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 13, 2018

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)	(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**. Ž**

Item 7.01 Regulation FD Disclosure.

On February 13, 2018, Avadel Pharmaceuticals plc (the "Registrant") announced that its wholly-owned subsidiary, Avadel Finance Cayman Limited (the "Issuer"), intends to offer, subject to market and other conditions, up to $125,000,000 aggregate principal amount of exchangeable senior notes due 2023 (the "Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933. The Issuer expects to grant the initial purchasers of the Notes a 30-day option to purchase up to an additional $18,750,000 aggregate principal amount of Notes. A copy of the slide presentation that the Registrant expects to use in connection with the marketing of the offering of Notes is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this 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 purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On February 13, 2018 the Registrant issued a press release announcing the proposed offering of the Notes. The press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1		Slide Presentation, titled "Avadel Pharmaceuticals plc Corporate Presentation."
99.2		Press Release, dated February 13, 2018, titled "Avadel Pharmaceuticals Announces Proposed Exchangeable Senior Notes Offering."

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: February 13, 2018

Exhibit Index

99.1		Slide Presentation, titled "Avadel Pharmaceuticals plc Corporate Presentation."
99.2		Press Release, dated February 13, 2018, titled "Avadel Pharmaceuticals Announces Proposed Exchangeable Senior Notes Offering."

Exhibit 99.1

Avadel

Avadel Pharmaceuticals plc

Corporate Presentation
February 2018

CONFIDENTIAL

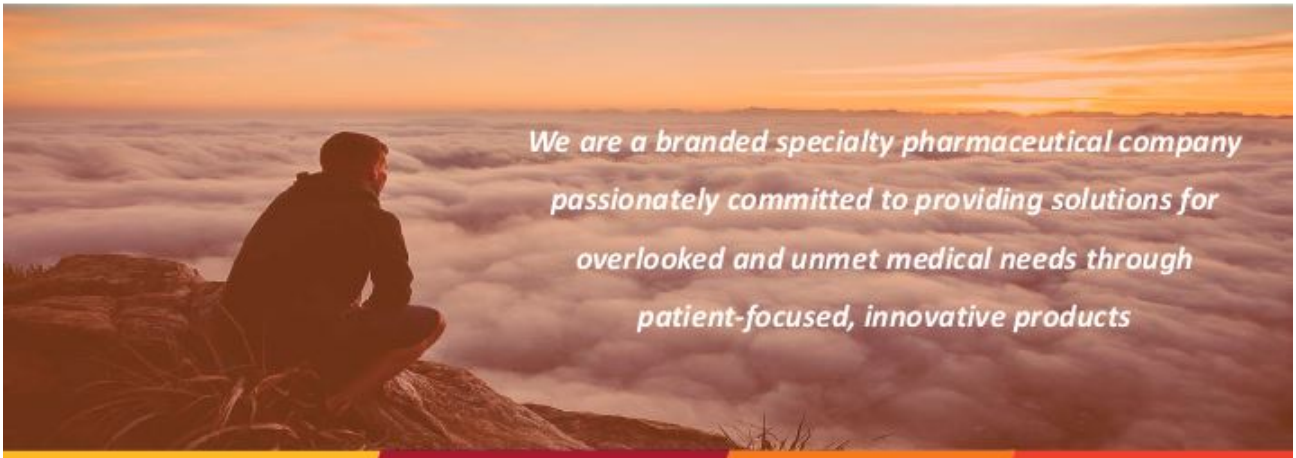
Safe Harbor

This 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," "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 forward-looking statements include 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," and our other SEC filings and the offering memorandum for this offering. 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 presentation.

