



## **Avadel Pharmaceuticals plc** *Repositioned: Executing New Strategy*

Piper-Jaffray Healthcare  
Conference

December 2019



# Safe Harbor

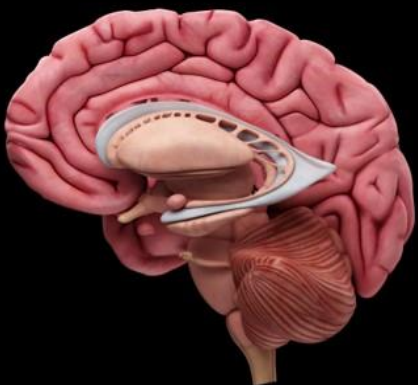
This presentation may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives 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) 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; (b) 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 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; and (c) 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, 2018, and our quarterly reports on Form 10-Q for the periods ended March 31, 2019, June 30, 2019, and September 30, 2019, in particular disclosures that may be set forth 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 our Bloxivert®, Vazculep® and Akovaz® products, which are not patent protected, could continue to face substantial and increased competition resulting in a further loss of market share and/or forcing us to further reduce the prices we charge for those products; the possibility we could fail to successfully complete the research and development for 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 and/or patent protection for such products before us; the possibility 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; and our dependence on key personnel to execute our business plan. 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.*

