UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 27, 2020

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)	(IRS Employer Identification No.)

10 Earlsfort Terrace **Dublin 2, Ireland, D02 T380** (Address of principal executive offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: +353 1 920 1000

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares*	AVDL	The Nasdaq Global Market
Ordinary Shares, nominal value $0.01 per share**	N/A	

*American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) Ordinary Share.

** Not for trading, but only in connection with the listing of American Depositary Shares on The Nasdaq Global Market.

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 April 27, 2020, Avadel Pharmaceuticals plc (the "Company") issued a press release to announce topline results from its Phase 3 REST-ON clinical trial for FT218. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The Company also updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the updated corporate presentation is furnished herewith as Exhibit 99.2 and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials furnished herewith as Exhibit 99.2.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, 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 of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

FT218 Phase 3 Clinical Trial Topline Results

On April 27, 2020, the Company announced topline results from its Phase 3 REST-ON clinical trial of FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The REST-ON trial is a randomized, double-blind, placebo-controlled study that enrolled 212 patients and was conducted in clinical sites in the United States, Canada, Western Europe and Australia. Patients who received 9g of once-nightly FT218 demonstrated a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. P-value was <0.001 for all three co-primary endpoints.

	Change from Baseline (Week 13)		FT218 Difference
	Once-nightly FT218 (9g)	Placebo	from Placebo
MWT[1]	10.82	4.69	LS Mean 6.13
CGI-I[2]	72	31.6	Odds ratio 5.56
Mean Weekly Cataplexy Attacks	-11.51	-4.86	LS Mean -6.65

1 Measured in minutes.
2 Measured by percentage of patients determined to be "much" or "very much" improved.

The Company observed the 9g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients and 3.9% of the patients who received 9g of FT218 discontinued the trial due to adverse reactions.

The Company also assessed the three co-primary endpoints in patients who received 7.5g of once-nightly FT218. Patients who received 7.5g of once-nightly FT218 also demonstrated statistically significant, clinically meaningful improvements compared to placebo for each of the three co-primary endpoints. P-value was <0.001 for all three co-primary endpoints.

	Change from Baseline (Week 13)		FT218 Difference
	Once-nightly FT218 (7.5g)	Placebo	from Placebo
MWT[1]	9.55	3.34	LS Mean 6.21
CGI-I[2]	62.6	22.8	Odds ratio 5.67
Mean Weekly Cataplexy Attacks	-9.98	-3.71	LS Mean -6.27

1 Measured in minutes.
2 Measured by percentage of patients determined to be “much” or “very much” improved.

Patients who received 6g of once-nightly FT218 also demonstrated statistically significant, clinically meaningful improvements compared to placebo for each of the three co-primary endpoints. P-value was <0.001 for all three co-primary endpoints.

	Change from Baseline (Week 13)		FT218 Difference
	Once-nightly FT218 (6g)	Placebo	from Placebo
MWT[1]	8.08	3.1	LS Mean 4.98
CGI-I[2]	40.1	6.1	Odds ratio 10.29
Mean Weekly Cataplexy Attacks	-7.42	-2.59	LS Mean -4.83

1 Measured in minutes.
2 Measured by percentage of patients determined to be “much” or “very much” improved.

Item 9.01. Exhibits

(d) Exhibits

99.1 Press release issued by the Company on April 27, 2020, furnished herewith.

99.2 Corporate presentation of Avadel Pharmaceuticals plc, dated April 27, 2020, furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

April 27, 2020

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: Corporate Secretary

Exhibit 99.1

Avadel Pharmaceuticals Announces Positive Topline Results from its Pivotal Phase 3 REST-ON Trial of Once-Nightly FT218 for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy

- - -

The primary analysis of investigational, once-nightly FT218 at 9 g demonstrated highly statistically significant (p<0.001), and clinically meaningful improvement across all three co-primary endpoints compared to placebo