We are relying on exemptions from registration under the Securities Act for offers and sales of securities that do not involve a public offering. The initial purchasers are relying on exemptions from the provisions of the Securities Act provided by Rule 144A in connection with the initial sale of the notes. The sale of the securities described herein has not been registered under the Securities Act or under the securities laws of any other jurisdiction. Unless their sale is registered, the notes may be offered only in transactions that are exempt from these securities laws. This presentation is neither an offer to sell nor a solicitation of an offer to buy securities nor shall there be any sale of securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

Avadel

THE POWER OF MEDICINE, REINVENTED



Performance	Integrity	Entrepreneurship	Collaboration
• Results-oriented • Sense of urgency • Patient-focused	• Highest ethical standards • Accountable • Quality without compromise	• Leadership • Passionate/driven • Flexible/Agile • Innovative	• Aligned/Supportive • Communication • Respectful • Inclusive

Transition to Specialty Pharma

Key Dates:

1990	– Flamel Technologies SA est. in Lyon, France with focus on drug delivery & reformulation for large pharma
2012	– Acquired Éclat Pharmaceuticals – transitioned from drug delivery to specialty pharma model
2013 - 2016	– FDA approved 3 UMD products, Bloxiverz™ (2013), Vazculep™ (2014), Akovaz™ (2016)
2016	– Acquired FSC Pediatrics
	– Initiated REST-ON Phase III Trial of FT 218 for EDS & Cataplexy
2017	– Reincorporated in Ireland
	– In-licensed Noctiva™*
2018	– Granted Orphan Drug Designation for FT 218
	– Launch of Noctiva™ in 2Q
	– Divested portfolio of pediatric products to Cerecor, Inc.

*Noctiva™ is not yet available for prescription

Recent Highlights

Profitable base business for 2017

- *Operating cash flow of $30 million nine months ended September 30, 2017*

$115 million in cash & marketable securities at September 30, 2017

REST-ON Phase III trial for FT218

- *Orphan Drug Designation for FT 218*

Noctiva™ License Acquisition (9/1/17)

- *Expected to accelerate revenue growth – launch in 2Q 2018*
- *Anticipate reduction to effective tax rate*

4th hospital product in development, expected NDA filing in 2018

- *Current market for intended indication estimated between $30 - $40 million / year*

Continued growth through internal pipeline development & selective M&A

Noctiva™ is not yet available for prescription

Noctiva™

First & Only FDA-Approved Treatment for Nocturia due to Nocturnal Polyuria

Noctiva is not yet available for prescription
For full prescribing and important safety information, please see appendix

Noctiva™: Issues & Opportunities

- Nocturia due to nocturnal polyuria causes patients to awaken 2 or more times / night to urinate
- Nocturia is an under-recognized condition with substantive consequences, morbidities & diminished quality of life[1,2,3]
- In clinical practice, nocturia is often treated ineffectively[1,2]

Noctiva™ fills unmet medical need for effective, safe, & clinically meaningful treatment for nocturia

Noctiva™ is not yet available for prescription
For full prescribing and safety information please see appendix
1.Weiss, Rev Urol. 2012 ; 14(3-4) 48-55
2. Weiss J Campbell-Walsh Urology, 2016
3. Tikkinen et al. Eur Urol 2010;57:488-496.
QoL = quality of life

Noctiva™: Overview

- *Noctiva™ is a proprietary, low-dose, intranasal formulation of desmopressin acetate, a synthetic analogue of anti-diuretic hormone, vasopressin*
- *Past formulations of desmopressin unable to reliably control anti-diuretic effect beyond hours of sleep, creating risk of hyponatremia**
- *Noctiva™'s low-dose of desmopressin (7x – 27x lower than existing forms) seeks to address historical issues by controlling duration of anti-diuretic effect*

*Two-year safety extension study showed no instances of hyponatremia**

*Data on file
Noctiva™ is not yet available for prescription
The 0.83 mcg dose of Noctiva did not meet all prespecified efficacy endpoints in clinical trials but may have a lower risk of hyponatremia
For full prescribing and important safety information please see appendix

