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

FORM 8-K

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

Date of Report (Date of earliest event reported): **September 25, 2019**

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**	**Not Applicable**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Title of each class	**Ticker symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares*	AVDL	NASDAQ Stock Market LLC
Ordinary Shares**		(NASDAQ Global Market)

* American Depositary Shares may be evidenced by American Depository Receipts. Each American Depositary Share represents one (1) Ordinary Share.
** Nominal value $0.01 per share. Not for trading, but only in connection with the listing of American Depositary Shares.

Item 7.01 Regulation FD Disclosure.

On September 25, 2019, Dr. Michael Thorpy, Director of the Sleep-Wake Disorders Center at the Montefiore Medical Center and Professor of Clinical Neurology at Albert Einstein College of Medicine, will provide an oral presentation relating to the pharmacokinetic (PK) data derived from four Phase 1 studies of the once-nightly sodium oxybate product, FT218, being developed by Avadel Pharmaceuticals plc. A copy of the slide presentation to be used in the presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 may be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1		Slide Presentation dated September 25, 2019

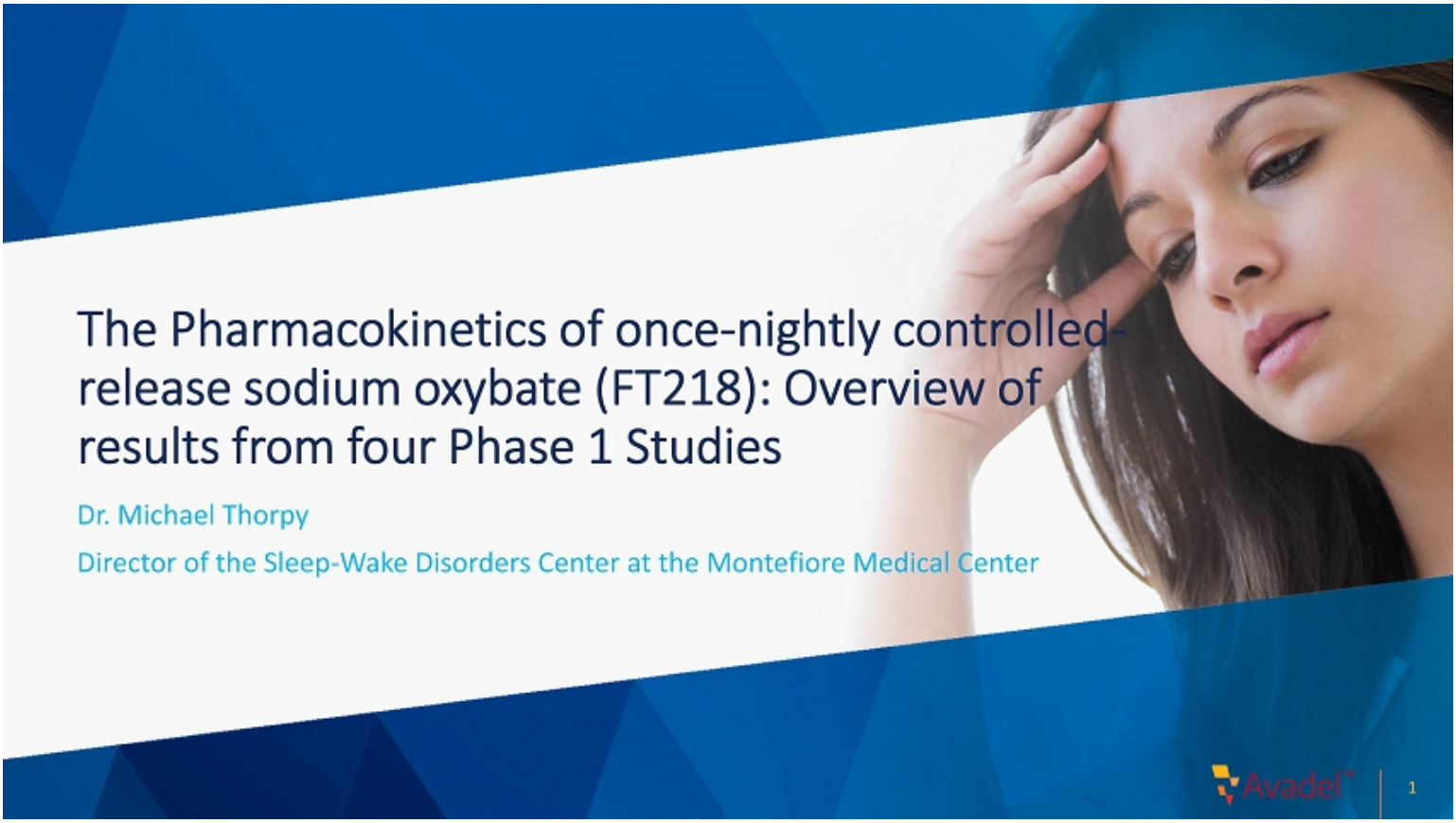
SIGNATURES

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

AVADEL PHARMACEUTICALS PLC

By: /s/ Phillandas T. Thompson
Phillandas T. Thompson
Senior Vice President, General Counsel and
Corporate Secretary

Date: September 25, 2019


The Pharmacokinetics of once-nightly controlled-release sodium oxybate (FT218): Overview of results from four Phase 1 Studies
Dr. Michael Thorpy
Director of the Sleep-Wake Disorders Center at the Montefiore Medical Center
Avadel™