- - -

Once-nightly FT218 at 9 g was generally well-tolerated with commonly known sodium oxybate adverse reactions occurring at low rates

- - -

Once-nightly FT218 at the 7.5 g and 6 g dose levels achieved highly statistically significant (p<0.001), clinically meaningful improvements across all three co-primary endpoints compared to placebo

- - -

Management is scheduled to host a conference call at 8:30 a.m. EDT today to present the topline data

DUBLIN, Ireland, April 27, 2020 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) announced today positive topline data from its pivotal Phase 3 REST-ON trial assessing the safety and efficacy of FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The REST-ON trial, under a Special Protocol Assessment agreement with the FDA, met its three co-primary efficacy endpoints at all three doses (9 g, 7.5 g, and 6 g) demonstrating highly significant, clinically meaningful improvements on the Maintenance of Wakefulness Test (MWT), Clinical Global Impression-Improvement (CGI-I) and mean weekly cataplexy attacks.

“We are excited to see these positive topline data from the REST-ON study, where all three dose levels of once-nightly FT218 demonstrated a statistically significant and clinically meaningful improvement on the measures of the two prominent symptoms of narcolepsy, as well as an improvement in overall functioning compared to placebo,” said Jordan Dubow, M.D., Chief Medical Officer of Avadel. “Once-nightly FT218 delivered a clinically meaningful response within three weeks of treatment initiation, which was sustained through each treatment period. Commonly known sodium oxybate adverse reactions occurred at low rates at the highest dose level. We think once-nightly FT218, if approved, has the potential to be a meaningful contributor to patient care. We look forward to presenting more detailed data from the REST-ON study in publications and at upcoming medical conferences.”

Greg Divis, Chief Executive Officer of Avadel, added, “The successful outcome of the REST-ON study strengthens our belief that, if approved, once-nightly FT218 has the potential to be a significant advancement for patients in the estimated $1.7 billion twice-nightly sodium oxybate market.[1] Our proprietary market research with physicians and patients informs us that there is a strong interest in a once-nightly sodium oxybate formulation. We look forward to sharing the results from the REST-ON study with the FDA and progressing toward a potential approval that would allow us to bring this important treatment to the patients who need it most. If approved, FT218 would be the first once-nightly therapy to address both excessive daytime sleepiness and cataplexy in patients with narcolepsy. We extend our appreciation to the patients, investigators, study staff, and advocacy groups who contributed to the REST-ON Phase 3 study and supported the development of this potentially life-changing treatment.”

Summary of Topline Results

Results from the 212 patient, double-blind, randomized, placebo-controlled study showed that the 9 g dose of once-nightly FT218 demonstrated a highly significant and clinically meaningful improvement compared to placebo across all three co-primary endpoints.

	Change from Baseline (Week 13)[2]		FT218 Difference	
	Once-nightly FT218 (9 g)	Placebo	from Placebo	p-value
MWT (minutes)	10.82	4.69	LS Mean 6.13	<0.001
CGI-I (% of patients much/very much improved)	72.0	31.6	Odds ratio 5.56	<0.001
Mean Weekly Cataplexy Attacks	-11.51	-4.86	LS Mean -6.65	<0.001

Overall, the 9 g dose of once-nightly FT218 was generally well-tolerated with the most commonly known adverse reactions for sodium oxybate occurring at low frequencies (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3%, enuresis 9%). The discontinuation rate due to adverse reactions at the 9 g dose of once-nightly FT218 was 3.9%.

Following the achievement of statistical significance on the three co-primary endpoints by patients on the 9 g dose, the same analyses were conducted comparing the 7.5 g dose. Following the achievement of statistical significance on the three co-primary endpoints by patients on the 7.5 g dose, the same analyses were conducted comparing the 6 g dose of once-nightly FT218 to placebo. The 7.5 g and 6 g doses also demonstrated highly statistically significant ($p<0.001$), clinically meaningful improvements compared to placebo across the three co-primary endpoints. Safety data for these doses and additional secondary endpoint data for all doses will be presented at future scientific meetings after the data becomes available.

