Galmed Pharmaceuticals (NASDAQ:GLMD)

November 6, 2018

SanaCurrents

SUMMARY

November Catalyst: Aramchol

SanaCurrents forecasts an **advantageous probability** Galmed (GLMD) will post positive results in an abstract report focused on its phase IIb study of Aramchol in patients suffering from NASH (non-alcoholic steatohepatitis). The phase IIb results will be presented at the American Association for the Study of Liver Diseases in mid-November.

NASH is a condition in which excessive amounts of fat is stored in one's liver. Due to the growing prevalence of obesity and diabetes, NASH is expected to become a severe economic burden in the next two decades. The market to treat NASH is expected to increase to $25.3 billion annually by 2026, up from more than $618 million currently. The competitive market includes Gilead (GILD), Intercept (ICPT) and several other companies. While Galmed's lead candidate is further behind than competitors, its novel mechanism of action could allow it to capture selective market share.

Unlike most NASH drugs in development, which focus on increasing fat and cholesterol metabolism, Aramchol blocks the liver enzyme SCD1 directly. Aramchol also has an additional mechanism of action that allows it remove excess cholesterol from the liver. Galmed claims the combination of the two actions results in a superior safety profile over competing NASH drugs. To some extent, this claim has been validated in previous clinical trials.

Early in 2018, Aramchol reported disappointing results for its phase IIa study, ARRIVE, which recruited more than 50 patients suffering with HIV-associated lipodystrophy and NAFLD. However, Galmed rebounded quickly in June, reporting positive results from a phase IIb study, ARREST, which focused on treating a less specific population of NASH patients. Diving more into the data from the ARRIVE study the percentage of patients with at least a 5% reduction was 36.7% and 47.0% for the 400mg and 600mg arms, respectively. And patients given 600 mg dose achieved NASH resolution without worsening of fibrosis at 12% higher rate than the placebo.

One concern regarding these data points, however, is the underwhelming statistical significance, as many of the p values were above .05, or failed to meet the .05 threshold of statistical significance. In addition, ARREST'S primary endpoints were not pace with other NASH players like Madrigal $MDGL. Using a specific example, Madrigal's MGL-3196 patients achieved a 27% rate of NASH resolution (p=0.02), compared to only a 19.2% for Aramchol (p=0.05). And MGL-3196 posted its results in a shorter time frame.

PROBABILITY SENTIMENT

Advantageous

Key Catalyst(s)