Noctiva™: Clinical Development*

Avadel

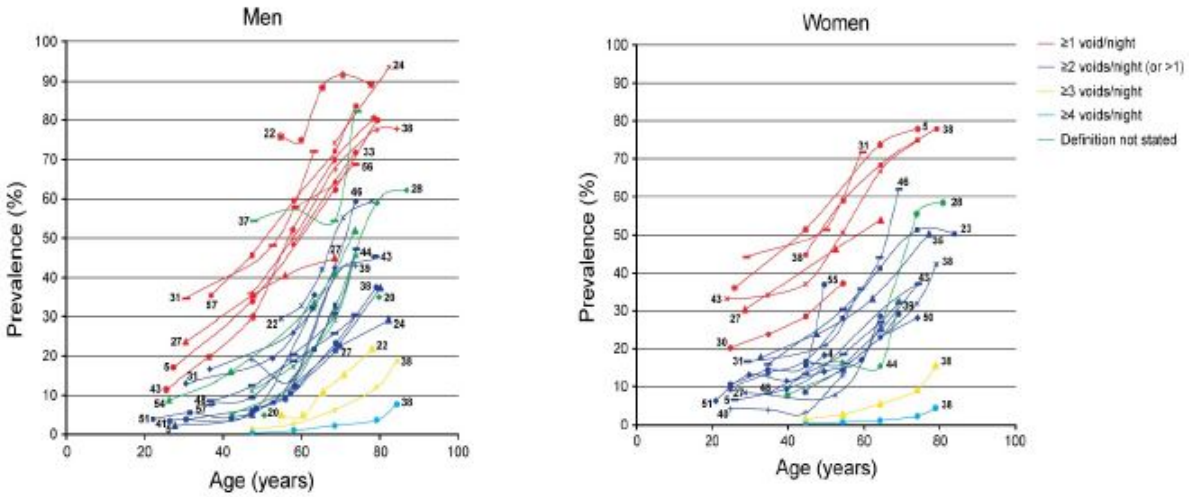
Noctiva

- *Over 2,300 patients evaluated in clinical studies*
- *Two randomized pivotal trials of 1,045 patients*
- *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

*Data on file
The 0.83 mcg dose of Noctiva did not meet all prespecified efficacy endpoints in clinical trials
Noctiva™ is not yet available for prescription
For full prescribing and safety information please see appendix

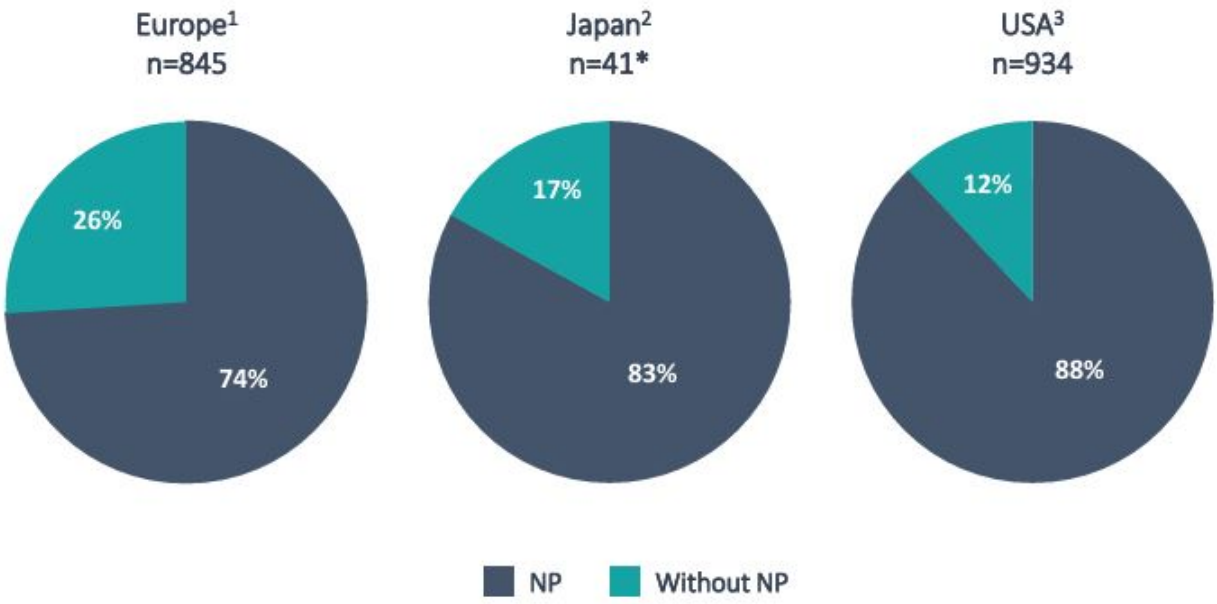
Nocturia: Prevalence in Men & Women



Prevalent condition in both men & women – increases with age

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

Nocturia: Nocturnal Polyuria in Majority of Patients



*Males only
[1]Abrams et al. *Neurourol Urodyn* 2004;23:466. Abstract 48
[2]Chang et al. *Urology* 2006;67:541-544.
[3]Weiss et al. *J Urol* 2009;181:538