Conference Call Details
Avadel Pharmaceuticals management will hold a conference call to discuss the positive results from the REST-ON study on Monday, April 27, 2020 at 8:30 a.m. EDT.

Dial-in Number: (877) 407-9716 (U.S. and Canada) or (201) 493-6779 (International)
Conference ID number: 13702937

A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.avadel.com. A replay of the webcast will be archived on Avadel's website for 90 days following the event.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The company conducted the REST-ON study, a double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company's primary focus is the development and potential FDA approval of FT218, which is the subject of a recently completed Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness and cataplexy. In addition, Avadel markets a portfolio of sterile injectable drugs used in the hospital setting. For more information, please visit www.avadel.com.

Cautionary Disclosure Regarding Forward-Looking Statements
This press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "look forward," "on track," "could," "would," "guidance," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof (if applicable).

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. Actual results (including, without limitation, announcement of additional data from our Phase 3 REST-ON study or any other FT218-related study, timing of filing the NDA for FT218, our ability to achieve FDA approval for FT218, and our ability to successfully commercialize FT218) may differ materially from those set forth or implied in the forward-looking statements. These forward-looking statements involved certain risks and uncertainties that are subject to change based on various factors (many of which are beyond our control) including those set forth in our 2019 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission and subsequent filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise the forward-looking statements contained in this Annual Report.

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Footnote:
1. Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020
2. CGI-I does not have a baseline endpoint

Exhibit 99.2

REST-ON

Pivotal Phase 3 Trial: Topline Results

April 27, 2020

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 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: (a) risk relating to potential negative impacts resulting from public health epidemics, such as the current coronavirus, on our employees, contractors, customers, and supply chain, as well as the global economy; (b) risks relating to our recent cost-saving actions, including risks that (i) such actions may not result in the amount of cost savings we anticipate, and (ii) such cost-saving actions may cause us to incur one-time costs in amounts greater than we anticipate; (c) risks relating to the development of our investigational "FT218" sodium oxybate product, including risks that (i) we may not have adequate capital to complete the development of FT218, we may need to obtain additional capital for such purpose, and such additional capital may not be available on attractive terms or at all, (ii) we could experience delay or failure in completing the remaining data compilation and processing steps of the Phase 3 REST-ON clinical trial, (iii) we may encounter challenges in the remaining development efforts for FT218, (iv) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218, (v) FT218 may not have the therapeutic benefits we anticipate, (vi) the commercial launch of FT218 could be delayed, (vii) FT218 may not achieve commercial acceptance, and (viii) other companies may develop competing products that may receive FDA approval before FT218; (d) risks related to the commercialization of Nouress™, including risks that (i) we delay the commercial launch Nouress or do not commercially launch Nouress at all, (ii) the current patent infringement suit alleging that Nouress infringes the intellectual property of a third party may prevent or delay our commercial launch of Nouress, (iii) we may be required to pay royalties to a third party if we commercially launch Nouress, and (iv) third parties may infringe our intellectual property covering Nouress and we may incur substantial costs to defend our intellectual property; and (e) 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, 2019, and our subsequent filings with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.

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Gregory Divis

Chief Executive Officer

REST-ON Phase 3 Study – Positive Topline Results

Once-nightly FT218 demonstrated highly statistically significant ($p<0.001$), clinically meaningful improvement compared to placebo at all three doses for all three co-primary endpoints

Once-nightly FT218 was generally well-tolerated at the highest dose with commonly known sodium oxybate adverse reactions occurring at low rates

Overall, once-nightly FT218 demonstrated statistically significant and clinically meaningful improvement within 3 weeks of treatment initiation ($p<0.001$)

Once-nightly FT218 offers an exciting opportunity targeting the estimated $1.7 billion[1] twice nightly sodium oxybate market

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[1]Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020