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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 risks include: (a) risks relating to our recent cost-saving actions, including the risks that (i) such actions may not result in the amount of cost savings that 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 the 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 may be unsuccessful in accelerating the pace of our clinical trial enrollment for the Phase 3 REST-ON clinical trial, or we could experience delay or failure in completing that 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 and June 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 that our Bloxiverz®,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 that 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 such products before us; 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; 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.

Introduction

- Sodium oxybate is an effective treatment for excessive daytime sleepiness and cataplexy in patients with narcolepsy
- The approved effective doses of sodium oxybate are 6, 7.5 and 9 g per night, divided in two doses – the first taken at bedtime and the second 2.5 – 4 hours later.
- FT218 is an investigational controlled-release formulation of sodium oxybate intended for once-nightly dosing, using Avadel's proprietary Micropump™ technology
- Here we present pharmacokinetic (PK) data from four Phase 1 studies of FT218

FT-218 PK Data

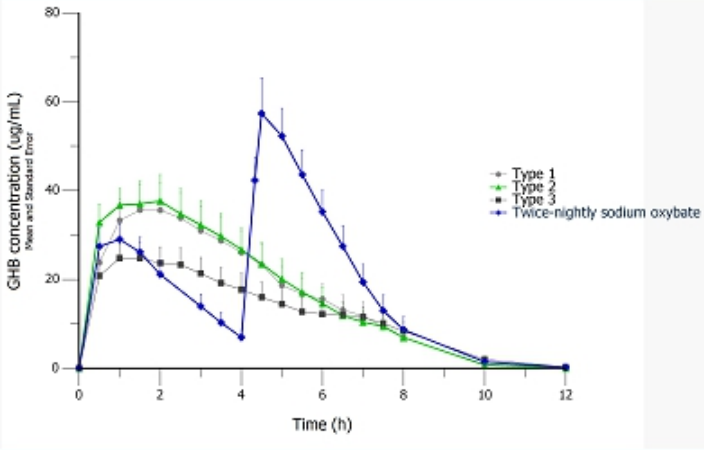
Four crossover, single-dose pharmacokinetic studies were conducted in healthy volunteers

- Pilot PK Study
- Dose Proportionality Study
- Relative Bioavailability Study
- Food Effect Study

Pilot PK Study

Crossover Study comparing Once-Nightly FT218 4.5 g v. Twice-Nightly Sodium Oxybate IR 4.5 g (2.25 + 2.25)

Crossover Study of Three Formulations of Once-Nightly (FT218) 4.5 g vs. Twice-Nightly Sodium Oxybate IR 4.5 g (2.25+ 2.25): N=16