Nocturia: Falls in Elderly Patients

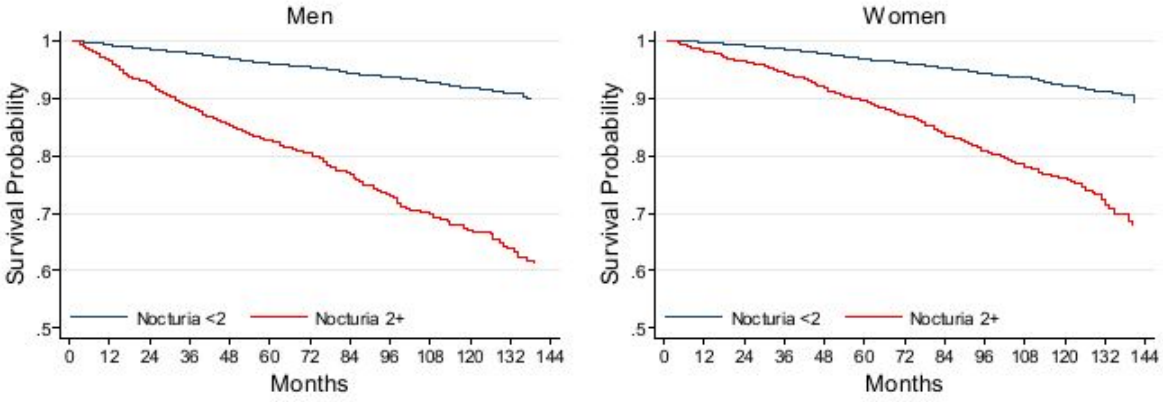
- Primary outcome: 1-year cumulative incidence of falls with moderate/severe vs mild lower urinary tract symptoms (LUTS) at baseline*
- Nocturia was among the LUTS most strongly associated with falls*

	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)

Relative risk of 1 or more falls increases with number of nocturic episodes•

*5,872 community-dwelling US men aged ≥65 years
RR = Relative risk
Parsons et al. *BJU Int* 2009;104:63-68

Nocturia: Mortality

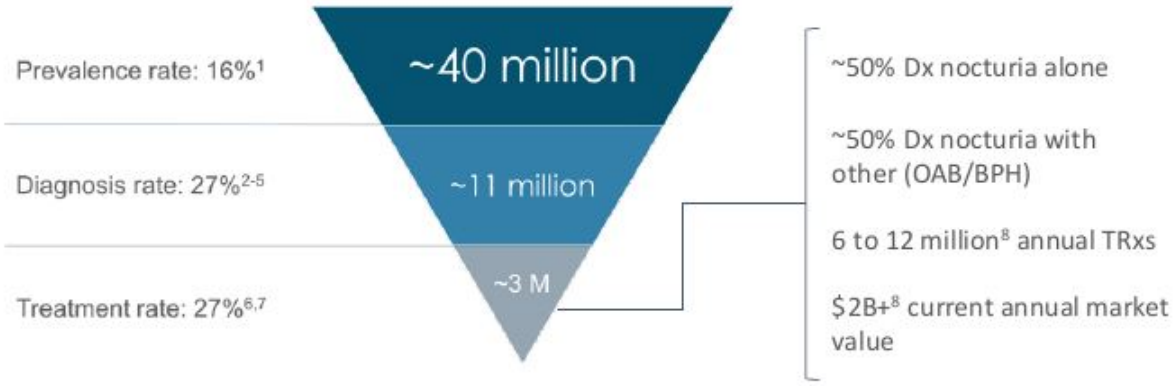


*≥2 voids/night associated with worse survival in population-based sample of 7,455 men and 8,533 women**

*US Data NHANES III

Kupelian V, Fitzgerald MP, Kaplan SA, Norgaard JP, Chiu GR, Rosen RC. Association of nocturia and mortality: results from the Third National Health and Nutrition Examination Survey. J Urol. 2011;185(2):571-577.

