	Moderate %	Major %
One	52.2	41.1	5.9	0.7
Two	29.3	53.8	13.9	3.1
Three	17.4	26.7	41.9	14.0
Four or more	11.3	7.0	46	35.7

(N=3,474)

Baseline number of nocturic episodes was 3.1



## Nocturia: Falls in Elderly Patients

- 5,872 community-dwelling US men aged  $\geq 65$  years
- Primary outcome: 1-year cumulative incidence of falls with moderate/severe vs mild LUTS at baseline
- Nocturia was among the LUTS most strongly associated with falls

	2-3 Episodes/Night % RR (95% CI)	4-5 Episodes/Night % RR (95% CI)
Relative risk of at least 1 fall	5 1.05 (0.96, 1.16)	23 1.23 (1.08, 1.41)
Relative risk of at least 2 falls	11 1.11 (1.08-1.41)	42 1.42 (1.16, 1.74)

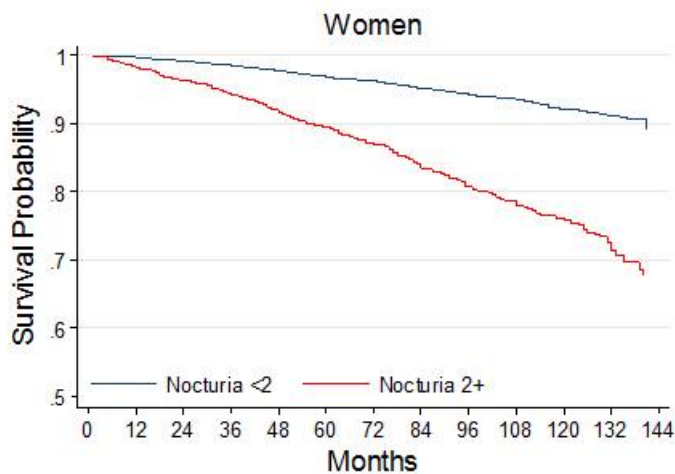
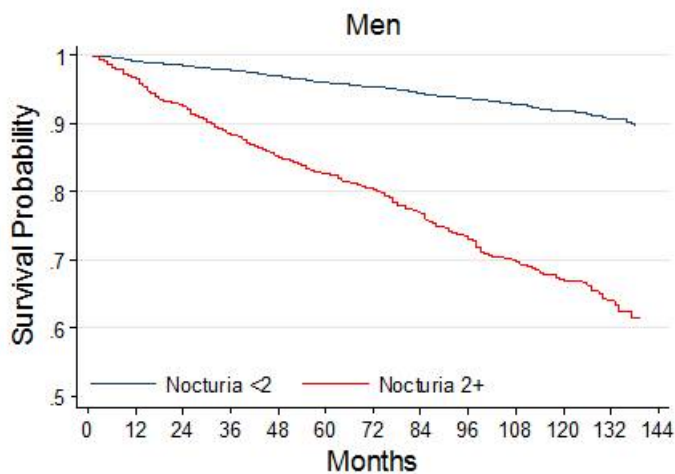
LUTS=Lower urinary tract symptom  
Parsonset al. *BJU Int* 2009;104:63-68

September 6, 2017



Age Group	Outcome	Unadjusted HR (95% CI)	Adjusted* HR (95% CI)
40–59	Diabetes mellitus	1.26 (0.75, 2.11)	1.06 (0.61, 1.85)
	Hypertension	1.19 (0.89, 1.59)	1.05 (0.77, 1.43)
	<b>CHD</b>	1.68 (1.13, 2.49)	<b>1.36 (0.87, 2.12)</b>
	Death	1.32 (0.79, 2.21)	1.31 (0.73, 2.35)
≥60	Diabetes mellitus	0.85 (0.40, 1.81)	0.74 (0.32, 1.74)
	Hypertension	0.81 (0.57, 1.16)	0.74 (0.51, 1.07)
	CHD	0.95 (0.69, 1.31)	0.92 (0.65, 1.31)
	<b>Death</b>	1.37 (1.10, 1.70)	<b>1.48 (1.15, 1.91)</b>

\*Adjusted for baseline age, BMI, use of alpha blockers, 5ARIs, and/or OAB medications; death adjusted for baseline age, BMI, use of alpha blockers, 5ARIs, and/or OAB medications, and coronary heart disease (CHD).



≥2 voids/night associated with worse survival  
in population-based sample of 7,455 men and 8,533 women



- Behavioral modification has not shown durable efficacy in clinical practice
- Drugs for OAB & BPH have marginal efficacy
- Desmopressin has been used for almost 40 years in all age groups in clinical practice
- Noctiva™ is an improved dosage formulation with sustained efficacy & minimal side effects



***Noctiva™ fills the unmet medical need for an effective, safe, and clinically meaningful treatment for nocturia***

September 6, 2017

14



- *Noctiva: a synthetic analogue of antidiuretic hormone, vasopressin. Historically, unable to reliably control duration of action, resulting in cases of hyponatremia*
- *Noctiva's low-dose of desmopressin (7x– 27x lower than existing forms) addresses historical issues – patented formulation & delivery improves bioavailability & produces predictable stable PK profile*



September 6, 2017

- *Over 2,300 patients evaluated in clinical efficacy studies*
- *Two randomized pivotal trials*
- *Statistical efficacy in terms of nocturic episodes & percentage of patients with 50% or greater reduction in nocturic episodes*
- *Average reduction of nocturic episodes in responders was 2.1*
- *Two long term safety extension studies – no instances of hyponatremia*

*Noctiva Has No Therapeutic Equivalents*

## Noctiva Launch: 4Q17 & 1H18



- Prepare the market for Noctiva
  - Disease-state educational outreach programs targeting health care professionals & targeted patients
- Best-in-class commercial organization
- Market access and Medical Science Liaison (MSL) teams
- Focused approach to health care professionals currently treating nocturia patients
  - Urologists
  - Gynecologists
  - Selective primary care physicians



September 6, 2017

17





- 
- Prevalence:** ~40 million U.S. patients with nocturia
  - Diagnosed:** Independent research & claims data estimate 3 million diagnosed & treated
  - Growing Population:** Data shows treated nocturia patients has grown 15% in last 3 years
  - Course of Treatment:** Most prescribed drugs to treat nocturia are Overactive Bladder (OAB), Benign Prostatic Hyperplasia (BPH) & desmopressin
    - Estimated 6 – 12 million total prescriptions (TRxs) per year
    - Current treated patient pool today estimated at >\$2 billion\*





### Summary Terms:

- \$50 million upfront payment ; \$20 million at commercial launch, or by June 30, 2018
- Up to \$220 million in sales milestone payments on net sales between \$50 - \$1.5B
- Tiered mid-double digit royalty range based on a threshold of annual net sales

### SG&A Investment

- Industry standard launch investment to commercialize Noctiva and build infrastructure

### Tax Implications

- Anticipate reduction to effective tax rate

### Adequate near-term funding to launch Noctiva & complete REST-ON Phase III Trial

- Will continue to evaluate future capital raise opportunities as needed

### Guidance

- 2017 diluted adjusted EPS guidance to be updated during Q3 earnings conference call