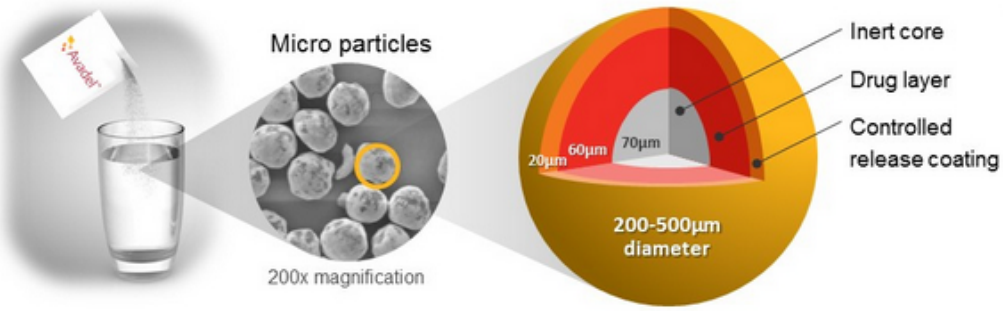
Characteristics of Narcolepsy – Serious Disease with Large Unmet Need

- Under-diagnosed, chronic, disabling neurological disease
- Characterized by excessive daytime sleepiness (EDS), cataplexy, disrupted nocturnal sleep, hypnagogic hallucinations, and sleep paralysis
- Twice-nightly sodium oxybate is the only medication that is approved for both cardinal symptoms of narcolepsy – EDS and cataplexy
- Market expected to grow significantly over period to 2027[1]

Note: 1 Narcolepsy Drugs Market by Type, Application, and Drug Formulation: Global Opportunity Analysis and Industry Forecast, 2019 - 2026 Source: Research and Markets Syndicated Report – October 2019

Leveraging Our Proprietary Micropump™ Technology – Delivering Sodium Oxybate Once Nightly

The Technology



- **Technology contains thousands of micro particles**
  - Each is a miniature delivery system
- **Microparticulate design can be adapted to each drug's specific challenges**
  - Modify coatings / thickness

The Advantages

- Delayed delivery of small molecule drugs taken orally
- Potential to: improve efficacy, reduce toxicity, improve compliance

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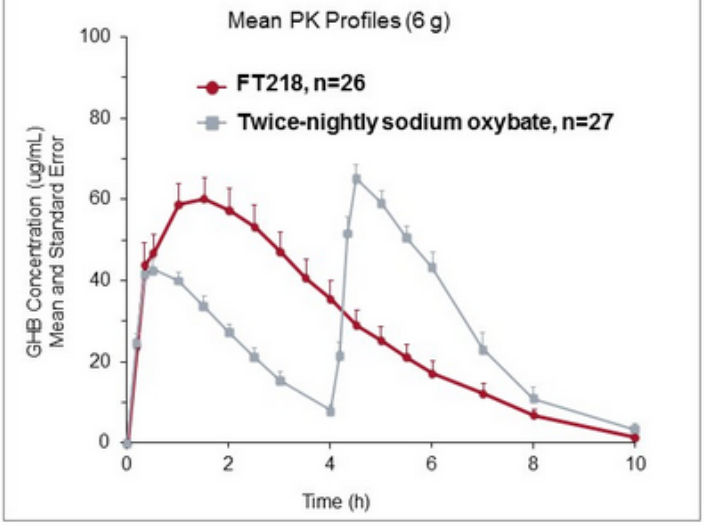
Initial Pharmacokinetic (PK) Studies Indicated Potential Advantages of Once-Nightly FT218

The Results



The Comparison to 2X Nightly

Single dose	Advantage
No middle of the night dosing	Advantage
Overall Peak concentration (Cmax) - lower	Advantage
Overall exposure (AUC) - bioequivalent to SoC	Similar
Onset time	Similar
Morning blood levels (C8H)	Similar

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Jordan Dubow, MD

Chief Medical Officer

Positive Topline Phase 3 Results Across All Doses Studied For All Co-Primary Endpoints