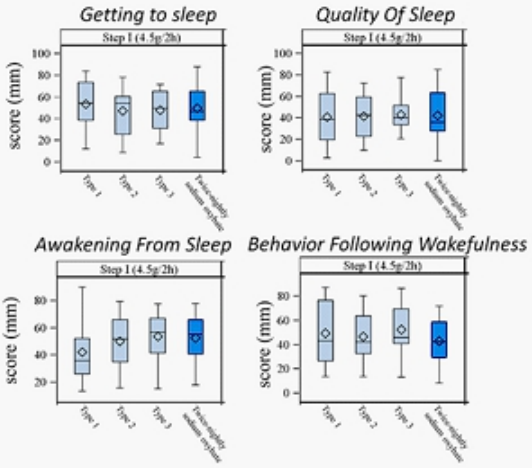


	FT218 Type 1	FT218 Type 2	FT218 Type 3	Twice-nightly sodium oxybate
Cmax (µg/mL)	43 ± 6	46 ± 5	30 ± 4	66 ± 7
AUCinf (h.µg/mL)	189 ± 28	210 ± 28	153 ± 22	214 ± 27
C8h (µg/mL)	6.85 ± 2.09	7.40 ± 1.63	8.33 ± 1.93	9.24 ± 3.15

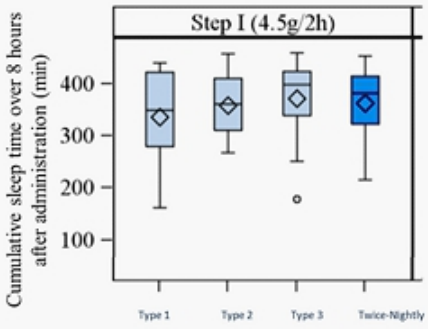
- ✓ Similar overall exposure (AUC) to twice nightly dosing
- ✓ Lower overall peak concentrations (Cmax)
- ✓ Similar morning blood levels (C8h)

Exploratory Endpoints: Leeds Sleep Evaluation Questionnaire – No formal Statistical Analysis

LSEQ - Sleep quality and alertness upon wakening



Actigraphy – Total Sleep Time



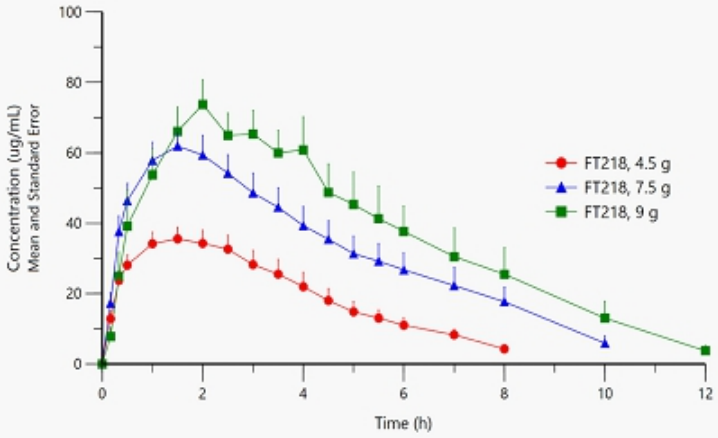
Safety Profile Comparable For Single Dose Administration: All Adverse Events (AEs) mild to moderate, No SAEs, No discontinuation Due to AE

	Type 1 N=15 n(%)	Type 2 N=14 n(%)	Type 3 N=15 n(%)	Twice-nightly sodium oxybate IR N=15. n(%)	Overall N=16 n(%)
Pharyngitis	1 (6.7%)	0	0	0	1 (6.3%)
Flu-like syndrome	1 (6.7%)	0	0	0	1 (6.3%)
Gastroenteritis	0	0	1 (6.7%)	0	1 (6.3%)
Nausea	0	0	0	1 (6.7%)	1 (6.3%)
Headache	0	0	0	1 (6.7%)	1 (6.3%)
Overall	**2 (13.3%)**	**0**	**1 (6.7%)**	**1 (6.7%)**	**4 (25%)**

