

**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): **March 16, 2017**

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

000-28508
(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))
-

Item 7.01 Regulation FD Disclosure.

On March 16, 2017, the Company posted to its website a "Corporate Presentation" containing certain information that management may use during various presentations to enhance an understanding of the Company's business and operations. A copy of this "Corporate Presentation" is attached hereto as Exhibit 99.1.

The information responsive to this Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of 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 may be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Avadel Pharmaceuticals plc Corporate Presentation

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: March 16, 2017



Avadel Pharmaceuticals plc

Corporate Presentation

March 2017

March 2017

This presentation 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: 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 the pipeline product 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 product and apply for FDA approval of such product 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; our dependence on key personnel to execute our business plan; the amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; and 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, 2015, all of which filings are also available on the Company's website. 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.

Who is Avadel?



- Established in 1990 to provide life cycle solutions to large pharma using its polymer-based drug delivery technology



- Coreg CR[®] using Micropump[®] received FDA approval (GSK partnered product)



- Acquired Éclat Pharmaceuticals and transitions to specialty pharma model

- FDA approval for Bloxiverz[®]

- FDA approval for Vazculep[®]
- Moved IP to Irish subsidiary

- FDA approval for Akovaz[®]
- Acquired FSC Pediatrics
- Phase III Trial for FT218 initiated

- Reincorporated in Ireland
- Avadel established

March 2017

2017 Outlook

- Revenue guidance of \$170 - \$200M up from \$150.2M in 2016
- Adjusted diluted EPS of \$0.20 - \$0.35 up from a loss of (\$0.06) in 2016
 - Cash flow positive
 - \$25M share buyback

Phase III Trial

- Phase III trial FT218
 - Current market size > \$1B
 - Data expected 1H 2018

Growing Product Portfolio

- 4 branded pediatric products acquired in 1Q 2016
 - 3rd branded hospital product, Akovaz[®], launched 3Q 2016
 - File NDA for AV001 in 4Q 2017
 - Actively seeking to acquire products

Strong Financials

- Revenues of \$150.2M in 2016
 - \$154.2M cash & marketable securities at 12/31/2016
 - \$60M of cash flow over last two years
 - No bank debt

March 2017

- ✓ **Generated total revenues of \$150.2 million in 2016**
- ✓ **Completed cross-border merger from France to Ireland**
- ✓ **Commenced dosing for REST-ON Phase III trial of Micropump[®] sodium oxybate (FT218)**
- ✓ **Initiated development of 4th unapproved marketed product (UMD), AV001 – NDA filing expected year end 2017**
- ✓ **Board authorized \$25 million share repurchase program**



Pipeline



Completed feasibility and PK studies for both Medusa™ exenatide and Trigger Lock™ hydromorphone, and actively seeking to out license or divest these platforms*

* Please see our appendix for more details on these technologies



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)

STILL NO GENERIC TO COREG CR

Phase III Clinical Trial of Micropump® Sodium Oxybate (FT218) Initiated 2H 2016

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



Out licensed rights to Perrigo for OTC cough / cold products, and internally conducting feasibility assessment on several Rx products

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



~ 25%



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

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

- ~12,900 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® generated between \$1.1 billion in revenue in 2016**

*Narcolepsy Network foundation <http://narcolepsynetwork.org/about-narcolepsy/>

**Jazz Pharmaceuticals plc 4Q2016 Earnings Conference Call

*** Xyrem prescribing information

FT218: Once-nightly formulation of sodium oxybate utilizing Avadel's proprietary extended-release Micropump[®] microparticle technology for oral suspension

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 a single dose of medication





REST-ON Phase III Clinical Trial

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

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Trial Design*

- 264 Patients, ages 16 +
- 50 – 60 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

Key Milestones

- First clinical sites initiated in September 2016
- First patient dosed in December 2016
- Target enrollment completion December 2017
- Data lock expected end of 1Q 2018
- NDA filing date expected in 2H 2018

*For more details, please see <https://clinicaltrials.gov/ct2/show/NCT02720744?term=flamel&rank=1>



Current Product Portfolio



Hospital Products



Pediatric Products



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



Akovaz[®] (epinephrine sulfate injection)

- Market volume ~ 7.5 million vials / year

Bloxiverz[®] (neostigmine methylsulfate injection)

- Market volume ~ 4 million vials / year



Vazculep[®] (phenylephrine hydrochloride)

- Market volume / year
1mL vial ~ 5.7 million; 5mL vial ~ 1 million; 10mL vial – 420,000

Hospital products generated \$139.5 million in revenue in 2016

For full prescribing information on these products, please see the appendix.