Nocturia: Market Overview



Attractive existing market with significant upside for market expansion

1. Bosch JLH, Weiss JP. The prevalence and causes of nocturia. J Urol. 2010;184(2):440-446.
2. QuintilesIMS Secondary Research.
3. Lee UK, Goren A, Zou KH, et al. Potential benefits of diagnosis and treatment on health outcomes among elderly people with symptoms of overactive bladder. *Int J Clin Pract*. 2016;70(1):66-81.
4. Decision Resources, *Treatment Algorithm in OAB*.
5. Vuichaud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. J Urol. 2015;22(S1):1-6.
6. Helfand BT, Evans RM, McVary KT. A comparison of the frequencies of medical therapies for overactive bladder in men and women: analysis of more than 7.2 million aging patients. Eur Urol. 2010;57(4):586-591.
7. Goldman HB, Anger JT, Bilnduy CB, et al. Real-world patterns of care for the overactive bladder syndrome in the United States. Urology. 2016;87:64-69.
8. Data on file.

Revenue Opportunity

Avadel

Specialist-focused launch

$250M-400M peak revenue opportunity

Assumes **6% to 10%** penetration of currently treated pool at peak

Expanded launch opportunity

$500M-750M+ revenue opportunity

Assumes **11% to 15+%** penetration and a 20% growth in the treated patient pool at peak

Maximizing specialist opportunity will lead to expanding treater base and building broader awareness of nocturia and Noctiva™

Noctiva™ is not yet available for prescription

Avadel

First to gain FDA approval for neostigmine, ephedrine and full-line phenylephrine

2006 FDA announced Marketed Unapproved Drugs – Compliance Policy Guide:

- Receive NDA approval – FDA will remove competing unapproved products until generic entry

2013 – 2016 Avadel received 3 NDA approvals with "UMD Strategy"

- Bloxiverz™
- Vazculep™
- Akovaz™

4th UMD in active development – NDA filing 2018

Proven cash generation strategy with >90% gross margins

Proprietary Technologies & Pipeline

Micropump®

LiquiTime™

REST-ON Phase III Trial

Micropump® Overview

Avadel

Microparticulate system that allows the development of modified and/or controlled release of solid, oral dosage formulations of drugs

Micropump® Granules:
- Drug granulate or layered neutral core
- Polymer coating
- Consists of multiple-dose system containing from 5,000 – 50,000 micro particles

Coating:
- Diffusion control
- pH independent/dependent
- Film integrity preserved during GI track transit

Validated Technology

- Allows achievement of precise pharmacokinetic profiles through extended and/or delayed release of single or combinations of drugs
- Formats include tablets, capsules, sachet, or liquids (LiquiTime™)
- Technology validated in 2006 through approval in GSK's COREG CR (Carvedilol)