AT A GLANCE

# The New Avadel: All the Ingredients for Success

## FT218

a differentiated product with high potential



## 100%

enrolled in pivotal Ph3 study REST-ON, single study required for approval

## ZERO

new chemical entity risk



## \$72M

cash, funding well into 2021 including completion of REST-ON trial

## ZERO

debt due until 2023

## 18 YEARS

intellectual property protection – until 2037



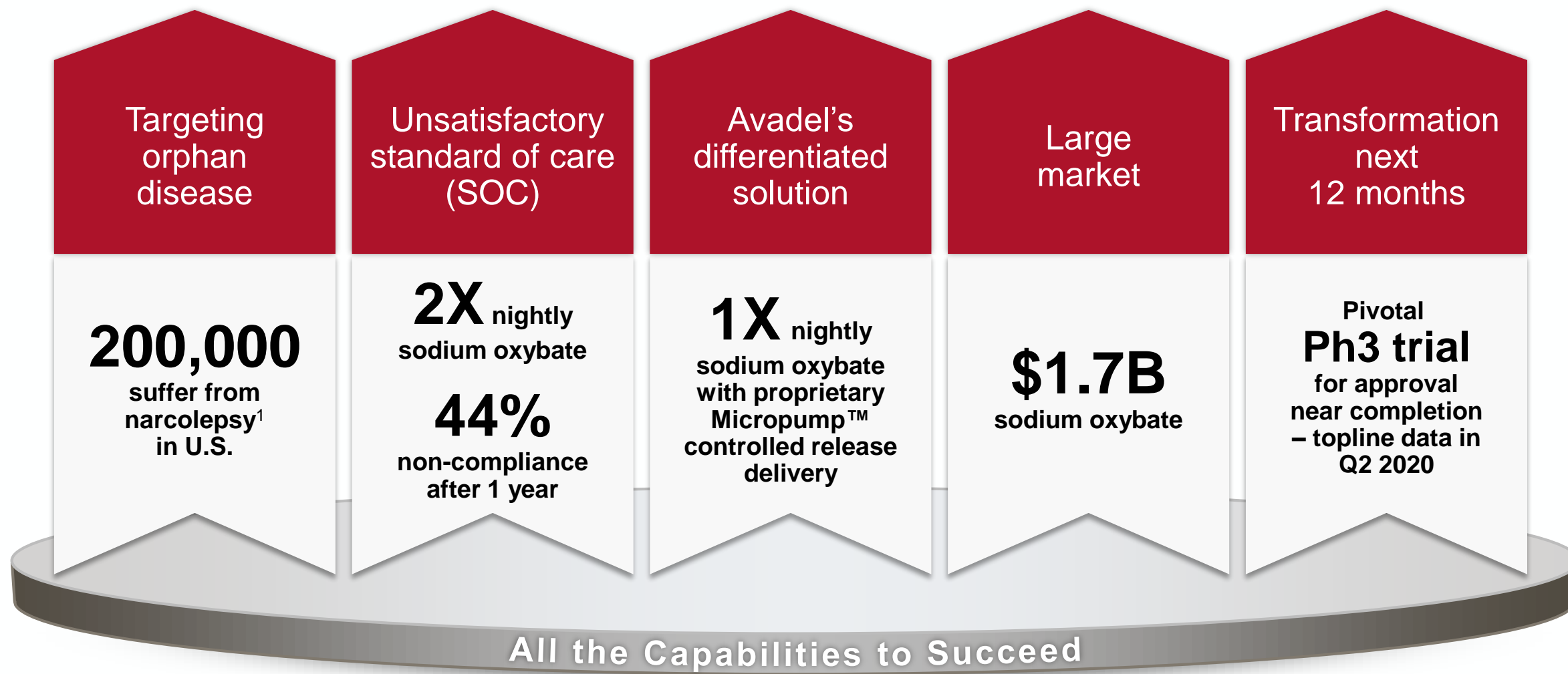
## \$55M+

estimated 2019 revenues from legacy hospital portfolio of 3 products – helps fund FT218



The  
**RIGHT TEAM**  
in place

# Repositioned, Executing New Strategy. Transformative Next 12 Months



# Characteristics of Narcolepsy – Serious Disease with Large Unmet Need

- ✓ An under-researched and under-diagnosed disease; pathogenesis poorly understood
- ✓ Unmet medical need despite current treatment options
- ✓ Market expected to grow significantly over period to 2027<sup>1</sup>
- ✓ Twice-nightly sodium oxybate is currently the only FDA approved treatment for the symptoms of narcolepsy – excessive daytime sleepiness (EDS) and cataplexy





# A New Paradigm of Treatment is Welcomed by Physicians

## There is high unmet need in patients treated with Xyrem

*"... I don't know of another medication where the patient has to wake up in the middle of the night to take it again, this is a serious problem for patients that already have a sleep disorder ..."*

**Sleep Specialist KOL, Major Academic Hospital Sleep Center in PA**

*"... The dosing schedule makes it complicated. It's hard for them to wake up, so they may miss their second dose or take it at the wrong time. It's also a burden on their spouse or parents or roommates ..."*

**Primary Care Physician, Private Clinic in NJ**

## FT218 target product profile strongly resonates with physicians

*"... [FT218] is what we have been expecting, this is what we want. Patients wouldn't be so confused about starting therapy... we would almost only use [FT218] over Xyrem ..."*

**Sleep Specialist, Academic Hospital Sleep Center in WV**

*"... I would very much prefer [FT218], patients need quality sleep and that's what [FT218] offers. I would welcome it ..."*

**Neurologist, Private Clinic in SC**



**81%<sup>1</sup> of physicians would prescribe FT218**

... And Could be Life Changing for Patients...



**1X nightly**  
Our Micropump™  
delivers one single  
dose at bedtime



## Life Changing

*“That would be life changing.  
To not have to get up in the  
middle of the night,  
**EVERY SINGLE NIGHT.**”*