Dose Proportionality Study

Three-Period Single Ascending Dose Study comparing Once-Nightly FT218 4.5g, 7.5g and 9g dosages

Three-Period Single Ascending Dose Study (n=20): Subjects received single doses of 4.5, 7.5 and 9 g with at least 7 day washout between doses



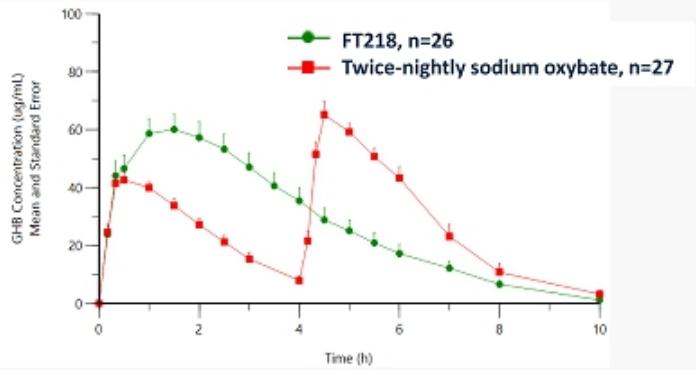
- For the 3 doses, mean pharmacokinetics exhibited similar overall profiles with median Tmax between 1.5 and 2 hours
- FT218 was dose proportional for Cmax
- FT218 was slightly more than proportional for AUC
- Thirteen subjects (65%) reported a total of 31 treatment emergent adverse events:
  - The incidence of AEs increased with increasing doses
  - Most AEs were mild to moderate in severity and consistent with known AEs associated with sodium oxybate
  - The most common AEs (at the 9 g dose) were vomiting (25%), nausea (16.7%), diarrhea (16.7%) and headache (16.7%)

Relative Bioavailability study at 6 g

Two-Period Crossover Study comparing Once-Nightly FT218 6 g v. Twice-Nightly Sodium Oxybate IR 6 g (3+3)

Randomized, crossover, two period, two sequences design of FT218 6 g or twice-nightly sodium oxybate IR 6 g (3 + 3)

Mean PK Profiles



MAIN ANALYSIS:

- AUC of FT218 meets bioequivalence criteria compared to AUC of Twice-nightly SO IR
- Cmax of FT218 is lower than overall Cmax of Twice-nightly SO IR

POST-HOC ANALYSIS:

- AUC0-8h meets bioequivalence criteria compared to AUC0-8h of Twice-nightly SO IR
- C8h of FT218 is similar to C8h of Twice-nightly SO IR

Mean PK parameters

Arm	Tmax (h)[a] [min-max]	Cmax (µg/mL) ± SE (CV)	$AUC_{0\text{-}inf}$ (µg/mL.h) ± SE (CV)	$AUC_{0\text{-}8h}$ (µg/mL.h) ± SE (CV)	C8h (µg/mL)[b] ± SE (CV)
FT218 (N=26)	1.5 [0.33-3.5]	64.6 ± 5 (40)	273 ± 27 (51)	267 ± 27 (51)	6.6 ± 1 (108)
Twice-nightly SO IR (N=27)	4.5 [0.33 -7]	70.9 ± 4 (28)	259 ± 22 (44)	248 ± 18 (39)	10.7 ± 3 (145)