Phase III clinical trial of Micropump® sodium oxybate (FT 218) initiated 2H 2016

LiquiTime™ Overview

Avadel

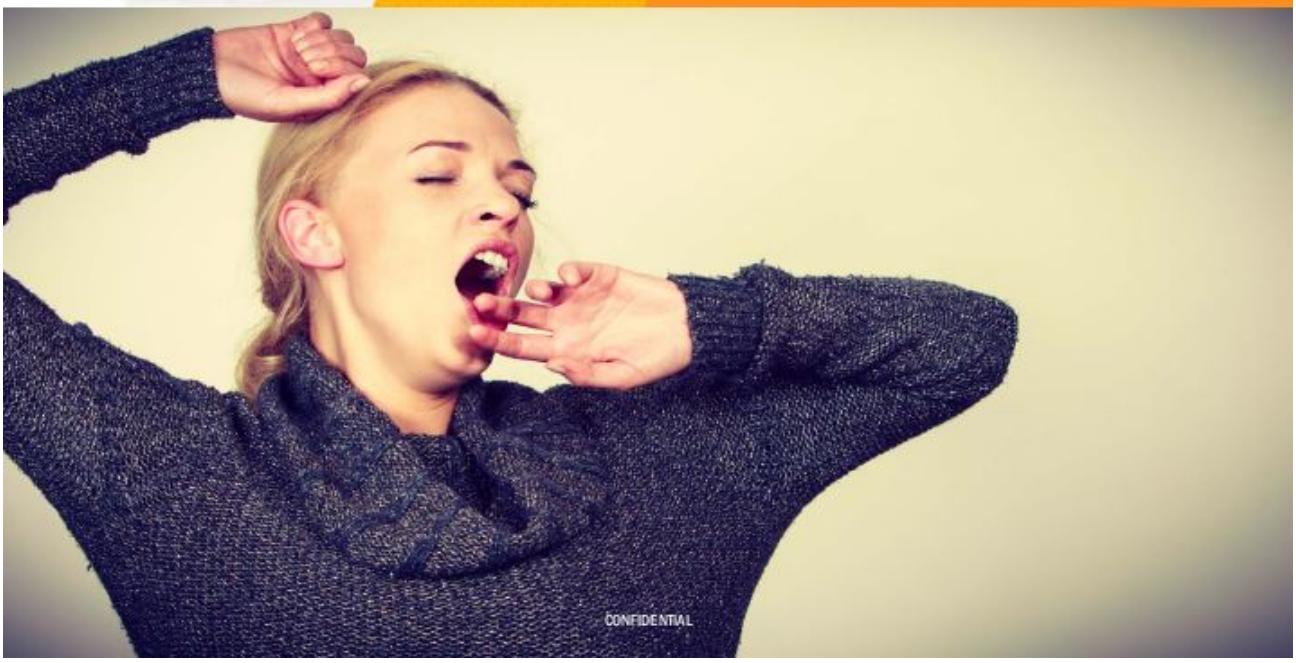
Potential Advantages

- Intended for development of modified/controlled release liquid formulations for patients having issues swallowing tablets/capsules
- Not limited to working solely with ionic drugs as with resin-complex based technologies
- Easy-to-swallow, good mouthfeel, taste-masked and dosing flexibility

Ongoing development partnerships include Perrigo for OTC cough / cold products, & undisclosed products with Cerecor, Inc.

REST-ON

REST-ON Phase III Clinical Trial



Narcolepsy Overview

Avadel

A sleep disorder, involving irregular patterns in Rapid Eye Movement (REM) sleep and significant disruptions of normal sleep/wake cycle

- Estimated ~ 200,000 Americans suffer from Narcolepsy*
- Prevalent symptoms include Excessive Daytime Sleepiness (EDS) and Cataplexy*

~ 25%

- Only 25% of people with narcolepsy have been diagnosed and are receiving treatment*

- ~13,000 diagnosed patients are treated with sodium oxybate**
- Sodium oxybate (Xyrem®) dosed 2x / night – doses totaling between 6 - 9g***
- Only drug indicated for BOTH EDS and Cataplexy***

- Xyrem® 2017 Revenue Guidance $1.18 - $1.2 B**

*Narcolepsy Network foundation http://narcolepsynetwork.org/about-narcolepsy/
**Jazz Pharmaceuticals plc 3Q 2017 Earnings Conference Call
***Xyrem prescribing information

FT218: Potential for Improved Treatment

FT218: Once-nightly formulation of sodium oxybate utilizing Avadel's proprietary extended-release Micropump® technology

Studied in 40 healthy volunteers*:

- ✓ Comparable AUC as Xyrem® on dose-for-dose basis
- ✓ Similar onset of action to Xyrem®
- ✓ Similar blood levels at hrs 7-8
- ✓ Slightly lower C-max

FT218 potential to provide:

- One single dose at bedtime
- Possible reduction of sleep disruption
- Potential for additional benefits, including improved safety

Goal: Provide 7-8 hours of restful sleep and effective relief of EDS and cataplexy with single dose of medication