Once-Nightly FT218 at 9 g demonstrated a high degree of statistical significance, compared to placebo, for each of the three co-primary endpoints:

- Maintenance of Wakefulness Test (MWT) ($p<0.001$)
- Clinical Global Impression-Improvement (CGI-I) ($p<0.001$)
- Mean weekly reduction in cataplexy attacks ($p<0.001$)

FT218 7.5 g and 6 g also demonstrated statistical significance for the three co-primary endpoints, compared to placebo

FT218 was generally well-tolerated; commonly known sodium oxybate adverse reactions occurred at low rates at the highest dose (9 g)

REST-ON Phase 3 Study Design

safety and efficacy assessments

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REST-ON Phase 3 Study – Key Inclusion and Exclusion Criteria

Key Inclusion Criteria

- Age: 16 and over
- Documented diagnosis of narcolepsy (NT1 or NT2) as defined by the International Classification of Sleep Disorders-3 criteria
- Epworth Sleepiness Score (ESS): >10
- May be on stimulants, as long as stable for three weeks prior to entry
- Prior to randomization
  - Maintenance of Wakefulness Test (MWT): < 11 minutes
  - A mean of at least 8 cataplexy attacks per week during the Baseline Period

Key Exclusion Criteria

- Prior use of sodium oxybate
  - In 2018, protocol amended to allow prior use of sodium oxybate of 4.5 g or less, for less than 2 weeks and at least 1 year prior to study entry
- Current use of sodium oxybate
- Must be tapered off any medications for the treatment of cataplexy – SSRIs, SNRIs, TCAs, MAO inhibitors

REST-ON Study – Three Co-Primary Endpoints and Statistical Analysis Plan

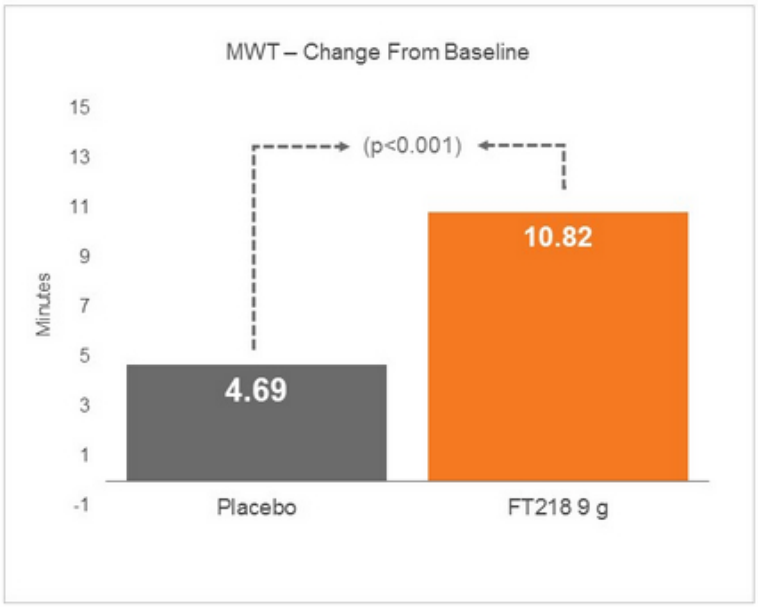
Change from baseline to endpoint for FT218 compared to placebo at 9 g for:

1. Maintenance of Wakefulness Test
2. Clinical Global Impression-Improvement (% of patients "much" or "very much" improved)
3. Mean weekly cataplexy attacks

If 9 g dose was positive, then each of the three endpoints will be assessed at the 7.5 g dose level in the same hierarchical manner

If 7.5 g dose was positive, then each of the three endpoints will be assessed at the 6 g dose level in the same hierarchical manner

