Swedish Orphan Biovitrum AB (OTCPINK:BIOVF) (STO:SOBI)

January 31, 2020

SUMMARY

Stockholm-based Swedish Orphan Biovitrum AB (OTCPINK:BIOVF) (STO:SOBI) last year purchased privately held, North Carolina-based Dova Pharmaceuticals for $915 million. Through the deal Sobi acquired Doptelet (avatrombopag), an oral drug already approved to treat thrombocytopenia (very low platelet counts) in two indications, chronic liver disease (CLD) and chronic immune thrombocytopenia (ITP).

Doptelet competes with drugs from Novartis (NYSE:NVS) and Amgen (NASDAQ:AMGN) in the two indications above, but it owns the pole position to be the first thrombopoietin receptor (TPO) agonist to be approved to treat chemotherapy-induced thrombocytopenia (CIT). *SanaCurrents* assigns a pivotal sentiment that Sobi will report positive phase III data in the middle of 2020 for Doptelet in CIT.

Sobi, which has $1 billion in revenue from sales of hematology and immunology drugs, had its eye on the CIT indication. To compete against Novartis' Promacta/Revolade (eltrombopag) and Amgen's Nplate (romiplostim), Sobi and Dova understood Dova would face stiff headwinds as a small biotech. However, because Sobi's marketing base in the US and Europe can push Doptelet into the market quickly, Sobi bought Dova. In fact, all Dova employees were retained after the acquisition and Dova shareholders stand to receive an additional $1.50 per share in cash, once Doptelet is approved in CIT.

Doptelet owns several practical advantages over Promacta and Nplate, in addition to becoming the only drug to be indicated in CIT. Patients on Promacta need to be hospitalized, whereas Doptelet may not; Nplate need to be injected every week by a physician. Patients on Promacta must have failed prior treatments while Doptelet patients need to fail only one previous treatment. Promacta, an oral medication, also can only be used in patients with increased bleeding risks; Doptelet does not have that restriction in ITP.

While physicians and hospitals likely do not consider prescribing Promacta and Nplate off label to treat CIT as an egregious practice, regulators in Europe and the US increasingly ask why is the approved drug not used? And is the off label drug more expensive than approved drug? Promacta, which recorded $1.17 billion in sales in 2018, costs about $60,000 per year. Weekly dosing of Nplate for one year costs approximately $55,250. Last June, Dova reduced the price of Doptelet to about 1/3 of the Promacta price.

THE EDGE

Sobi's purchase of Dova considerably minimizes the risk of a sputtering commercial launch of Doptelet. A common biopharma strategy is for a small company like Dova to gain approval or strong data in an orphan indication like CIT and wait for the partnership or acquisition offers to roll through the door. And while they wait, the share price barely moves higher. Or often slides.

Amarin (NASDAQ:AMRN) reportedly turned down a $9 billion bid after it reported positive phase III data of its fish oil drug to treat heart disease in September 2018. After reaching $22.87 per share in October 2018,

PROBABILITY SENTIMENT

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

Key Catalyst(s)

- Phase III data of Doptelet in CIT

Key Catalyst Date(s)

- Mid-2020

Key Executives

Guido Oelkers, President, CEO

Hakan Bjorklund, Independent Chairman of the Board

Mats-Olof Wallin, CFO, Senior VP

Armin Reininger, Senior VP, Medical and Scientific Affairs

Lars Dreioee, Senior VP, Chief Quality & Compliance Officer

Location

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Solna 112 76
Sweden
46 86 97 20 00

Website

http://www.sobi.com

General Guidelines for SanaCurrents Strategy

In most situations, SanaCurrents partners take a position in a stock (or buy shares) shortly after a report on a catalyst is published. This is particularly true if the catalyst is within 90 days of the published report. For catalysts with horizons of 6-9 months, or longer, SanaCurrents anticipates the biopharma and device stocks from which it selects catalysts can rise or fall 20-30% in the months following the date of the published report. While buying at a dip, naturally, is preferred, SanaCurrents does not forecast or model in swings in share price prior to the catalyst. SanaCurrents' analytics score models the probability a compelling catalyst will be positive. SanaCurrents expects a positive announcement regarding a catalyst will drive a company's stock to higher level than the price on the date of the report, based on the company's value and capital structure when the report was published. That said, subscribers should exercise their preferred, individual discipline when timing trades, buy or sell, regarding the catalyst forecast.

THE EDGE cont'd

Amarin's shares since have traded between $13 per share and $25 per share. Amarin's market cap has ranged between $6 billion and $7 billion over the last 15 months.