Safety Profile

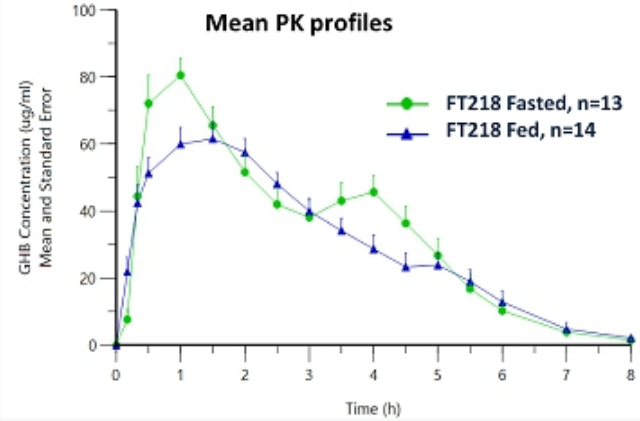
Preferred Term	FT218 6 g (N=27) n (%)	Twice-nightly Sodium Oxybate 6 g (3+3) (N=27) n (%)
Somnolence	9 (33.3)	6 (22.2)
Dizziness	1 (3.7)	4 (14.8)
Headache	1 (3.7)	3 (11.1)
Feeling Drunk	3 (11.1)	2 (7.4)
Nausea	3 (11.1)	2 (7.4)
Rhinitis	0 (0)	3 (11.1)
Hyperhidrosis	1 (3.7)	3 (11.1)

- All AEs were mild or moderate in severity
- There were no SAEs reported
- 1 subject dropped out in each treatment group due to AE (Nausea for FT218 and influenza for Twice nightly sodium oxybate)
- In general, the safety profile appeared comparable between the two groups

Food-effect study

Two-Period Crossover Study comparing Once-Nightly (FT218) 6 g in Fed and Fasted states

Randomized, Crossover, two-period, two-sequences design (N=16) at 6 g: Fed (30 min after high-fat breakfast) vs. Fasted (10-hour Overnight Fast) State



- Cmax in the Fed state is below Cmax in the Fasted state (66.7%)
- AUC in the Fed state is slightly lower than AUC in the Fasted state (PE 86%)
- Tmax in the Fed state longer than Tmax in the Fasted state

Mean PK parameters

Arm	Tmax (h)[a] [min-max]	Cmax (µg/mL) ± SE (CV)	$AUC_{0\text{-}inf}$ (µg/mL.h) ± SE (CV)	$AUC_{0\text{-}8h}$ (µg/mL.h) ± SE (CV)	C8h (µg/mL) ± SE (CV)
FT218 fed n=14	1.5 [0.5 -2.5]	64.0 ± 5 (27.3)	242 ± 24 (36.5)	239 ± 23 (35.5)	2.09 ± 1 (150.5)
FT 218 fasted n=13	0.53 [0.33 – 1]	90.5 ± 4 (17.5)	267 ± 24 (32)	266 ± 23 (31.2)	1.43 ± 1 (142.7)

Safety Profile

Preferred Term	FT218 6 g single dose Fasted (N=16); n (%)	FT218 6 g single dose Fed (N=15); n (%)
Somnolence	13 (81.3)	10 (66.7)
Dizziness	7 (43.8)	3 (20.0)
Nausea	6 (37.5)	1 (6.7)
Headache	4 (25.0)	2 (13.3)
Feeling Drunk	4 (25.0)	4 (26.7)
Vomiting	3 (18.8)	1 (6.7)
Fatigue	3 (18.8)	1 (6.7)

- All AEs were mild or moderate in severity with higher incidences in fasted vs. fed state
- There were no SAEs
- 1 subject discontinued due to vomiting after receiving FT218 in the fasted state

Conclusions

- Once-nightly FT218 at 4.5 and 6 g demonstrated:
  - a lower overall Cmax and equivalent exposure to twice-nightly sodium oxybate IR
  - similar morning plasma levels (C8h) and variability to twice-nightly sodium oxybate IR
- For FT218, Cmax was dose proportional and AUC was slightly higher than dose proportional
- In the Fed state, as expected, both AUC and Cmax of FT218 were lower than in the Fasted State
- Up to the 9 g dose level, FT218 was generally well tolerated and the safety profile appeared comparable to twice-nightly sodium oxybate IR at the 4.5 and 6 g dose levels
- The efficacy and safety of FT218 on excessive daytime sleepiness and cataplexy in narcolepsy is currently being evaluated in the pivotal, randomized, double-blind, placebo-controlled Phase 3 REST-ON study
  - Enrollment anticipated to be completed by the end of the year with topline data 2Q 2020