SanaCurrents

Avadel Pharmaceuticals (NASDAQ:AVDL)

September 25, 2019

SUMMARY

Narcolepsy, an uncontrollable condition that causes people to fall asleep in daytime settings, is treated in the US primarily with Xyrem, a sodium oxybate formulation marketed by Jazz Pharmaceuticals (NASDAQ:JAZZ). Xyrem is administered two times, with the first dose at bedtime and a second dose 2.5 hours to 4 hours later.

Avadel Pharmaceuticals plans to release results of its phase III trial of FT218 testing a single-dose formulation of sodium oxybate in the second quarter of 2020. SanaCurrents assigns a **low pivotal sentiment** to a positive outcome for Avadel's phase III trial, named Rest-On.

Like many central nervous system (CNS) drugs, sodium oxybate carries risks for patients. The most common side effects are headache, nausea, excess salivation and amnesia. The drug also can induce euphoria and lead to coma and delirium, if abused through an illegal street sale or in an overdose. Accordingly, the drug is tightly monitored and sold only in centralized pharmacies.

In spite of these risks, two-dose Xyrem is expected to produce approximately $1.6 billion in sales this year for Jazz. Moreover, even though the exact mechanism of action of sodium oxybate is unknown, the drug has proven to be effective in treating narcolepsy and cataplexy. Xyrem also is indicated to treat cataplexy, the onset of muscle weakness in narcolepsy patients when they are awake.

Avadel re-structured earlier this year to focus on advancing FT218. The company spun out its Noctiva drug into a separate entity, citing its disappointing launch. Noctiva was designed to treat Noctura, a medical condition that awakens people multiple times during the night to urinate. The company said the re-structuring resulted in net savings of $80 million, which can be applied to the approval and launch of FT218. Avadel also markets three drugs that are used in hospitals.

THE EDGE

In addition to the one-time administration of FT218 compared to Xyrem, Avadel this week released data that claimed in four phase I trials FT218 demonstrated at 4.5g and 6g lower overall maximum plasma concentrations (Cmax) and equivalent exposure (AUC) to twice-nightly sodium oxybate. The Cmax figure is significant. CNS drugs have a tight window to operate: the difference between an effective therapeutic dose and a toxic dose can be very narrow. The only means of measuring the window is through plasma.

The lower Cmax number of FT218, combined with equivalent AUC, indicates FT218 is providing the same effectiveness, and perhaps a safer administration, as two doses of Xyrem. The side effect risk of FT218 could be less than Xyrem because it is being administered less frequently. However, in announcing the results, Avadel said the FT218 side effect profile of 4.5g and 6g doses appeared comparable to corresponding strengths of twice-nightly sodium oxybate.

PROBABILITY SENTIMENT

- ☐ SUPERIOR (highest)
- ☑ Pivotal
- ☐ Advantageous

Key Catalyst(s)

- Results of FT218 Rest On trial to treat narcolepsy, cataplexy

Key Catalyst Date(s)

- 2Q 2020

Insider & Institutional Holdings

2.74% - % of Shares Held by All Insider

55.90% - % of Shares Held by Institutions

57.48% - % of Float Held by Institutions

74 - Number of Institutions Holding Shares

Key Executives

Mr. Michael F. Kanan, Sr. VP & CFO

Mr. Phillandas T. Thompson, Sr. VP, Gen. Counsel & Corp. Sec.

Mr. Gregory J. Divis, VP of Corp. and Bus. Devel.

Ms. Sandra L. Hatten, Sr. VP of Quality & Regulatory Affairs

Mr. Gregory J. Divis Jr., CEO & Director

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THE EDGE cont'd

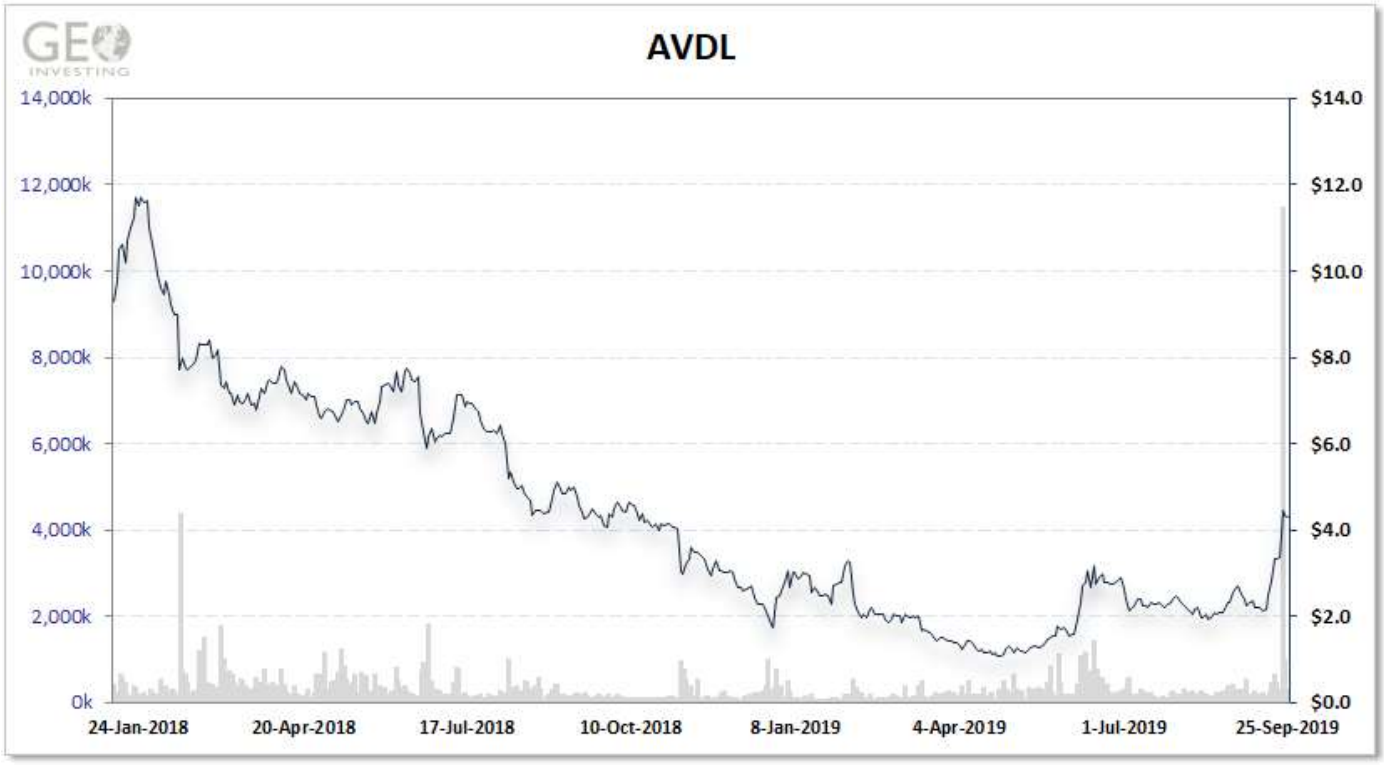
More details will be released in the phase III results but to gain approval, FT218 likely will need to only establish equivalence.