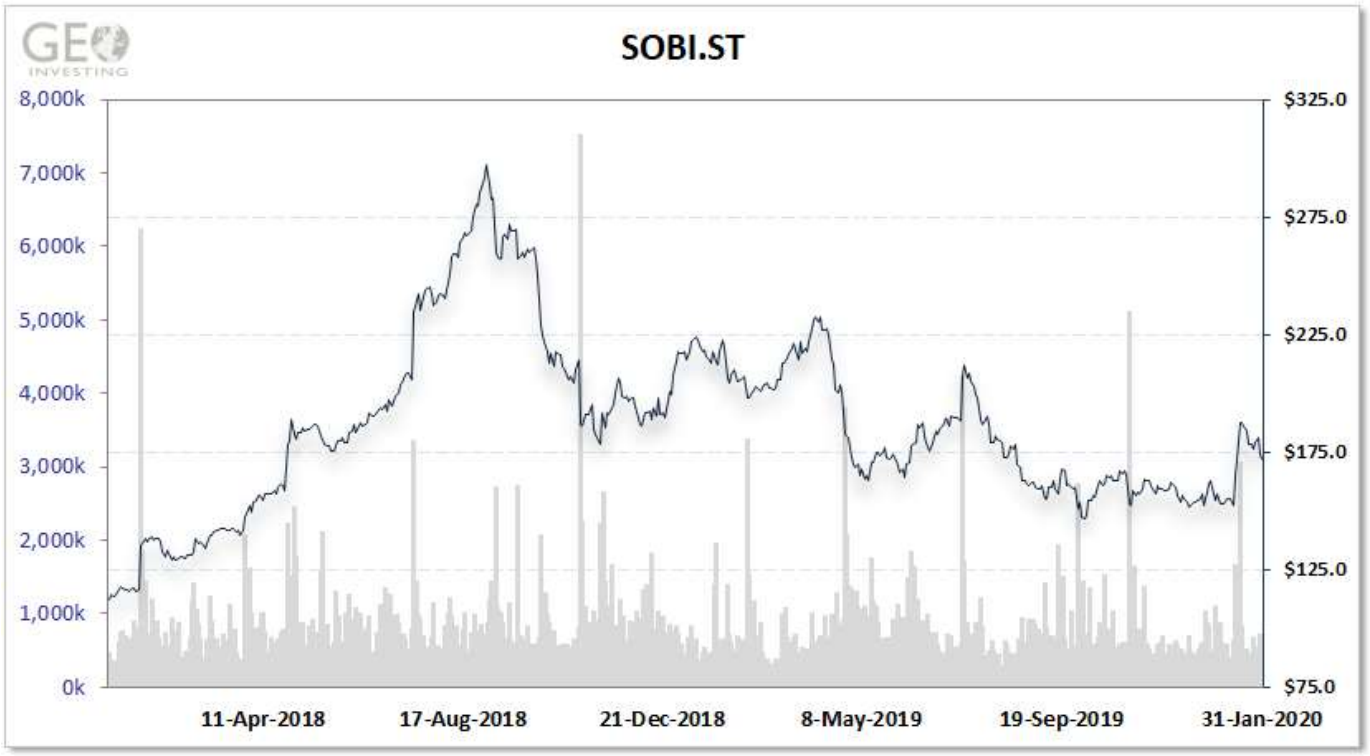
The principals at Dova embraced a different approach, agreeing to the Sobi offer in order to move Doptelet more rapidly into the market for all three indications. Analysts estimate Doptelet could capture up to $1.88 billion in CLD and ITP, because of its better profile. Sobi estimates the CIT market for Doptelet to be $2 billion in the US alone; analysts' forecasts call for Doptelet to rein in approximately $600 million of that total.

In addition, neither Novartis nor Amgen have made significant progress in seeking formal approval for CIT.

The phase III trial of Doptelet in CIT is a double-blind, placebo-controlled test of the efficacy and safety in 120 subjects with active non-hematological cancers, such as ovarian, lung and bladder, who develop CIT (platelet count <50K/µL) during the previous cycle of chemotherapy. The primary endpoint is to measure the proportion of subjects who do not require platelet transfusion, a dose reduction in chemotherapy by 15%, or a chemotherapy delay of more than four days.

In the Doptelet (avatrombopag) phase III trial to treat ITP, avatrombopag administration resulted in a platelet count of at least 50,000 per µL at day 8 of therapy for most patients with ITP. Avatrombopag appeared to be superior to placebo for maintaining platelet counts in the target range during the 6-month target period.

Given the success of Doptelet (avatrombopag) in two previous trials, *SanaCurrents* expects the drug will be able to replicate previous results in maintaining platelet counts in cancer patients.



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Swedish Orphan Biovitrum AB — SEK 172.15 -1.85 -1.06%

Country	Sweden	Next FQ/FH End Date	Dec 31, 2019
Exchange	Stockholm Stock Exchange	Next FY End Date	Dec 31, 2019
GICS Sector	Health Care	Next earnings Date	Feb 13, 2020
GICS Industry	Biotechnology	Latest earnings Date	Oct 31, 2019
Currency	SEK		

SOBI.ST

General Information (*in millions USD, except per share data)

Price (Previous Close)	172.15	Div. Yield, Last year (FY0)	
Price - 52 Week High	234.30	Shares Outstanding	269.9 MM
Price - Current vs 52wk High	-26.53%	Short Interest Shares	
Price - 52 Week Low	144.70	SI % of O/S	
Price - Current vs 52wk Low	18.97%	Market Capitalization	6,212
Beta - Sampling last 1y, Daily	0.66 vs. iShares OMX Stockholm Capped UC	Net Debt	344
		Enterprise Value	6,556