FT218 9 g was Significant on the MWT Compared to Placebo



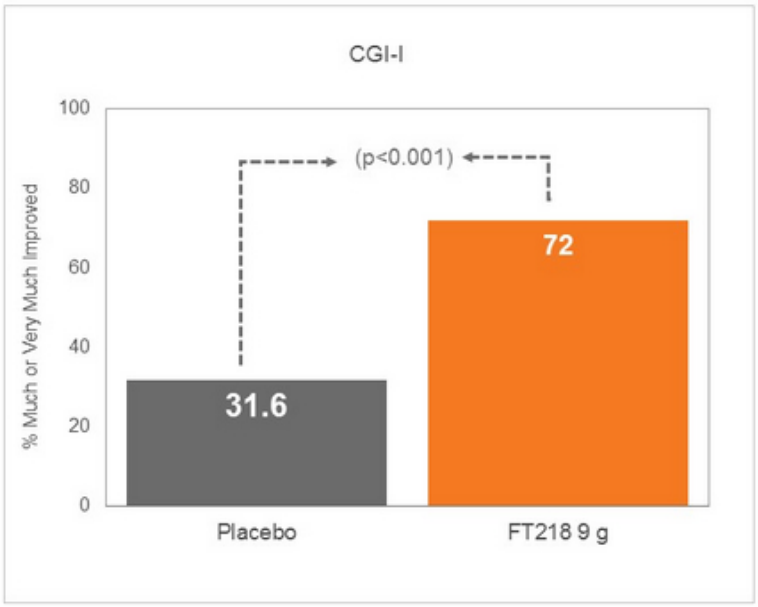
Change From Baseline in MWT

Change from Baseline to Week 13 for FT218 was 10.82

Change from Baseline to Week 13 for Placebo was 4.69

LS Mean difference between FT218 and Placebo was 6.13 (*p<0.001)*

FT218 9 g Had Significant Improvement on the Clinical Global Impression-Improvement (CGI-I) Compared to Placebo



CGI-I - Percent Much or Very Much Improved at Week 13

72.0% of patients on FT218 compared to 31.6% of patients on placebo were rated as much or very much improved at Week 13; odds ratio 5.56 *(p<0.001)*

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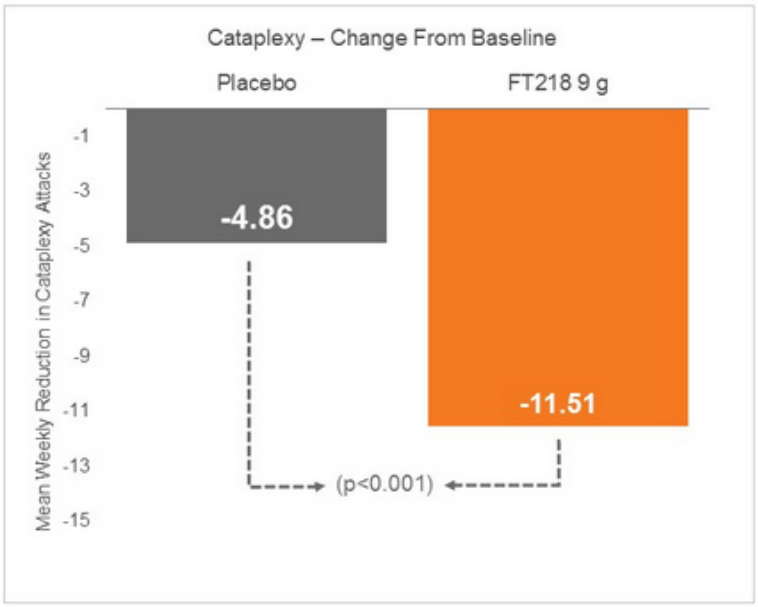
FT218 9 g Had Significant Reduction in Mean Weekly Cataplexy Attacks Compared to Placebo