Karbinal.ER
(carbinoxamine maleate) extended-release
oral suspension | 4mg/5mL

CEFACLOR
For Oral Suspension, USP
125 mg/5 mL • 250 mg/5 mL • 375 mg/5 mL


AcipHex[®]
Sprinkle[™]
(rabeprazole sodium)
Delayed-Release
Capsules

flexichamber[®]
Anti-static Valved Collapsible Holding Chamber *Rx Only*

- Acquired 3 commercial stage pediatric-focused products (February 2016)
- *flexichamber[®]* launch planned for the end of 1Q 2017
- Actively seeking to acquire additional products to fold into sales force



For full prescribing information on these products, please see the appendix.

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Technology	U.S.	Europe
Micropump®	July 2027	July 2023
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026 (pending)
Medusa™	June 2031	June 2027 (pending)

Product	U.S.
Karbinal™ ER	March 2029
Flexichamber®	March 2028

Product specific IP combined with platform IP extends patent life

Non GAAP Financial Results



(in 000s)	Twelve Months Ended	
	12/31/16	12/31/15
Sales	\$ 150,246	\$ 173,009
Cost of products and services sold	12,742	11,410
Research and development expenses	34,611	25,608
Selling, general and admin expenses	44,179	21,712
Intangible asset amortization	-	-
Operating expenses	91,532	58,730
Contingent consideration payments and accruals	26,966	32,081
Operating income (loss)	31,748	82,198
Interest and other expense (net)	672	1,236
Other Expense - changes in fair value of related party payable	(3,636)	(4,414)
Income (loss) before income taxes	28,784	79,020
Income tax provision	31,373	37,290
Net income (loss)	\$ (2,589)	\$ 41,730
Diluted earnings (loss) per share	\$ (0.06)	\$ 0.96

* Reconciliations from GAAP to Non-GAAP can be found in the appendix

March 2017

Cash Flow Summary



in \$000's

	Twelve Months Ended December 31,	
	2016	2015
TOTAL Cash and Marketable Securities		
Beginning Balance	\$ 144,802	\$ 92,834
Operating Cash Flows (excl tax and earnout payments)	68,801	126,414
Tax Payments	(27,180)	(42,121)
Earnout/Royalty Payments	(30,837)	(27,897)
Capital Spending	(1,200)	(1,629)
Repayment of Debt	(277)	(5,658)
Issuance of Ordinary Shares and Warrants	440	6,990
FX	(165)	(3,508)
Other	(189)	(623)
Change in Total	9,393	51,968
Ending Balance	\$ 154,195	\$ 144,802

Balance sheet remains strong with no bank debt and \$154.2 million in cash and marketable securities

Investment Highlights

2017 Outlook

- Revenue guidance of \$170 - \$200M up from \$150.2M in 2016
 - Adjusted diluted EPS of \$0.20 - \$0.35 up from a loss of (\$0.06) in 2016
 - Cash flow positive
 - \$25M share buyback

Phase III Trial

- Phase III trial FT218
 - Current market size > \$1B
 - Data expected 1H 2018

Growing Product Portfolio

- 4 branded pediatric products acquired in 1Q 2016
 - 3rd branded hospital product, Akovaz™, launched 3Q 2016
 - File NDA for AV001 4Q
 - Actively seeking to acquire products

Strong Financials

- Revenues of \$150.2M in 2016
 - \$154.2M cash & marketable securities at 12/31/2016
 - \$60M of cash flow over last two years
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March 2017



Appendix

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GAAP to NON-GAAP Reconciliations



Twelve Months Ended December 31, 2016:

(In thousands - US\$)