Per Share Metrics (*in USD)

	FY-2	FY-1	FY0	FY1
Book Value:	19.06	24.89	33.49	38.39
Free Cash Flow:	0.66	4.43	6.60	8.61
Dividend:	0.00	0.00	0.00	0.00
Earnings (EPS):	3.01	4.26	8.93	10.45

Estimates revision momentum (*in millions USD, except EPS)

	Last reported FY	Current Year FY1			Next Year FY2		
		6mth ago	3mth ago	Today	6mth ago	3mth ago	Today
Consensus date		8/1/2019	11/1/2019	2/1/2020	8/1/2019	11/1/2019	2/1/2020
Revenue	1,061	1,439	1,421	1,404	1,586	1,553	1,543
% diff to today		-2.5%	-1.2%		-10.4%	-0.6%	
Gross Profit	773	1,083	1,084	1,080	1,180	1,176	1,169
% diff to today		-1.4%	-1.4%		-1.0%	-0.6%	
EBIT	359	440	434	436	511	471	464
% diff to today		-0.9%	0.4%		-11.3%	-1.6%	
EBITDA	415	612	590	593	680	647	638
% diff to today		-3.5%	-0.5%		-7.6%	-2.6%	
EPS	1.03	1.19	1.12	1.06	1.27	1.20	1.19
% diff to today		-1.2%	-2.0%		-14.0%	-0.7%	

Valuation ratios

	LTM	NTM	FY1	FY2
EV/Sales	4.9 x	3.9 x	4.2 x	3.9 x
EV/EBITDA	12.5 x		10.0 x	9.4 x
P/E	19.5 x	13.4 x	14.7 x	14.8 x
PE to Growth (PEG)	invalid parameter	invalid parameter	invalid parameter	invalid parameter
EV/FCF	nm			
P/Sales	4.2 x	3.3 x	3.7 x	3.4 x
P/BV			3.0 x	2.6 x
P/Tangible BV	nm		3.3 x	2.7 x

Consolidated Income Statement (*in millions USD, except diluted EPS (adj.) and common shares)

	FY-5	FY-4	FY-3	FY-2	FY-1	FY0	5yr-CAGR
Period end date	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	
Sales	334	380	383	639	762	1,061	26.1%
Gross Income	197	226	238	427	545	773	31.4%
EBITDA (adj.)	37	49	55	164	244	415	62.1%
EBIT (adj.)	-10	4	17	139	197	359	
Earnings Before Tax (adj.)	-19	6	8	123	179	354	
Net Income (adj.)	-14	12	8	96	134	276	
Diluted EPS (adj.)	-0.06	0.06	0.03	0.36	0.50	1.03	
Common Shares	266	267	268	269	269	270	0.3%

Consolidated Balance Sheet (*in millions USD)

	FY-2	FY-1	FY0
Period end date	12/31/2016	12/31/2017	12/31/2018
Cash & ST Investments			
Inventory	670	1,053	1,284
Total Assets	9,974	10,983	17,183
Current Liabilities	1,758	2,368	6,961
Total Debt	604	5	3
Total Liabilities	4,689	4,783	8,143
Total Shareholders Equity	5,285	6,701	9,040

Margins & Profitability Ratios

	FY-5	FY-4	FY-3	FY-2	FY-1	FY0	vs. last 5y average (% pts)
Period end date	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	
Gross Margin	59.0%	59.4%	62.2%	70.1%	71.5%	73.0%	9.1pp
R&D % of Sales	20.9%	19.1%	15.8%	16.0%	13.8%	11.6%	-5.1pp
SG&A % of Sales	28.1%	28.3%	32.4%	26.2%	26.2%	22.4%	-5.6pp
EBITDA Margin (adj.)	11.1%	13.0%	14.4%	30.2%	32.0%	39.5%	19.3pp
EBIT Margin (adj.)	-3.1%	1.0%	4.5%	21.8%	24.6%	34.2%	24.4pp
Net Margin	-4.3%	3.2%	2.1%	15.5%	17.6%	26.5%	19.6pp
Tax Rate	24.7%	15.9%	22.9%	23.6%	25.0%	21.5%	-0.5pp
ROA	-1.5%	1.2%	0.8%	6.8%	11.0%	17.2%	13.1pp
ROE	-1.9%	1.8%	1.5%	16.1%	19.0%	30.7%	23.4pp

Consolidated Cash Flow Statement (*in millions USD)

	FY-2	FY-1	FY0
Period end date	12/31/2016	12/31/2017	12/31/2018
Net Income	609	1,149	2,410
D&A	441	474	485
Change in WC	-299	-86	-260
Cash From Operations	343	1,333	2,896
Capital Expenditures	-165	-159	-570
Cash From Investments	-158	-139	-571
Shares Repurchased			
Cash From Financing	388	-588	-2
Cash & Cash Eq. - Period end	706	1,478	2,899

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