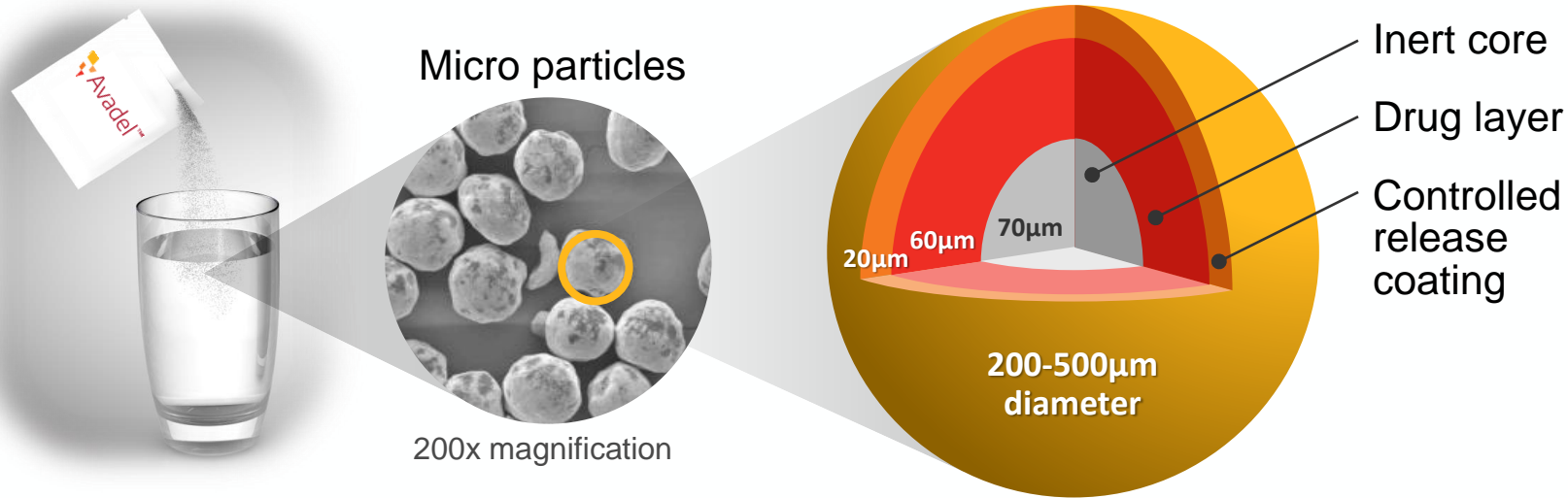
– A twice-nightly sodium  
oxybate patient