	GAAP	Adjustments						Total Adjustments	NON-GAAP
		Exclude			Include				
		In tangible asset amortization	Foreign exchange (gain)/loss	Cross-border merger impacts	Purchase accounting adjustments - FSC	Contingent related party payable fair value re-measurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 147,222	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 147,222
License and research revenue	3,024	-	-	-	-	-	-	-	3,024
Total revenue	150,246	-	-	-	-	-	-	-	150,246
Cost of products and services sold	13,248	-	-	-	(506)	-	-	(506)	12,742
Research and development expenses	34,611	-	-	-	-	-	-	-	34,611
Selling, general and administrative expenses	44,179	-	-	-	-	-	-	-	44,179
Intangible asset amortization	13,888	(13,888)	-	-	-	-	-	(13,888)	-
Changes in fairvalue of related party contingent consideration	49,283	-	-	-	-	(49,283)	26,966	(22,319)	26,966
Total operating expenses	155,211	(13,888)	-	-	(506)	(49,283)	26,966	(36,713)	118,498
Operating income (loss)	(4,965)	13,888	-	-	506	49,283	(26,966)	36,713	31,748
Investment income	1,633	-	-	-	-	-	-	-	1,633
Interest Expense	(963)	-	-	-	-	-	-	-	(963)
Other Expense - changes in fair value of related party payable	(6,348)	-	-	-	-	6,348	(3,636)	2,912	(5,636)
Foreign exchange gain (loss)	1,123	-	(1,123)	-	-	-	-	(1,123)	-
Income (loss) before income taxes	(9,718)	13,888	(1,123)	-	506	55,833	(30,602)	38,502	28,784
Income tax provision	31,558	4,896	-	(6,754)	192	3,068	(1,697)	(183)	31,373
Income Tax Rate	(32.5%)	36%	-	-	36%	5%	5%	(0.3%)	(0.3%)
Net Loss	\$ (41,276)	\$ 8,902	\$ (1,123)	\$ 6,754	\$ 324	\$ 52,765	\$ (28,935)	\$ 38,687	\$ (2,589)
Net loss per share - Diluted	\$ (1.00)	\$ 0.22	\$ (0.03)	\$ 0.16	\$ 0.01	\$ 1.28	\$ (0.70)	\$ 0.94	\$ (0.06)
Weighted average number of shares outstanding - Diluted	41,248	41,248	41,248	41,248	41,248	41,248	41,248	41,248	41,248

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GAAP to NON-GAAP Reconciliations



Twelve Months Ended December 31, 2015:

(in thousands - US\$)

	GAAP	Adjustments				Total Adjustments	NON-GAAP
		Exclude		Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 172,288	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 172,288
License and research revenue	721	-	-	-	-	-	721
Total revenue	173,009	-	-	-	-	-	173,009
Cost of products and services sold	11,410	-	-	-	-	-	11,410
Research and development expenses	25,608	-	-	-	-	-	25,608
Selling, general and administrative expenses	21,712	-	-	-	-	-	21,712
Intangible asset amortization	12,564	(12,564)	-	-	-	(12,564)	-
Changes in fair value of related party contingent consideration	30,957	-	-	(30,957)	32,081	1,124	32,081
Total operating expenses	102,251	(12,564)	-	(30,957)	32,081	(11,440)	90,811
Operating income (loss)	70,758	12,564	-	30,957	(32,081)	11,440	82,198
Investment Income	1,236	-	-	-	-	-	1,236
Interest Expense	-	-	-	-	-	-	-
Other Expense - changes in fair value of related party payable	(4,883)	-	-	4,883	(4,414)	469	(4,414)
Foreign exchange gain (loss)	10,594	-	(10,594)	-	-	(10,594)	-
Income (loss) before income taxes	77,705	12,564	(10,594)	35,840	(36,495)	1,315	79,020
Income tax provision	35,907	4,397	(3,178)	1,709	(1,545)	1,383	37,290
<i>Income Tax Rate</i>	<i>46%</i>	<i>35%</i>	<i>30%</i>	<i>5%</i>	<i>4%</i>	<i>105%</i>	<i>47%</i>
Net Loss	\$ 41,798	\$ 8,167	\$ (7,416)	\$ 34,131	\$ (34,950)	\$ (68)	\$ 41,730
Net loss per share - Diluted	\$ 0.96	\$ 0.19	\$ (0.17)	\$ 0.78	\$ (0.80)	\$ -	\$ 0.96
<i>Weighted average number of shares outstanding - Diluted</i>	<i>43,619</i>	<i>43,619</i>	<i>43,619</i>	<i>43,619</i>	<i>43,619</i>	<i>43,619</i>	<i>43,619</i>