The reason FT218 can provide effective administration is Avadel's Micropump drug delivery technology for small molecules, which was developed when the company was known as Lyon, France-based Flamel Technologies. Flamel's platform was aimed at developing safer, more efficacious formulations of exiting drugs. Its technologies, including the Micropump, work effectively, as evidenced by the improvement in delivery and subsequent sales of Coreg CR (carvedilol phosphate), which was marketed in the USA originally by GlaxoSmithKline.

Reimbursement for many drugs improved by Flamel has been declining, forcing Flamel to consolidate with another subsidiary to form Avadel. The company's shift to focus on FT218 represents a concerted effort to bring a proprietary drug to Avadel. And the science behind FT218 continues to gain support.

Last week, Avadel's shares rose 40% after the FDA agreed to reduce the required number of patients for the Rest On trial to 205, a decrease from 264 previously specified. Avadel executives said the trial adjustment was validated by outside clinicians and the trial is still powered to achieve statistical significance in narcolepsy and cataplexy. So far, Avadel has enrolled 193 patients. The decrease in required patients allowed Avadel to shorten the completion of the trial by 12 months.

Because of the known adverse effects of sodium oxybate, FT218 likely will have to demonstrate its adverse profile is only no worse than other brands on the market. This could be a tricky hurdle for Avadel, as the company will have to ramp up its medical, clinical and regulatory efforts to gain approval for a significant, proprietary drug. However, with $79 million in cash on its balance sheet, proven technology, and a reduced trial size, Avadel has the resources to complete Rest-On successfully.



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AVADEL PHARMACEUTICALS (AVDL)

data provided by Sentieo

Avadel Pharmaceuticals, PLC is a specialty pharmaceutical company. The Company offers various drug delivery platforms, including Micropump, LiquiTime, Trigger Lock and Medusa. The Company offers its products in various categories, including hospital, including Bloxiverz, Vazculep and Akovaz, and pediatrics, including Karbinal ER, Cefaclor for Oral Suspension, AcipHex Sprinkle and Flexichamber. Bloxiverz is a drug used intravenously in the operating room for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery. Vazculep is used to treat clinically hypotension resulting primarily from vasodilation in the setting of anesthesia. Akovaz is indicated to treat clinically hypotension in the setting of anesthesia. Cefaclor is indicated for the treatment of otitis media, lower respiratory infections, pharyngitis and tonsillitis, urinary tract infections, and skin and skin structure infections, caused by susceptible organisms.

GICS Sector	Pharmaceuticals
GICS Industry	Health Care
Next FQ/FH End Date	09/30/2019
Next FY End Date	12/31/2019
Next Earnings Date	11/05/2019
Latest Earnings Date	08/09/2019

In millions USD, except per share data	
Market Cap	162.13
EV	217.58
Shares Outstandin	37.36
Annual Dividend	0.00
Dividend Yield	n/a
Dividend Payout	0.0%

FIN. SUMMARY			
Period end	12/31/2018	12/31/2019	12/31/2020
Revenue	103.269	45.599	33.380
Gross Profit	85.753	35.658	25.202
Gross Margin	83.0%	78.2%	75.5%
Operating Profit	(38.84)	(30.20)	(19.27)
Operating Margin	-37.6%	-66.2%	-57.7%
Net Income	-29.22	-42.52	-36.41
EPS	-0.78	-1.19	-0.75

VALUATION RATIOS	12/31/2019
EV/Sales	4.77 x
EV/EBITDA	
P/E	-3.65 x
P/B	
FCF Yield	

STOCK PRICE PERFORMANCE*	*As of 9/25/2019
Last price	4.31
52 Week High	5.35
52 Week Low	1.03
YTD Change	96.7%
1 Year Change	61.5%
5 Year Change	1.4%
10 Year Change	119.6%

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