*Data on file

REST-ON Phase III Trial

Avadel

Double-Blind, Randomized, Placebo-Controlled, Study to Assess Safety and Efficacy of Once Nightly Sodium Oxybate (FT218) for the Treatment of Excessive Daytime Sleepiness (EDS) and Cataplexy in Patients with Narcolepsy

Trial Design*

- 264 Patients, ages 16 +
- 55 clinical sites across US, Canada, Western Europe
- Patients must be sodium oxybate naive
- Efficacy measured by Maintenance of Wakefulness Test (MWT), Clinical Global Impression (CGI) rating of sleepiness and number of cataplexy attacks
- Efficacy assessed at doses of 6.0g , 7.5g and 9g

Progress

- 81% of all clinical sites actively screening and enrolling patients
- Active social media campaign to raise trial awareness
- US & European Patient Advisory Group (PAG)
- Additional study sites identified in US and UK

*For more details on our clinical trial, please visit www.rethinknarcolepsy.com

Intellectual Property

Product	U.S.
Noctiva™	June 2030

Technology	U.S.	Europe
Micropump®	September 2025	October 2022
LiquiTime™	April 2023	April 2023

Noctiva is not yet available for prescription

GAAP Financial Results

(in $000s, except for per share amounts)	Years Ended December 31,			Nine Months Ended September 30,	
	2016	2015	2014	2017	2016
Product sales and services	$147,222	$172,288	$12,193	$138,009	$104,858
License and research revenue	3,024	721	2,782	484	2,303
Total revenues	**150,246**	**173,009**	**14,975**	**138,493**	**107,161**
Operating expenses:					
Cost of products and services sold	13,248	11,410	3,383	12,253	10,657
Research and development	34,611	25,608	17,298	22,093	21,135
Selling, general and administrative	44,179	21,712	15,698	35,804	33,491
Intangible asset amortization	13,888	12,564	11,749	1,692	10,918
Changes in fair value of related party contingent consideration	49,285	30,957	57,491	(30,107)	52,989
Loss on early repayment of related party acquisition-related note	--	--	3,013	--	--
Restructuring costs (income)	--	--	--	3,173	--
Total	**155,211**	**102,251**	**108,632**	**44,908**	**129,190**
Operating income (loss)	(4,965)	70,758	(93,657)	93,585	(22,029)
Investment and other income	1,635	1,236	927	2,689	1,080
Interest expense	(963)	--	(5,747)	(789)	(702)
Other expense - changes in fair value of related party payable	(6,548)	(4,883)	(3,525)	2,988	(6,135)
Foreign exchange gain (loss)	1,123	10,594	11,871	(127)	(12)
Income (loss) before income taxes	(9,718)	77,705	(90,131)	98,346	(27,798)
Income tax provision (benefit)	31,558	35,907	(644)	21,830	18,212
Net income (loss) from continuing operations	(41,276)	41,798	(89,487)	76,516	(46,010)
Net income from discontinued operations	--	--	4,018	--	--
Net income (loss)	**($41,276)**	**$41,798**	**($85,469)**	**$76,516**	**($46,010)**
Earnings (loss) per share - diluted:	**($1.00)**	**$0.96**	**($2.36)**	**$1.81**	**($1.12)**

Cash Flow Summary

(in $000's)	Nine Months Ended September 30,	
Total Cash and Marketable Securities	**2017**	**2016**
Beginning Balance	154,195	144,802
Operating Cash Flows (excl tax and earnout payments)	73,258	49,636
Earnout/Royalty Payments	(29,136)	(24,227)
Income Taxes	(14,605)	(22,200)
Acquisition of Noctiva Asset	(52,139)	—
Share Repurchases	(16,707)	—
Capital Spending	(533)	(1,000)
Other	1,277	2,656
Change in Total	(38,585)	4,865
Ending Balance	115,610	149,667

Balance sheet remains strong with no bank debt and $115.6 million in cash & marketable securities

Appendix

Noctiva™ (desmopressin acetate) Boxed Warning

WARNING: HYPONATREMIA

NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest or death.

NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled Glucocorticoids.

Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.

If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.