Change From Baseline in Weekly Cataplexy Attacks

Change from Baseline to Week 13 for FT218 was -11.51

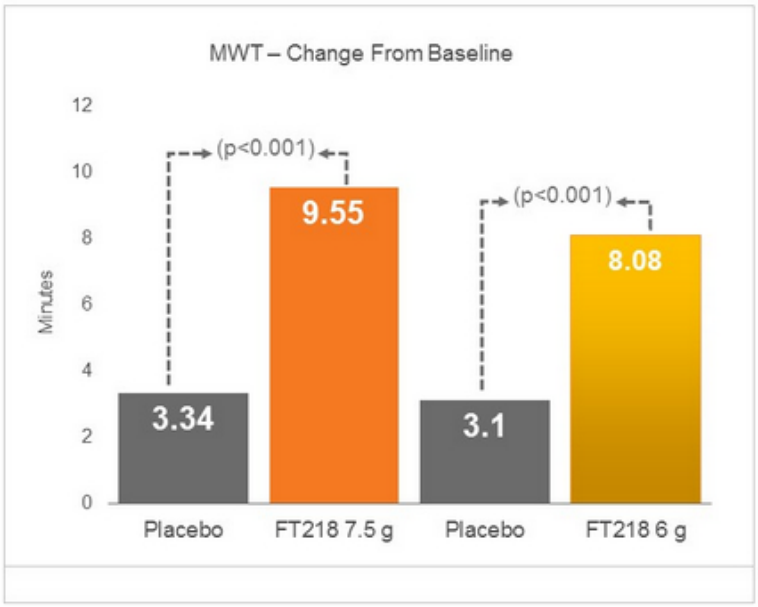
Change from Baseline to Week 13 for Placebo was -4.86

LS Mean difference between FT218 and Placebo was -6.65 *(p<0.001)*

FT218 9 g was Generally Well Tolerated with Low Rates of Commonly Reported Sodium Oxybate Adverse Reactions

	FT218 (%)	Placebo (%)
Any Adverse Drug Reaction (ADR)	35.1	5.0
Any Serious ADR	1.3	0.0
ADR Leading To Discontinuation	3.9	0.0
Common ADRs		
Nausea	1.3	1.3
Vomiting	5.2	0.0
Decreased Appetite	2.6	0
Dizziness	5.2	0.0
Somnolence	3.9	1.3
Tremor	1.3	0.0
Enuresis	9.1	0.0

FT218 7.5 g and 6 g was Significant on the MWT Compared to Placebo



Change From Baseline in MWT

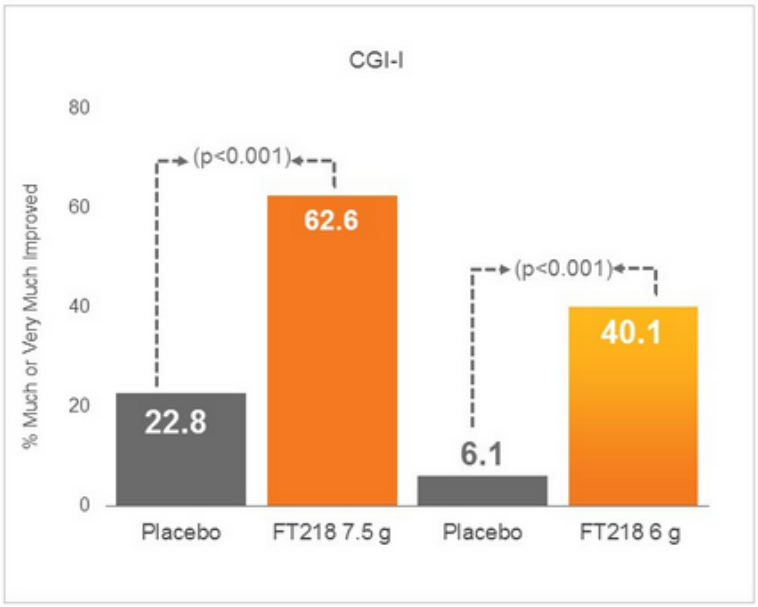
Change from Baseline to Week 8 for FT218 7.5 g was 9.55, compared to 3.34 for placebo