# Leveraging Our Proprietary Micropump™ Technology

## – Delivering Sodium Oxybate Once Nightly

### The Technology



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

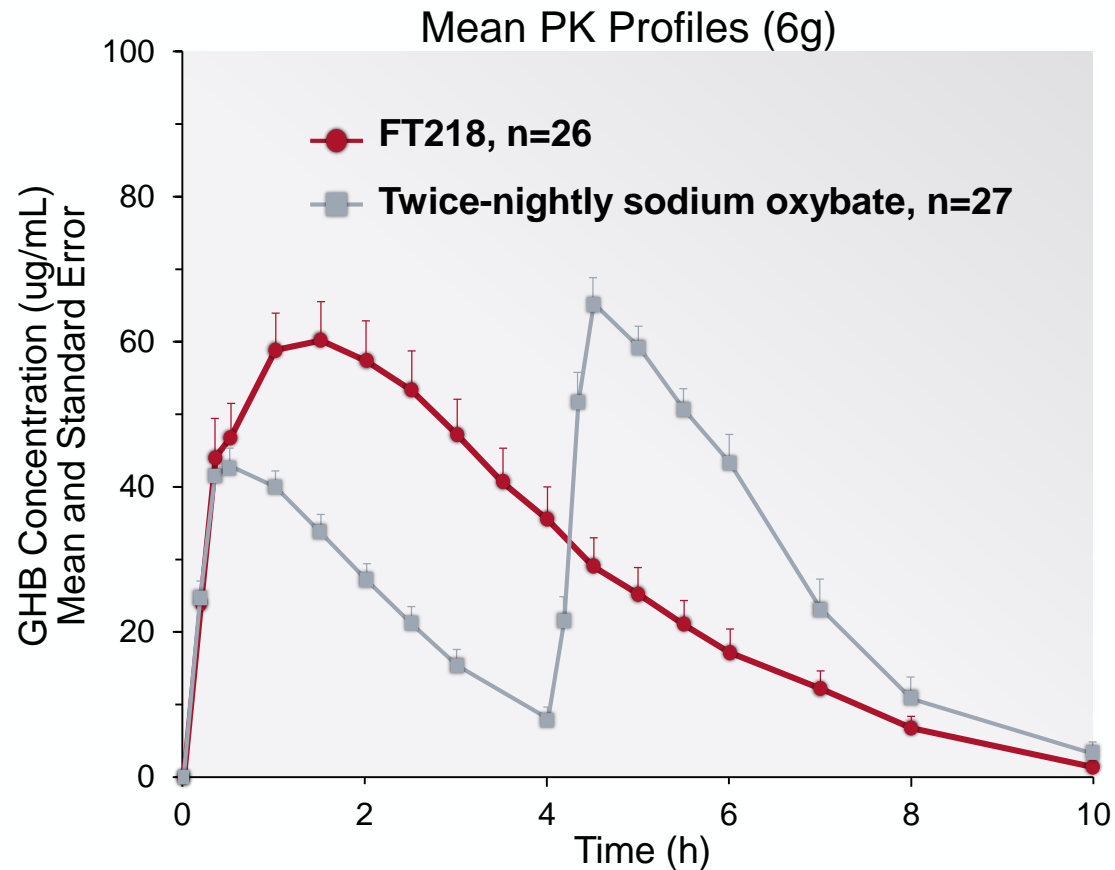
### The Advantages

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



# Investigational Study Clearly Indicated Powerful Potential Advantages of FT218

## The Results



## The Comparison vs. 2X Nightly

Single dose

**Advantage**

No disruption of sleep

**Advantage**

Overall Peak concentration (Cmax) - lower

**Advantage**

Overall exposure (AUC) - bioequivalent to SOC

**Similar**

Onset time

**Similar**

Morning blood levels (C8H)

**Similar**

# Overview of the Phase 3 Trial, REST-ON

## Regulatory Pathway / Study Design

### Pathway

- Abbreviated 505(b)(2) approval process; study conducted under SPA agreement with FDA, requires only 1 pivotal study for approval

### Study Type

- Randomized, double-blind, parallel-group placebo-controlled study with 1:1 randomization to FT218 or placebo in patients with Narcolepsy, either NT1 or NT2

### Objectives

- Primary objective is to evaluate the efficacy of FT218
- Secondary objective is to evaluate the safety and tolerability of FT218

### Primary Endpoints

- Maintenance of Wakefulness Test (MWT), Clinical Global Impression (CGI) and number of Cataplexy attacks

### Dosage / Duration / Participants

- Starting dose of 4.5g and titrating up to 9g
- 13-week duration
- N = 205 (**completed**)



# Advantage of Legacy Portfolio of Cash Flow Positive Hospital Products

**3**

Commercial sterile injectable products used in the hospital setting



+

**A new 4<sup>TH</sup>**

Sterile injectable NDA accepted May 2019; PDUFA date of Dec 15, 2019



2019 annual revenues of  
**\$55M+**  
supporting development of FT218

Estimated Market value of  
**>\$30-35M**

# Priorities Going Forward

- 1.** Laser focus on successful completion of pivotal FT218 Ph3 trial
- 2.** Continue to ensure strong liquidity to support FT218 program
  - includes maximizing cash flow from Hospital products
- 3.** Scale up FT218 manufacturing and complete NDA requirements
- 4.** Advance FT218 “go to market” planning
- 5.** Build strong credibility with investors by delivering on our commitments



# Near-Term Key Milestones

Event		Date	
• Completion of patient enrollment (205)	▶	<b>Complete</b>	✓
• AV001 PDUFA date	▶	<b>Dec 15, 2019</b>	
• AV001 launch	▶	<b>1H 2020</b>	
• Completion of REST-ON study	▶	<b>1H 2020</b>	
• REST-ON topline data readout 2Q 2020	▶	<b>1H 2020</b>	





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