Late-breaking abstract for ARREST study

Key Catalyst Dates

- Mid-November 2018, Study of Liver Disease Meeting

Select Statistics

Market

Estimated Market Size by 2025: $20-25B

Insider & Institutional Holdings

22.68% - % of Shares Held by All Insiders

43.84% - % of Shares Held by Institutions

56.71% - % of Float Held by Institutions

48 - Number of Institutions Holding Shares

Location

16 Tiomkin Street

Tel Aviv 6578317

Israel

Executives

Mr. Yohai Stenzler, CFO & Controller

Mr. Guy Nehemya, VP of Operations

Dr. Liat Hayardeny, Chief Scientific Officer

Ms. Yael Hollander, VP of Legal Affairs & Strategy

Dr. Tali Gorfine, Chief Medical Officer

Website

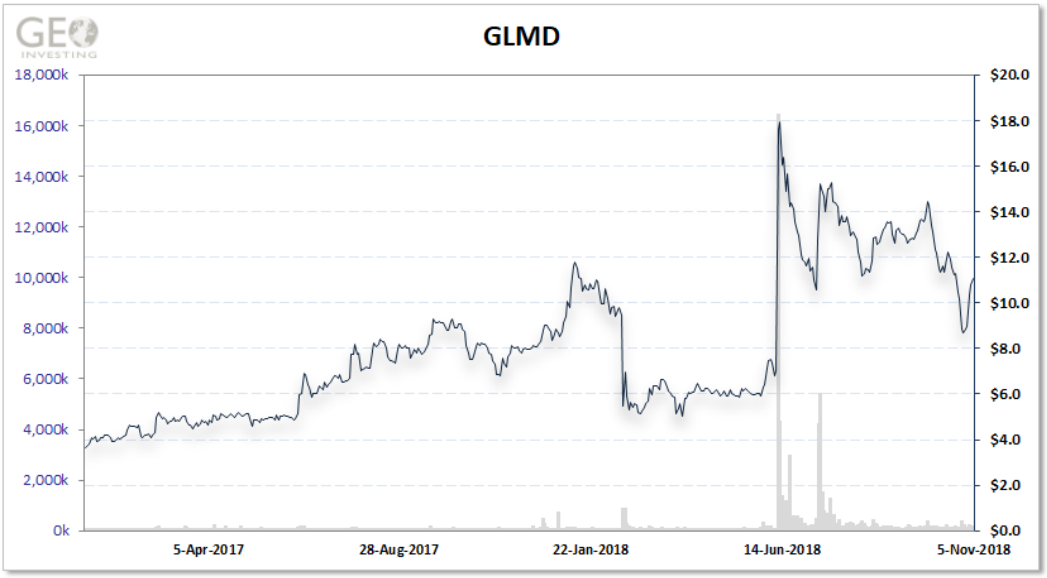
http://galmedpharma.com

Galmed Pharmaceuticals (NASDAQ:GLMD) Probability Sentiment

THE EDGE

When Galmed was initially slotted to present at the American Association for the Study of Liver Disease, it originally planned to report preclinical combination studies. On October 2, Galmed announced a late abstract to be added for the ARREST study. The timing of the announcement indicates subsequent data analysis may have revealed more positive results As a result, Galmed shares may move significantly upon this news, as Galmed is trading 50% lower than it was after the ARREST study results were first announced.

Predicting Galmed's long-term future is difficult. Galmed is pushing Aramchol through a phase III trial, and still has to meet with the FDA to determine the structure of the trial. In the past, FDA has been insistent on two endpoints for any late stage studies: A NASH resolution without the worsening of fibrosis, and an improvement in fibrosis without the worsening of NASH. Interestingly, these were the two endpoints that did not meet statistical significance in the ARREST study. Even if a larger patient pool helps improve the p value for these endpoints, the overall efficacy from competitor drugs could still outperform Aramchol. Aramchol's safety profile, however, may be enough to convince regulators Aramchol is a viable NASH treatment. If approved, there may be a niche in the crowded NASH market for Aramchol, possibly in patients suffering from milder symptoms of NASH. Another possibility is in NASH patients suffering from type II diabetes, as Aramchol mechanism of action can decrease insulin resistance.



Galmed Pharmaceuticals Ltd. (GLMD) data provided by Sentieo

Galmed Pharmaceuticals Ltd. is a clinical-stage biopharmaceutical company. The Company focuses on the development and commercialization of once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones utilizing its synthetic fatty-acid/bile-acid conjugate (FABAC), called aramchol. Its product candidate, aramchol, is a disease modifying treatment for fatty liver disorders, including Non-Alcoholic Steato-hepatitis (NASH). The Company's Aramchol is a conjugate of cholic acid and arachidic acid, which is a member of synthetic Fatty-Acid/Bile-Acid Conjugates (FABACs). FABACs are composed of endogenic compounds. Aramchol affects liver fat metabolism and has been shown in a Phase IIa clinical study to reduce liver fat content, as well as improve metabolic parameters associated with Nonalcoholic steatohepatitis (NASH). Aramchol is in Phase IIb clinical trials.

GICS Sector	Biotechnology
GICS Industry	Health Care
Next FQ/FH End Date	12/31/2018
Next FY End Date	12/31/2018
Next Earnings Date	
Latest Earnings Date	11/05/2018

**in millions USD, except per share data*

Market Cap	*238.00*
EV	*151.71*
Shares Outstandin	*20.91*
Annual Dividend	*0.00*
Dividend Yield	*n/a*
Dividend Payout	*0.0%*

FIN. SUMMARY

Period end	*'2/31/2017*	*12/31/2018*	*12/31/2019*
Revenue	1.085	1.165	0.529
Gross Profit	1.085		
Gross Margin	*100.0%*	*100.0%*	
Operating Profit	(11.28)	(9.61)	(23.57)
Operating Margin	*-1039.5%*	*-824.8%*	*-4456.3%*
Net Income	-12.30	-10.96	-22.34
EPS	-0.98	-0.56	-1.03

VALUATION RATIOS

	12/31/2018
EV/Sales	130.22 x
EV/EBITDA	
P/E	-20.43 x
P/B	
FCF Yield	-3.60 x

STOCK PRICE PERFORMANCE*

**As of*	11/6/2018
Last price	10.43
52 Week High	27.06
52 Week Low	3.61
YTD Change	21.2%
1 Year Change	56.1%
5 Year Change	-20.5%
10 Year Change	-20.5%

Galmed Pharmaceuticals (NASDAQ:GLMD) Probability Sentiment

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