LS Mean difference between FT218 7.5 g and Placebo was 6.21 (p<0.001)

Change from Baseline to Week 3 for FT218 6 g was 8.08, compared to 3.1 for placebo

LS Mean difference between FT218 6 g and Placebo was 4.98 (p<0.001)

FT218 7.5 g and 6 g Had Significant Improvements on the CGI-I Compared to Placebo

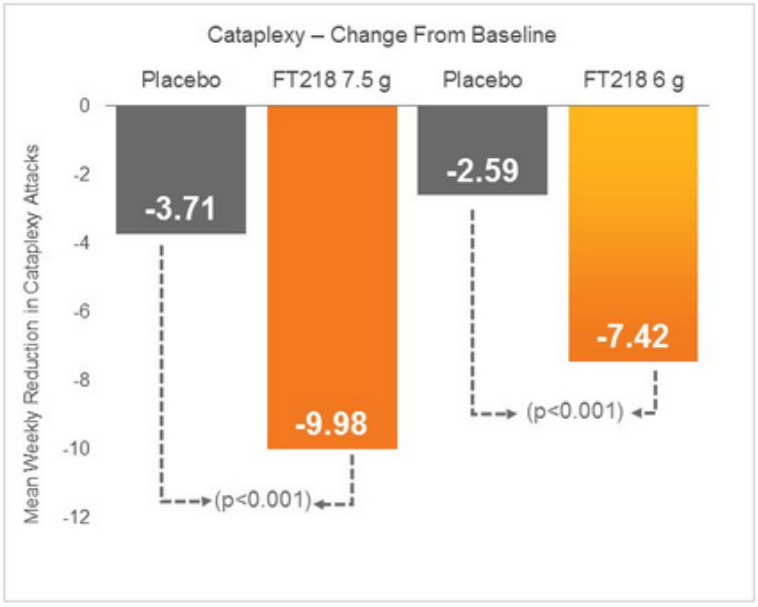


CGI-I - Percent Much or Very Much Improved

62.6% of patients on FT218 7.5 g compared to 22.8% of patients on placebo were rated as much or very much improved at Week 8; Odds Ratio 5.67 *(p<0.001)*

40.1% of patients on FT218 6 g compared to 6.1% of patients on placebo were rated as much or very much improved at Week 3; Odds Ratio 10.29 *(p<0.001)*

FT218 7.5 g and 6 g Had Significant Reductions in Mean Weekly Cataplexy Attacks Compared to Placebo



Change From Baseline in Weekly Cataplexy Attacks

Change from Baseline to Week 8 for FT218 7.5 g was -9.98, compared to -3.71

LS Mean difference between FT218 7.5 g and Placebo was -6.27 (p<0.001)

Change from Baseline to Week 3 for FT218 6 g was -7.42, compared to -2.59

LS Mean difference between FT218 6 g and Placebo was -4.83 (p<0.001)

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Q&A

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Closing Remarks

WHAT TO EXPECT:

Once-Nightly FT218 Next Steps

Event	Status
REST-ON completion and topline data	Complete
Switch and Open Label Extension study	In-progress
Full REST-ON analysis and complete study report	In-progress
Pre-NDA meeting	In-progress
NDA completion and submission	In-progress
Medical Communication Plan	In-progress
Market preparation and commercial planning	In-progress

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AT A GLANCE

Once Nightly FT218: All the Ingredients for Success

FT218
a differentiated product with high potential

Completed Pivotal Study
REST-ON Ph3 study, single study required for approval (SPA agreement)

DEMONSTRATED
highly significant results across all three co-primary endpoints at all doses studied

~$1.7B
Annualized and growing sodium oxybate market

ZERO
New Chemical Entity Risk

17 YEARS
intellectual property protection – until mid- 2037 with additional patents under development

THE RIGHT TEAM IN PLACE

Avadel™

Avadel™

REST-ON

Pivotal Phase 3 Trial: Topline Results