Avadel

Please click below or visit our websites for full prescribing and safety information for our marketed products

Bloxiverz™ https://www.avadel.com/products/hospital/bloxiverz-reg-/

Vazculep ™ https://www.avadel.com/products/hospital/vazculep-reg-/

Akovaz ™ https://www.avadel.com/products/hospital/akovaz-reg-/

Noctiva™ - website coming soon

Avadel Pharmaceuticals Announces Proposed Exchangeable Senior Notes Offering

Dublin, Ireland – February 13, 2018 – Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel" or "the Company") today announced that its wholly-owned subsidiary, Avadel Finance Cayman Limited (the "Issuer"), intends to offer, subject to market and other conditions, $125,000,000 principal amount of exchangeable senior notes due 2023 (the "Notes") in a private offering (the "Offering") to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933, as amended (the "Securities Act"). In connection with the Offering, the Issuer expects to grant the initial purchasers of the Notes a 30-day option to purchase up to an additional $18,750,000 principal amount of Notes.

The Notes will be general unsecured obligations of the Issuer, and will be fully and unconditionally guaranteed by Avadel on a senior unsecured basis. Subject to satisfaction of certain conditions and during certain periods, the Notes will be exchangeable, at the option of the holders, into (i) American Depositary Shares ("ADSs"), each of which represents one ordinary share of Avadel, (ii) cash, or (iii) a combination of both ADSs and cash at the Issuer's election. The interest rate, initial exchange price and certain other terms of the Notes will be determined at the time of pricing of the Offering. The Notes will be issued in minimum denominations of $200,000 and integral multiples of $1,000 in excess thereof.

Avadel currently intends to use the net proceeds from the proposed Offering for working capital and general corporate purposes. Avadel also expects to use cash on-hand to purchase up to $20,000,000 of ADSs through the purchase of ADSs concurrently with the pricing of the proposed Offering in privately negotiated transactions effected with or through a representative of the initial purchasers or an affiliate of such representative.

The Issuer expects the purchase price per ADS repurchased in such transactions to equal the closing sale price per ADS on the date of the pricing of the Offering. These purchases of ADSs could increase, or prevent a decrease in, the market price of the ADSs concurrently with the pricing of the Notes, and could result in a higher effective exchange price for the Notes.

The Notes will be offered to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The Notes, Avadel's guarantee thereof, and the ADSs, if any, deliverable upon exchange thereof have not been and are not expected to be registered under the Securities Act or the securities laws of any other jurisdiction and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the Notes, Avadel's guarantee thereof or any ADSs deliverable upon exchange thereof, nor shall there be any sale of the Notes, Avadel's guarantee thereof or any ADSs deliverable upon exchange thereof in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful. Any offers will be made only pursuant to Rule 144A under the Securities Act, including by means of a confidential offering memorandum.

About Avadel Pharmaceuticals

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company committed to providing solutions for overlooked and unmet medical needs through patient-focused, innovative products. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France.

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, including, but not limited to statements related to the proposed Offering, including the expected principal amount and terms of the Notes, and the expected use of the net proceeds from the proposed Offering. 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: (i) risks and uncertainties relating to the proposed Offering, including: risks and uncertainties relating to market conditions; whether the Issuer will be able to consummate the proposed Offering at the anticipated size or on the anticipated terms, or at all; the satisfaction of closing conditions related to the proposed Offering; and risks related to the application of the net proceeds, if any, from the proposed Offering; (ii) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including: that consumer purchases of Noctiva are subject to risks related to reimbursement from government agencies and other third parties; that our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (the "Drug") or we may not effectively exploit such market opportunity; that significant safety or drug interaction problems could arise with respect to the Drug; that we may not successfully increase awareness of nocturia and the potential benefits of the Drug; failures by the third-party supplier to deliver sufficient quantities of the Drug would have a material adverse effect on our business; that we may be unable to adequately protect or enforce the intellectual property rights relating to the Drug; that the costs to commercialize the Drug could exceed our estimates or such costs may not provide the intended results; and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (iii) 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 technologies 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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Contacts:

Michael F. Kanan
Chief Financial Officer
Phone: (636) 449-1844
Email: mkanan@avadel.com

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