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Two pilot PK studies comparing 3 Trigger Lock hydromorphone (FT227) prototypes to comparator product, Journista® at a dose of 32mg

FT227 PK Results

- **Studied in 30 healthy volunteers**
 - Fasted condition: 16 subjects
 - Fed condition: 14 subjects
- **No safety or tolerability issue observed**
- **Bioequivalence on Cmax and AUC is achieved in fasted state**
- **Bioequivalence on AUC is achieved in fed state**
- **No Food Effect expected**

Potential to Enable

- **Sustained release Micropump® -based particles that are resistant to crushing**
- **Resistance of drug extraction through alcohol, water and other mediums**
- **Prevention of abuse by injection through use of viscosifying ingredients**
- **Preservation of the drug's bioavailability**

Data on file

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Release of the unmodified drug by diffusion, disaggregation of the depot and competition with endogenous proteins over several days



Phase Ib – exenatide (FT228) in type II diabetes mellitus (T2DM)

- Demonstrated safety up to 4 weekly administrations of 140 mcg dose in 12 T2DM patients, 30 healthy volunteers administered with escalating doses up to 140 mcg
- 1st administration lead to continuous release of exenatide observed over 14 day period with relative bioavailability close to 100%.
- All biomarkers and surrogate endpoints consistent with effective exenatide after 4 weekly administrations
- PD performance of exenatide is comparable to marketed products, Victoza® (liraglutide IR gold standard) and Bydureon® (exenatide SR), on primary (FPG and HbA1c) and secondary (body weight) therapeutic measures

Data on file

*By adjusting polymer concentration and/or ions content

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Management Team



Michael Anderson

Chief Executive Officer

- Appointed CEO in 2012
- Former CEO of Éclat Pharmaceuticals
- Former President & CEO of generics business at KV Pharmaceutical Company
- Former President & CEO of Ther-Rx

Gregory Divis

EVP, Chief Commercial Officer

- Appointed CCO in January 2017
- Former President & CEO of Lumara Health
- VP, Business Development & Lifecycle Management at Sanofi-Aventis
- VP & General Manager, UK and Ireland, for Schering-Plough

Michael Kanan

SVP, Chief Financial Officer

- Appointed in 2015
- Former VP, Finance, Corporate Controller & Chief Accounting Officer at Sigma Aldrich
- Various finance leadership roles Meritor

Phil Thompson

SVP, General Counsel

- Appointed in 2013
- VP, Legal Affairs at West-Ward Pharmaceutical Corp
- VP, General Counsel for Paddock Laboratories
- VP, Strategic Business Transactions & Assistant General Counsel at KV Pharmaceutical Co.

Dhiren D'Silva

SVP, Irish & European Operations

- Appointed in 2015
- Former Sr. Director of International Business Operations at NPS Pharmaceuticals, Inc.
- Served as Director of Business Development for Product Ventures Group at Catalent Pharma

Sandy Hatten

SVP, Quality & Regulatory

- Appointed in 2015
- Former SVP, Quality & Regulatory Compliance at Mallinckrodt plc
- VP, Quality Assurance at KV Pharmaceutical Co
- Director, Quality Assurance at Perrigo

David Monteith

VP, Research & Development

- Appointed in 2014
- Former AVP, Pharmaceutical Development for Emerging Markets at Merck & Co
- Worked at Schering-Plough in various positions from Ass. Director, Pharmaceutical Development to Sr. Director, Product Value Enhancement

Gregg Davis

VP, Business Development

- Appointed in 2015
- Previously co-founder & CBO of Flag Therapeutics, Inc.
- Former VP, Corporate Development of Patheon
- Former Director, Worldwide Business Development at GlaxoSmithKline.

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

[Bloxiverz[®]](#)
www.bloxiverz.com

[Vazculep[®]](#)
www.vazculep.com

[Akovaz[™]](#)
www.akovaz.com

[Karbinal[™] ER](#)
www.karbinaler.com

[Aciphex[®] Sprinkle[™]](#)
<http://www.aciphexsprinkle.com>

[Cefaclor](#)
<http://cefaclororal.com>

[Flexichamber[®]](#)
<http://flexichamber.com>

